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VIVO.OQ - Q4 2021 Meridian Bioscience Inc Earnings Call

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PRESENTATION

Operator

Greetings. Welcome to Meridian Bioscience's Fiscal Fourth Quarter 2021 Earnings Call. (Operator Instructions)

Please note this conference is being recorded. At this time, I'll turn the conference over to Charlie Wood, Vice President of Investor Relations. Charlie, you may now begin.

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

Thank you, Rob. Good morning, and welcome to Meridian's Fiscal 2021 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 will post a copy of these prepared remarks after the call. With regards to our calendar, Jack and Bryan will be participating in the Piper Sandler 33rd Annual Healthcare Conference, November 30 to December 2, and the H.C. Wainwright Bioconnect Conference, January 10 to 13. The details of those events will be posted to our website as they are finalized. Finally, our Q1 fiscal 2022 earnings call is currently scheduled for Friday, February 4, 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, November 12, 2021, 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 are 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 is in part derived from management's estimates and beliefs, is inherently uncertain and imprecise, and has not been verified by an 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. Fiscal 2021 was another wild year. We started the year to be beginning of another wave of coronavirus infections affecting the world, with hopes that vaccines would bring us relief from the pandemic. While the introduction of vaccines has brought some relief to the spread of the virus and allowed most individuals to return to a more normal life, many countries are still battling this disease, and it is clear that COVID-19 will be present to varying degrees for years to come.

This time around, rather than being depressed due to government lockdowns, non-COVID testing demand was negatively impacted by healthcare systems that were stressed by surges in the virus. As compared to last year, testing volumes recovered throughout the year and, for us, remain fairly close to pre-pandemic levels. This suggests that we are at the point where the pandemic headwinds are limited to locations where healthcare systems see a surge in hospitalizations, limiting available care for non-COVID patients.

That said, it still remains to be seen at this upcoming respiratory season, we'll see infections at pre-pandemic levels or if continued masking in schools and among certain populations result in limited spread of seasonal infections. The consensus seems to be that this will be a stronger respiratory season relative to last year.

As a company, Meridian had a second consecutive record year, building off the record year of fiscal 2020. We exceeded the upper end of our original guidance, both at the top line and the bottom line, delivering substantial growth over the prior year. That performance, however, was not without a mix of both achievements and setbacks along the way. Expected growth for the Diagnostics segment was slowed by the delay in the EUA authorization of our Revogene SARS-CoV-2 assay and the LeadCare recall. These were more than offset by the continued commercial success of our Life Science segment's reagents, both for COVID and non-COVID-19 applications. Fortunately, these setbacks are just that, setbacks. The team is executing through them, and we look forward to seeing the benefits of the full strength of our product portfolio in the coming months.

With that, I would like to provide some further updates on a number of specific items, beginning with our Diagnostics segment and then our Life Science segment. As you know, we resubmitted our Revogene SARS-CoV-2 EUA to the FDA at the end of June and earlier this week announced that the FDA has now approved the EUA. As with any new product launch, you can expect that it will take a few weeks for us to begin shipping product as we finalize labeling and begin working with customers to validate the new assay.

This is an important milestone as it is the first RNA assay for the Revogene platform. We look forward to delivering this to our customers again later this quarter. Development of both the respiratory panel and the GI panel continue, and we anticipate those assays entering clinicals before the end of the fiscal year. Currently, our plans are to submit the GI panel for 510(k) clearance first, followed by the respiratory panel. Both of these panels will incorporate our own Life Science segment's molecular reagents to improve both cost and performance.

On the production side, the build-out of the new manufacturing lines have gone well. The second line in Quebec has completed its product performance qualification, and after some minor delays from equipment suppliers, the product performance qualification has begun on the first manufacturing line in Cincinnati. We expect to be producing salable product by the end of the month. The installation and validation of the second line in Cincinnati should begin towards the end of the quarter. As a reminder, these 2 new lines in Cincinnati, coupled with the 2 lines of Quebec, enable a maximum production capacity of 40,000 PIEs per day and offer significant opportunities to improve margins on the Revogene products.

As of September 30, the Revogene install base was 359 instruments. Commercially, installs of new Revogene instruments remained slow as customers continue to wait for the authorization of the SARS-CoV-2 assay. We did see a pickup in new orders in Q4, but still below our expectations and the peaks that we saw during the second half of calendar 2020. The approval of the SARS-CoV-2 EUA and the panels in development will be important additions to the portfolio and drive increased demand for the Revogene platform.

