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VIVO.OQ - Q4 2020 Meridian Bioscience Inc Earnings Call

EVENT DATE/TIME: NOVEMBER 13, 2020 / 3:00PM GMT

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Meridian Bioscience Fiscal Fourth 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 your speaker today, Charlie Wood, Vice President of Investor Relations. Thank you. Please go ahead.

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

Thank you, Lindsay. Good morning, and welcome to Meridian's Fiscal 2020 Fourth 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'll post a copy of these prepared remarks after the call. With regards to our calendar, Jack and Bryan will be participating in the Canaccord Genuity MedTech & Diagnostics Forum next Thursday, the Piper Sandler 32nd Annual Healthcare Conference in early December and the Singular Research virtual conference in mid-December. The details of those events will be posted to our website as they are finalized. Finally, our Q1 fiscal 2021 earnings call is currently scheduled for Friday, February 5, 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, November 13, 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 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.

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. Without any doubt, fiscal 2020 has been quite a wild ride. We began the year with expectations of accelerating investment in our new product development pipeline, with our sights set on the Diagnostics segment finally turning the corner and expecting modest growth in the

Life Science segment. Through March, that plan for Diagnostics was playing out better than expected with the segment delivering a positive growth quarter for the first time in 5 quarters and ahead of schedule. As we all know, March saw the shift from COVID-19 being an epidemic to a pandemic, greatly altering all of our lives for the foreseeable future and turning every company's plans on its head.

While we do not want to lose sight of the damage this pandemic has done across the globe, both to individuals and businesses, I do want to celebrate the heroic response of our team to support the diagnostic industry as well as health care professionals in such a time of need. In early January, we noticed the growing concern in China from this new coronavirus, prompting our Life Science team to take action. On January 27, we issued a press release, highlighting the application of our Lyo-Ready qPCR master mix in COVID-19 molecular assay. From there, demand grew rapidly for our molecular master mixes and our teams increased Meridian's manufacturing capacity to meet the demand through bringing new equipment online, process efficiency enhancements and sheer dedication of time and effort.

While demand was high for our existing products, our R&D teams knew their work was not done. This situation is not new to the team, having been first -- the first to respond to the Zika outbreak in 2016 and the African Swine Fever outbreak in 2018. Over the subsequent 8 months, we brought 19 new products to market, each playing a distinct role in expanding the testing approaches that needed to be deployed globally. These new products included high-performance antibodies and antigens for rapid lateral flow testing and serology assays and our inhibitor-tolerant mix that facilitated the development of molecular assays that did not require RNA extraction kits, which were in short supply. This continued innovation has positioned Meridian with the most comprehensive offering of key components for any COVID-19 diagnostics testing in the industry.

Not only does our Life Science division strive to be the first to market with its innovations but also second to none in quality and performance. According to comparative data from reputable regulatory agencies around the world, our key components are included in some of the top-performing tests in both molecular and serology COVID-19 testing. Our outstanding performance has led to inclusion of Meridian products in over 100 approved COVID-19 assays as of today with dozens of new samples for COVID-19 assays still being tested by potential customers. These tests are being deployed across the globe in North America, Europe, the Middle East and Asia, including both China and India. Beyond COVID-19, our Life Science division has one of the most comprehensive portfolios of antigens, antibodies and molecular reagents for in vitro diagnostics on the market.

In this fiscal year, we also released a novel air-dryable master mix that facilitates shipping dry test kits without the need for expensive lyophilization. This mix is for DNA-based assays, and an RNA version is under development to be launched this quarter. Just this past month, we launched a master mix specifically designed for liquid biopsy diagnostics. You should expect to see more targeted products from us in the future as we look to support our customers pushing the bounds of diagnostic test performance. We are already seeing the impact of new and strengthened relationships built during the pandemic, resulting in our products inclusion in several non-COVID assays.