The Curian platform made modest progress in growing its base. At the end of Q2, we submitted the Curian Campy assay for 510(k) clearance. Due to the pandemic and FDA resource constraints, timeline for approval of non-COVID-19 products have been delayed. While this assay is an important addition to the Curian portfolio, further menu expansion is needed to the platform to really gain steam.

On that front, the Shiga Toxin assay has begun clinical trials, and we expect to submit for 510(k) clearance within the fiscal year. The Curian C. diff assay has gone back into development to improve performance. With the addition of these 3 assays, we believe we will have a comprehensive

market-leading gastrointestinal assay menu. Our H. pylori breath testing business, led by BreathID, had a tremendous year. Operations are now fully integrated, and while the U.S.-based team has been unable to visit the team in Israel, members of the BreathID team have joined leadership in the U.S. on numerous occasions.

From an R&D perspective, the team is focused on enhancements to the product that will yield significant reductions in manufacturing costs as well as feature enhancements that customers are asking for. At the end of July, we added to the portfolio with the acquisition of BreathTek from Otsuka. That acquisition added over $20 million of revenue annually to the H. pylori franchise for an acquisition cost of approximately $20 million. Integration of those operations is ongoing, the bulk of which is expected to be complete in the first half of fiscal '22.

As a reminder, this was a product line carve-out, and we are integrating it without taking in any new employees from Otsuka, which provides for a significant operating margin contribution. H. pylori testing remains Meridian's largest disease state with our strongest portfolio of products. Not only is there a growth opportunity from incremental testing volume for this undertested disease, but there are opportunities to shift the industry in favorable ways. Serology testing is not clinically recommended, does not recommend -- does not detect an active infection, has high false positive rates, leading to inappropriate antibiotic treatment and is often not reimbursed. We estimate that approximately 25% of the testing volumes in the U.S. are from serology testing, and one of these growth areas is in shifting testing from serology to a Meridian testing solution. Both our stool antigen and urea breath test confirm active infection, produce results with significantly higher sensitivity and specificity, and have solid reimbursement rates.

Second, we estimate that approximately 2/3 of all H. pylori is performed in national reference labs. This compares to approximately 25% of typical diagnostic testing done at national reference labs, providing an opportunity for us to decentralize this testing at our hospital or IDN customers, a win-win for both Meridian and the customer. As the only company with both stool antigen test and urea breath test for H. pylori, Meridian is well positioned to capitalize on these market dynamics.

Next, I'd like to provide an update on the LeadCare recall situation. As you know, in May, we initiated a voluntary recall after identifying an issue with testing of the controls included in the kits for all of our LeadCare systems, including Plus and Ultra. This recall expanded to additional lots in June and again in August. As we announced in early September, we have stopped shipping LeadCare test kits, while the team identifies and implements changes that address the issue.

As of today, we are still not manufacturing kits and anticipate that we will not be shipping product for 3 to 5 months. To be clear, this is a complex supply chain issue involving contamination in the plastic treatment reagent tubes that occurred at the supplier's manufacturing site. We are actively testing alternative tubes, both in plastic and glass forms, across multiple suppliers. In order to ensure that any replacement tubes are free from contamination, this process takes some time, and we are working in conjunction with the FDA to do this as quickly and as safely as possible. LeadCare II is the only CLIA-waived lead test on the market in the U.S., so it is critical to get this back on the market as soon as possible, and we have all hands on deck to do so.

The Life Science segment had yet another blockbuster year, beating our expectations on all levels. First, the team continues to launch new innovative products at an exceptional rate. In Q4, the team added an Air-Dryable mix for isothermal amplification and completed the portfolio of sample-specific Air-Dryable Master Mixes with the introduction of products optimized for stool, blood and urine. This is a truly disruptive approach in the industry as evidenced by the number of companies starting to adjust their marketing to make similar claims. The difference with Meridian is that we have used our deep expertise to modify critical components in our mixes to address complex inhibitors present in a given sample type, resulting in the increased assay sensitivity even with crude clinical specimens.

The pandemic is creating an environment where R&D teams are expected to develop high-performance assays in shorter periods of time, and we are facilitating that by removing the need for our customers to optimize their own mix. They simply need to know the sample type and whether the target is RNA or DNA, and we have a fully optimized off-the-shelf mix for them to use. Currently, no one else in the industry can match this.

Looking ahead to fiscal '22, the team will expand this portfolio of sample-specific mixes to our Lyo ready and isothermal amplification formats.