On the Diagnostics side, the journey has been a bit different with a mix of struggles and successes. In Q2, the segment posted year-over-year growth for the first time in 5 quarters, a milestone in the multiyear turnaround for that business. The pandemic quickly stalled that growth as stay-at-home orders reduced testing for anything other than critical care and respiratory illnesses. We did not let that stand in the way of advancing our strategic plan, closing the acquisition of excellence, bringing urea breath testing to our H. pylori diagnostics portfolio and launching the Curian instrument and HpSA assay. The team in Québec also adapted the development plan for our respiratory panel on revogene to include SARS CoV-2. I'm happy to announce that we have completed the development of the stand-alone COVID-19 assay. And today, we informed the FDA of our intent to submit an application for EUA in the United States. We also entered into an agreement with a partner to bring a rapid antigen test to market, which is now being sold in Europe and Latin America under the CE Mark and is working towards FDA EUA approval here in the United States.

While Q3 was slow on the sales front, the team adapted to the situation conducting online training sessions and move forward -- more towards virtual sales calls. That work paid off with interest in new placements of our instruments picking up in the fourth quarter. That was particularly true for the revogene, which has now surpassed 200 installations ending the year at 231. In-person access at customer sites remains limited, and focus continues to be on COVID-19 testing. Nonetheless, the quarter did see the first wins for combo placements of both BreathID and Curian, validating our strategic approach to H. pylori.

Clinical trials have been a mixed bag. Q3 brought everything to a halt, and heading into Q4, we were optimistic things would return to normal. While some trials did get back to full swing, others got off to a slow restart, especially those in the GI syndromic area, driven by a lack of qualified

participants, decreased disease prevalence and availability of predicate devices that have been deprioritized by our peers in favor of COVID-19 assay production. I will discuss our pipeline in more detail later in the call.

This has truly been a monumental year for both of our businesses and our company in executing the strategic plan. Now I will hand the call over to Bryan to talk about our financial results for the quarter and the year.

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

Thank you, Jack. It is a pleasure to recap what was a record year in financial performance for the company. We finished fiscal year '20 with consolidated revenues of $254 million, up 26% year-over-year. Life Science drove that growth with a contribution of $133 million, a whopping 106% growth over fiscal year '19. COVID-19-related sales for the year were $72 million. That growth was partially offset by Diagnostics declining 11% to $121 million. Importantly, though, Diagnostics revenue in Q4 was up 38% over Q3, reflecting a rebound in our core assays outside of the respiratory category.

Consolidated gross margin was 62%, and consolidated operating income on an adjusted basis was $62 million, a margin of 24%. This was a blend of 2% for Diagnostics and 52% for Life Science. GAAP diluted EPS was $1.07, up 88% over fiscal '19. All of these metrics exceeded our original guidance set in November of last year as well as our revised guidance set in August. If you want to dig deeper into the drivers for the year, please refer to our press release and our 10-K, which will be filed by November 25.

Now let's focus on the fourth quarter. Consolidated revenues were $64 million, up 26% from $51 million in the fourth quarter of fiscal 2019. Excluding the impact of foreign currency exchange rate changes, revenues were up 25%. Gross profit margin was 60% in the quarter, up from 57% in the fourth quarter of last year. The story remains the same with this increase driven by strong improvements in Life Science gross margin, partially offset by a decline in Diagnostics gross margin, which I will discuss further in the segment review.

On an adjusted or non-GAAP basis, fourth quarter operating income was $12 million with a margin of 19%, an improvement from 15% last year. Adjusted operating expenses were $26 million, up $5 million year-over-year. Also on an adjusted basis, net earnings were $8 million and diluted EPS was $0.19. The year-over-year increase in operating expenses was driven by cash and equity incentive compensation, reflecting better performance relative to plan, incremental spending in R&D, primarily on new product development programs, including clinical trials, and the operating cost of the Exalenz acquisition.

On a GAAP basis, operating income was $9 million with operating expenses of $29 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses were impacted by a $1.1 million increase in contingent consideration related to the acquisition of GenePOC, a $700,000 increase in selected legal expenses, partially offset by a reduction in restructuring costs of $1.1 million. GAAP net earnings were $6 million, and GAAP diluted EPS was $0.15.

Now let's unpack those results by looking at the details of our 2 operating segments. We saw great progress in Diagnostics with revenues of $30 million, up 38% from Q3. While we recognize that this is still down about 11% year-over-year, we are pleased with the strong momentum and rebound from Q3 that we are seeing. As expected, the year-over-year decline is primarily attributable to continued softness in demand, resulting from the slow return to pre-pandemic conditions. Most of our products saw better-than-expected demand in the quarter, but notably, non-COVID-19 respiratory products are lagging the recovery. While this better-than-expected recovery is promising, we are still experiencing headwinds to demand in most products that we expect to continue into fiscal year '21.

Gross profit margin for the segment was 53%, an improvement from 52% in Q3, though down from 58% 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 $3 million. Similar to last quarter, this is a result of our continued investment in new product development and commercial excellence programs despite the lower sales levels. Our Diagnostics new product pipeline is included in our Q4 2020 investor presentation posted on our website. Diagnostics adjusted operating expenses for the quarter were up $3 million year-over-year

driven by planned increases in spending on new product development programs, including clinical trials and costs absorbed from the acquisition of Exalenz, including intangible asset amortization. Progress on clinical trials and related product development ramped up in the quarter but ultimately resulted in lower spending than anticipated.

Our Life Science segment recognized revenues of $34 million, an increase of 97% year-over-year. We estimate that increased revenue related to the pandemic was $18 million with 80% coming from molecular products and 20% coming from immuno products. This sequential quarter-over-quarter decline was as expected. And as you can see, demand for our COVID-19 products remains robust.

Gross profit margin exceeded 65% in the quarter, up from 55% in Q4 of last year. This continues to be driven by economies of scale for our molecular products. Adjusted operating income was $17 million, a margin of 50%, demonstrating the leverage this business brings when operating at such a large scale.

Turning to the balance sheet. As of September 30, we had $54 million in cash and a borrowing capacity of $91 million under our line of credit. During the quarter, we repaid $30 million on our revolving credit facility, bringing our net repayments for the year to $7 million after consideration of $50 million in borrowings earlier in the year for the Exalenz acquisition. We view our financial condition as strong, evidenced by a current ratio that exceeds 3:1 and a debt-to-equity ratio of 42%.

Turning to guidance. We are expecting another banner year at Meridian for fiscal '21 with Diagnostics revenues rebounding and Life Science demand remaining strong. While forecasting is still challenging given the ever-changing state of the pandemic, we plan to continue our approach from last year of providing guidance, including some of the key underlying assumptions.

We expect revenue of between $290 million and $310 million, an 18% increase over fiscal '20 at the midpoint. That includes between $140 million and $150 million of Diagnostics revenue and between $150 million and $160 million of Life Science revenue. We see the core Diagnostics revenue stabilizing as the year progresses, returning to pre-pandemic levels in the back half of the year. Additionally, we expect to see COVID-19 assays making a contribution to Diagnostics beginning in the second fiscal quarter.

Those dynamics combine not only to deliver growth over fiscal '20 but also a growth over fiscal '19. This assumes that there are no further lockdowns resulting in lower health care utilization or elective procedures. Life Science demand remains robust, and we expect it to continue through fiscal '21 with between $80 million and $85 million for COVID-19 key components, albeit with some of the same quarter-to-quarter volatility we saw in fiscal '20. Expect to also see some contribution from reagents included a new non-COVID-19 assays, particularly respiratory panels, coming out of our deeper customer relationships.

Adjusted operating margin is expected to be between 23.5% and 24.5%, roughly in line with fiscal '20. This is a result of a few key things. First, we continue to invest in future growth opportunities. Diagnostics R&D is expected to be around 18% of Diagnostics revenue as we complete the clinical trials delayed in fiscal '20 and start new trials. Additionally, we are investing in Life Science infrastructure across sales, R&D and manufacturing to support the new scale of the business. Second, we are absorbing the cost structure acquired with Exalenz. And finally, we have the annualization of headcount increases from fiscal year '20 and some return of normal travel.

Our expected tax rate of 23% to 24% reflects a greater portion of earnings coming from the United States as the Diagnostics business rebounds. This ultimately leads to expected adjusted EPS between $1.14 and a $1.28 based on a 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 or adversely affecting our supply chain for raw materials.