The team also launched a thermostable reverse transcriptase enzyme. This allows us to enter the multi-hundred million dollar market for RTase. We are working to incorporate this enzyme into our new master mixes, further improving manufacturing costs, while at the same time improving performance and thermal stability. We also have introduced 2 REACH compliant enzymes that are Triton-free and continue to look for other opportunities to make our products more environmentally friendly without sacrificing performance. Commercially, fiscal '21 was another successful year. We continue to build upon the relationships forged during the early days of the pandemic and are collaborating with customers on new assays across multiple disease states. A common concern of investors is the sustainability of these customers post-COVID.

I would like to offer a few statistics to demystify this a little for you. In fiscal '19, before the pandemic, only 7 of our IVD customers generated sales of greater than $1 million, accounting for approximately 30% of our total Life Science revenue. In fiscal '21, we had $41 million or more accounts, which made up approximately 75% of our total Life Science revenues. Each of those accounts are using our reagents in one or more regulated assays, which makes a recurring revenue stream probable given the cost and effort to change components of regulated assay.

While all but 4 of these IVD customers have our reagents in a COVID assay, approximately 80% use our reagents in the respiratory panel and over 70% use our reagents in at least one non-COVID regulated assay. In total, approximately 95% of our top IVD accounts use our reagents in at least one non-COVID assay and over 50% use our reagents in their single target COVID test, the respiratory panel and at least one other assay.

If you look beyond these top customers to include IVD customers with greater than $100,000 in sales, approximately 90% use our reagents in at least one non-COVID regulated assay. As you can see, not only do we have a highly diversified customer base, we are embedded in them beyond just COVID. Overall, a great year for Meridian.

I'll now turn the call over to Bryan to go through the 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 another record year in financial performance for the company. Starting with Q4, Meridian recorded consolidated net revenues of $76 million, up 19% year-over-year. Life Science accounted for $42 million, up 22%, and Diagnostics accounted for $34 million, up 15%. In Diagnostics, we are seeing strong demand for our respiratory products with the exception of flu. Demand began increasing much sooner than usual, and it is unclear if this is an early sign of a solid respiratory season or simply a shift in timing.

In Life Science, we estimate the products included in COVID assays accounted for $23 million, an increase of approximately 29% year-over-year, while other non-COVID-related revenue was up approximately 11%. Consolidated gross margin was 59% with a Life Science gross margin of 69% and a Diagnostics gross margin of 46%. Gross margin was and continues to be negatively impacted by the LeadCare recall with the overhead and manufacturing staff in Billerica recorded in cost of goods without offsetting revenue. Life Science continues to benefit from the increased scale, particularly from our molecular products.

Consolidated operating income on an adjusted basis was $13 million, a margin of 17%. This is comprised of an adjusted operating margin for Life Science of 55%, partially offset by an adjusted operating loss of $7 million from Diagnostics. We recorded a charge of approximately $5.6 million in Diagnostics for costs associated with the LeadCare recall. We have decided to proactively credit our customers for the recall kits, given the uncertainty around when replacement kits will be available. The combination of these factors led to a greater loss than in recent quarters for the segment.

Adjusted diluted EPS was $0.23, up 21% compared to Q4 fiscal '20, while GAAP diluted EPS was $0.15, flat to Q4 fiscal '20. We finished fiscal year '21 with consolidated net revenues of $318 million, up 25% year-over-year. Life Science drove that growth with a contribution of $190 million, 43% growth over fiscal year '20. COVID-19-related sales for the year were an estimated $112 million. Diagnostics segment revenue also posted growth of 5% to $128 million. The primary driver of the year-over-year revenue increase is Life Science COVID-related demand, coupled with a full year of BreathID and 2 months of BreathTek revenues, partially offset by soft demand for the Diagnostics' respiratory product and the LeadCare recall.

Consolidated gross margin was 63%, with a Life Science margin of 72% and a Diagnostics margin of 51%. Consolidated gross margin was favorably impacted by scale benefits in Life Science, but was partially offset by a drag from the LeadCare recall, Revogene scrap rates and provisions for short-dated products stemming from depressed sales levels during the pandemic.

Consolidated operating income on an adjusted basis was $95 million, a margin of 30%. This breaks down to an adjusted operating margin of 61% for Life Science, partially offset by an adjusted operating loss of $9 million for Diagnostics, including the costs associated with the LeadCare recall. Adjusted diluted EPS was $1.66, up 55% compared to fiscal '20, while GAAP diluted EPS was $1.62, up 51% over fiscal '20.

All of the consolidated metrics we guided to exceeded our original guidance at November of last year and were in line with our revised guidance set in August. If you want to dig deeper into the drivers for Q4 or the full fiscal year 2021, please refer to our press release and our 10-K, which will be filed by November 25.