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

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

Thanks, Bryan. As you can see, fiscal '21 is shaping up to be another fantastic year for Meridian. Diagnostics is positioned to deliver strong growth, not just as compared to depressed fiscal '20 but growth over fiscal '19. Our key strategic focus areas will be advancing new product development, the launch of an EUA-approved COVID-19 test, completing the integration of Exalenz, expanding revogene pie production capacity and executing on a number of operating efficiency initiatives. We plan to complete the clinical trials for the Curian Campylobacter and C. difficile assays and begin clinical trials for revogene RI and GI panels as well as the Curian Shiga Toxin assay. This will position us to launch 4 new products in fiscal '21 and between 2 to 4 new products per year in fiscal '22 and beyond.

Life Science will be focused on continuing to meet the demand for our customers, driven by the ongoing pandemic as well as delivering new innovative products. We have a number of new master mixes in the pipeline that will raise the bar for performance in molecular assays. Additionally, the team will be hard at work supporting the dozens of customers testing and validating our products in new non-COVID assays that fill the funnel for future growth beyond the pandemic.

Fiscal '20 was truly a transformative year for Meridian. All of our hard work over the previous 2 years prepared us to both weather the storm in Diagnostics and to excel as a critical partner to the IVD industry, battling a global pandemic in Life Science. We are excited about the opportunities that lie ahead. The best is yet to come.

Lindsay, with that, let's open it up for any questions that the folks might have.

QUESTIONS AND ANSWERS

Operator

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

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner & Healthcare Analyst*

It's actually Brian Weinstein in for Andrew. Andrew is letting me to ask questions on the call today, so I appreciate him doing that. So appreciate all the commentary here. Maybe you can just help me bridge a little bit the guidance from kind of where you were this year to where you're going next year in a little bit more detail. So Life Sciences, $132 million going to $150 million to $160 million. Can you help just give a little bit more color on maybe the mix there between immunoassay and molecular that you're thinking there? You talked about some new products, but just trying to help us get from that $132 million to -- call it $155 million at the midpoint. And then the same thing on Diagnostics, $121 million going to $145 million, just a little bit more color on sort of the buildup to those incremental revenue dollars there.

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

So I'll start, Bryan, and then you can add to this at the back end. So Brian, first of all, as you know, Life Science started with this pandemic and really played a big role in the whole response to COVID. And doubling our sales to $132 million was a pretty big move. What we have seen recently -- and we have continued to increase our overall bullishness in regards to our Life Science business, we see continued demand, and we see continued increase in the number of customers. From a -- Bryan can give you the -- a little bit more on the percentages, but the molecular reagents on the Life Science side is leading the way. We have picked up a large number of new customers on the molecular side. In our slide deck, we give you a little bit more color about the number of customers that are using our master mixes. And so that is probably the higher percentage.

However, we've also seen -- we took a good amount of share in antibody testing. Unfortunately, that testing has not done -- the market hasn't fully understood how to use antibody testing. We do see that there'll be a rebound to that as we start seeing a vaccine where people want to see if they got the antibodies after that. But we have also now seen an increased resurgence on the antigen test, and there's a number of companies doing rapid antigen test to increase the overall assessing capacity.

So we've continued to kind of raise even our internal numbers in regards to the Life Science side as we've seen the demand continued to be very, very strong. In our assumptions, we're really assuming pretty strong through first Q -- Q1 and Q2. We don't really know what will happen beyond Q3 and beyond, as the world moves closer towards normalcy over time. And so that's what I'd say on Life Science, and Bryan can come in the back end.

On the Diagnostics side, we see the slow-but-steady, continued improvement of kind of returning to normalcy. Our core business has been impacted but has been rebounding back somewhat slowly but consistently, and that continues as we go forward. So we see in the first half of the year an impact -- double-digit impact on the core business, for sure. And in the back half of the year, we are anticipating that will move closer to normal as we go forward.

Lead testing was one of the earlier ones that came back. The tests like Group B strep for pregnant women really didn't move a whole bunch. So certain parts of our Diagnostics business remained pretty strong even in the middle of this pandemic. But what really, really slowed up on the Diagnostics side, Brian, was things like Group A strep testing. I think with kids not going to school or taking school from home, we did see a decline in the overall respiratory testing like for Group A strep and things of that nature.

We are anticipating at this point a modest amount of COVID. We did just notify the FDA today of our intent, as we mentioned, on the revogene. So we're excited about that. Once we get acknowledgment from the FDA, we would begin shipping to some early customers. We're going to move slowly and then ramp up. We were ramping up production on that side as well. So think of a 10% to 15% of that number being in the Diagnostics side related to SARS-CoV-2 and the rest of the business with its recovery, moving back from that $120 million and moving up, that's how you get to the $145 million.

Bryan, do you want to add to that?

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

Yes. Let me just add a couple of things on the Life Science side of the business, Brian. So the $80 million to $85 million that we have in our guidance around the COVID-19 reagents, from a mixed perspective, the percentages that I cited for the fourth quarter, the 80-20, you can expect a similar mix between molecular and immuno on the $80 million to $85 million. On the remaining amounts to get to the guidance of $150 million to $160 million, you know, that translates into $70 million to $75 million. We're expecting a couple of things to happen there. One, recognize that in 2019, we were in the mid-60s, so we've got growth there. We are expecting our core infectious disease reagents to be coming back, like we've been talking about with our Diagnostics business. And then you also have the effect of just a greater assay penetration for our reagents in general.

And even though we are comfortable with that $80 million to $85 million right now, I will say it is becoming a little murkier to break out COVID from non-COVID. And what I mean by that is we are starting to see customers who have, call it, a second-generation respiratory panel assay. So they started with a single COVID test, right? And now they're looking at developing a respiratory panel with a COVID target included. We are selling the same reagents to that customer. So again, it just gets a little bit murky in terms of what's COVID and what's non-COVID. Hopefully, that helps.

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner & Healthcare Analyst*

Yes, that was great. On the antigen side, any update on timing for EUA capacity considerations and how you're viewing that market in particular?

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

So we have, as we mentioned in our thing, just started -- we just got product over to Europe. So we've just started to ship the product and to take customer orders in Europe. So it's pretty early on from that standpoint. We are working with the partner here to help them to get EUA in the United States. I think we're anticipating that it's a Q2 when that would come into play for us.

We haven't really gone too deep. We don't believe that capacity is going to be any kind of issue with this, but we're a little hesitant to go. And we want to work to make sure that these guys do everything that they can do to get this EUA approved before we get too bullish in regards to what that opportunity can bring. I will say that the performance of the product has worked very, very well in Europe and in testing that has been done. So we're optimistic about the product in general.

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner & Healthcare Analyst*

Okay. Great. And then last one for me. On revogene, can you just remind me on the ability to obtain CLIA waiver for that platform? And just general thoughts around the competitive environment for this type of platform. We're seeing a lot of companies starting to move into the space that are going after CLIA waiver here. So I just want to kind of make sure I understand kind of the positioning of the product a little bit more.

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

Yes. Absolutely, Brian. Thank you. So we have not -- first of all, we do believe that the ease of use and the product itself is very likely to be able to receive CLIA waivable. It's an incredibly simple test to run, and we do believe that it can do it. We view that as another claim that we would need to go get. We are going to consider looking at claims like that in the future. But first things first, we wanted to get this EUA product, specifically the COVID EUA, and get that out there. So we are considering additional claims in general, different sample types, and we're considering things like CLIA waiver, but we have not begun the work on that yet at this point as we were so focused on bringing this EUA to market.

Operator

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

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

My first question is with respect to your fiscal 2021 guidance, have you taken into consideration of the potential impact from the market entry of COVID-19 vaccines?

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

I'm assuming you're referring to in the Diagnostic side of the business, taking that into effect?

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

Correct. Yes.

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

Yes. So we have accounted -- we do have in our target of $140 million to $150 million. We have made an assumption of an approval for the COVID-19 assay. I would describe it as an initial path of that. We are working towards increasing capacity. So as we get this product out there and we can show the customers the -- how well the product works and to gain customer acceptance. We're working to increase the overall capacity. So we have a modest amount of COVID-19. As I said, I think, about 10% to 15% of our overall number for that $140 million to $150 million is COVID-19-related. And we will update as we work to, number one, now that we've submitted the EUA, once we can obtain EUA approval and begin selling the product, I would say that we'll have much more line of sight on that as we come in Q2.

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

Yes. That was -- you were talking about the Diagnostics segment. But if the COVID -- if the availability of COVID-19 vaccine have an impact on the Diagnostic business of your IVD customers, your Life Science segment could be subject to impact as well, right?

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

Yes. So we -- and I'm not sure I completely understand the question. Bryan, have you -- can you answer that one?

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

Yes. I'll take that one. So I think on the reagent side of our business, from the contacts that we've had with our customers, we're pretty confident in the $80 million to $85 million between molecular and immuno. And I would say the immuno piece of that does not include a large piece for serology testing. And I think the way we have thought about vaccines coming into play, that is where we believe that there would be a place for serology testing. So that's kind of how we're thinking about. That's what's in our guidance. And I think as more comes out around the vaccines, for example, we'll have more to say in the future around what we think the demand will be for reagents that would go into serology tests.

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

Okay. Okay. Got it. And also, second question regarding the recent resurging pandemic across the U.S. and Europe. So could you provide any color on the inventory level of the reagents at your IVD customers? And I mean, with the COVID-19 resurging, do you think your customers are likely to stack up on reagents in the near term again, and therefore, having a significant -- providing a significant driver of your near-term revenue, top line revenue, such as the one you experienced in fiscal third quarter of 2020?

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

Yes. So we are seeing strong demand in this quarter in regards to the Life Science reagents. So we -- as we said in Q4, we expected those customers who were working through inventory, those customers have worked through inventory, and we are seeing resurgence of our existing customers with orders but also then picking up new customers along the way. So we do anticipate a strong start to the year, and there's certainly strong demand for that product line as we go forward in Q1.

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

Okay. Okay. And for the revogene PCR test, once you get the EUA and enter the market, I mean, how large is the market opportunity for this product -- for this proprietary testing in the U.S., considering that essentially, you could be competing with your IVD customers' products, testing products as well, right?

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

Sure. Sure. So we're not providing forecast at the product level at this time, but let me give you some data points to help you give an idea of the opportunity. We mentioned before that we have 231 revogene systems in the field as of September 30. We've also seen really strong demand for revogene with orders outpacing our installations. So we would anticipate that the number of revogenes will continue to climb significantly as we go forward in the next quarter or 2, in particular.

So we are currently building inventory also for our other assays. One of the things that we've learned is some of the other diagnostic companies stop making other tests, and so we've been able to pick up business for other product lines as customers couldn't get those products from the

other manufacturers since they were only making COVID-19. So we have been working while we were preparing for this with our manufacturing to ramp up the capacity on the other products.

However, we also knew that we needed to expand our overall capacity. We hired a second shift in Québec. And that shift is up and running now. That gives us capacity of around 80,000 to 100,000 ties per month. And so we are actively making plans to increase this capacity further as well. And with the launch of revogene, the scale for both instruments and production of the assay really have intensified the plans to build capacity 3 to 4x of where we are today. So we anticipate that the -- between now and our Q1 call that we do that we'll be really pushing forward on trying to drive the capacity initiatives, and we should be able to give a lot more color in regards to the market opportunity there. But I think 80,000 to 100,000 ties per month right now and a high majority of those would be COVID in the near term.

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

Got it. And last question, could you provide some color on how the new cancer liquid biopsy solution is trending, the one you recently launched?

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

So we just recently launched that product. We've had some initial customer reactions. I would describe it as very early. There has not been any significant revenue uptick from this. We also believe that products like that will take some time to grow. The customers have to do their validations and all the other regulatory work. So we see a slow build on that. That's really something that can be significant a year or 2 from now as customers who've tested it start bringing those products to market. So at this point, it's a pretty limited impact on our financials. We view that more as a longer-term play for our Life Science business.

Operator

Our next question comes from the line of Steven Mah with Piper Sandler.

Poon Mah - *Piper Sandler & Co., Research Division - Director & Senior Research Analyst*

Congrats on the quarter. Yes. So just a few questions. A lot of -- covered a lot of ground in the Q&A already. But maybe if you could walk us through the assumptions on the 2021 guide and maybe like the cadence throughout the year. I know you said Diagnostics will probably be back end-weighted -- or in the back half of the year. Do you think that's going to be offset by COVID-19 reagents in the front half of the year? How should we think about the guide as it spread out through the 4 quarters?

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

Yes. So this is Bryan, Steven. I think on both a consolidated basis and certainly, some of this is Life Science-driven, the first half of the year, like we were alluding to in our guidance discussion, we are expecting the first half of the year to be stronger without a doubt. I think as you talk about Diagnostics, it's a little more even quarter-to-quarter. A little bit more on the back end, but a little more even, particularly compared to Life Science. And I think part of that is you've got COVID coming online here late first quarter or beginning in the second quarter for us with this EUA product, and then you really have the recovery of our core Diagnostics business then coming back online, as we mentioned in the second half of the year. So a little more even distribution on Diagnostics at this point and then definitely more in the first half on the Life Science side of the business. And again, that's based on the current line of sight that we have. And we may have more to say on that come our call after the first fiscal quarter.

Poon Mah - *Piper Sandler & Co., Research Division - Director & Senior Research Analyst*

Okay. All right. That's helpful. And then maybe a follow-up question on the Life Science segment. I know in Q3, you had a big jump because of stocking issues. Do you see that happening again in the future? Or has Life Science stabilized?

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

So I think what we would say right now is we've seen -- Jack, just -- I think alluded to this in his comments that we have seen some renewed demand here during our first fiscal quarter kind of similar to what we were seeing in our third fiscal quarter from last year. I think it's still a little too early to call third quarter of this year until we get a better line of sight on the second half of the year.

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

In general, Steven, though, I think that we feel that you're likely to be strong in Q1 and Q2. We don't know that we'll have the same lumpiness, but the Life Science side does tend to have a little more lumpiness with the way that the customers order because they order a big bat of the key components that then they manufacture over time. But I would say that our line of sight into the first half is -- it will be a good start to the year for the Life Science business, for sure.

Poon Mah - *Piper Sandler & Co., Research Division - Director & Senior Research Analyst*

Okay. That's helpful. I appreciate that. And maybe one question on revogene. So yes, I appreciate you're going to wait to get the EUA before you start really pushing on manufacturing. But given that it's sort of a land grab in COVID-19, has there been an increase in your sales and marketing activity ahead of the revogene launch and talking about the respiratory panel?

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

Absolutely. So we -- this -- when we announced at the -- in the summer when we had our call in August, we announced that we were working on EUA. We saw very, very strong customer interest. Customers are struggling to meet the testing demands. And it's unusual in Diagnostics because normally, you have one type of vendor that you use for a product, but they're looking to source multiple vendors for COVID because of the supply chain challenges. And so we saw increased demand very, very high in the instrument side with people looking to secure instruments as well. We've been working hard to do that, but we're also trying to make sure that we don't overpromise and under-deliver.

So we're going to -- as we build our capacity and we build kits, we're going to bring more customers on to the COVID products. We don't want to start somebody and then back-order them. So we're going to try to bring a batch of customers on, be able to supply their needs as we increase our capacity, bring on the next batch of customers, and we're going to go that way. But we have seen very, very strong interest in demand. But we've also, as we said, seen demand for the other products as well because, quite frankly, a lot of the manufacturers haven't been making things like Group B strep and other products. So we're helping those customers out with those tests as well.

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

And Jack, if I can just add to that. I think on the placements, to put some numbers to it, Steven. We saw our fourth quarter placements tick up quite a bit because we got to the 231 mark as of the end of September. We were sitting on 169 as of the end of June as far as our revogene placements, and we had, I would say, limited activity during the June quarter. And we probably had 3 -- at least 3x the number of placements in the September quarter as we did in the June quarter.

Poon Mah - *Piper Sandler & Co., Research Division - Director & Senior Research Analyst*

Okay. Got it. Yes, that's helpful. Those are all kind of like preorders, getting the instrumentation. And yes, okay, that makes a lot of sense.

Operator

That's all the time we have for questions today. I'll now turn the call back over to Jack Kenny for closing comments.

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

Thank you, Lindsay. As we close this call, I want to again thank our team for their hard work this year. They truly help to deliver the best year in our company's history and have positioned us to do it again in fiscal '21. I also want to thank each of you for joining the call today, and we look forward to speaking to you again next quarter. Thank you, and have a great day.

Operator

This concludes today's conference call. You may now disconnect.