Turning to the balance sheet. As of September 30, we had $50 million in cash. In late October, we amended our line of credit, which among other favorable changes, increased the total capacity to $200 million, maturing in 2026. During the quarter, we paid approximately $20 million for the BreathTek asset with cash-on-hand and settled the remaining GenePOC acquisition earn-out obligation for $20 million with a combination of $10 million of cash-on-hand and a $10 million draw under our line of credit. We also repaid $5 million of contingent grant obligations due to the Israel Innovation Authority. With all that taken into account, we currently have borrowing capacity of $140 million.

Turning to guidance. In fiscal '22, we expect revenue of between $285 million and $300 million, which includes between $145 million and $150 million of revenue for our Diagnostics segment and between $140 million and $150 million for our Life Science segment. We expect Diagnostics revenue in the second half to be moderately higher than the first half as LeadCare production comes back online. For the purposes of guidance, we are assuming that we begin shipping LeadCare kits in April.

Life Science revenues assume solid double-digit growth on the core non-COVID-related business, offset by lower demand for reagents used in COVID-19 testing. As we have mentioned in the past, because our molecular reagents are disease target agnostic and the same products can be used in multiple tests, accurately recording the split of COVID and non-COVID-related revenues is becoming increasingly challenging. For that reason, we are no longer going to provide guidance on the amount of revenue generated from COVID testing and will not report a split in our quarterly commentary. Our view is that we have moved into a period where COVID is endemic and will just be part of the regular respiratory testing landscape. To that end, our guidance contemplates higher revenue in the first half of the year aligned with the respiratory season. We are not forecasting a first half to second half decline to be as dramatic as last year and expect it to be somewhat mirror the second half increase we are expecting in Diagnostics.

Adjusted operating margin is expected to be between 21% and 22%. This reflects slightly lower gross profit margin in Diagnostics due to the impacts of the LeadCare recall and a lower Life Science gross profit margin due to a combination of lesser scale with our molecular products and an increased mix of our lower-margin immuno products. On a blended basis, this implies a consolidated gross margin range of 58.5% to 59.5%, lower than fiscal '21 due to the aforementioned reasons, coupled with revenue contribution mix changes between the segments.

In operating expenses, we are increasing our investments in R&D in our commercial infrastructure, which, among other things, includes an assumption that travel returns to pre-pandemic levels throughout the year. Combined with the gross profit margin impact I mentioned, Life Science operating margin is expected to be greater than 50% and Diagnostics is expected to be breakeven to having an operating margin in the low single digits. Our expected tax rate of 23.5% reflects a greater percentage of revenues and taxable income coming from the United States. This ultimately leads to expected adjusted EPS between $0.98 and $1.08 based on a fully diluted share count of 44.5 million shares.

Similar to last year, there are a number of unknowns that make setting guidance challenging, in particular, timing of FDA approval for the Curian Campy assay, the resolution of the LeadCare recall situation, the anticipated demand for COVID-19 testing globally and supply chain interruption considerations. The guidance presented today reflects our current visibility into these matters and overall market conditions.

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

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

Thanks, Bryan. As you can see, we fully expect fiscal '22 to be another strong year for Meridian. While we still have some operational challenges to overcome, the consolidated business is 50% larger than fiscal '19, the last full pre-pandemic period. We believe this is the new base from which we will be able to grow consistently. After a period of heavy investment through acquisitions, new product development spending and manufacturing expansions, Diagnostics will be focused on operational execution. Our key strategic focus areas will be advancing new product development, including the submission of 3 to 4 new assays, the commercial launch of the Revogene COVID-19 and Curian Campy assays, completing the integration of BreathTek, expanding Revogene PIE production capacity and executing on a number of operating efficiency initiatives. These will position the Diagnostics segment for strong organic growth in fiscal '23 and beyond.

Life Science will continue to focus on growing relationships with our largest customers and meeting their supply demands. As I mentioned earlier, we have a number of new master mixes in the pipeline that will continue to solidify Meridian as a leader of innovation. Additionally, the team will be hard at work supporting the dozens of customers testing and validating our products in new assays across a variety of disease states to fill the funnel for future growth beyond fiscal '22.

Fiscal '21 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 excel as a critical partner to the IVD industry battling a global pandemic in Life Science. We're excited about our opportunities that lie ahead and have no doubt that our best is yet to come.

Now Bryan and I are here for your questions. Rob, can you open it up for questions for us?

QUESTIONS AND ANSWERS

Operator

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

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner, Group Head of Life Sciences & Healthcare Analyst*

So just a couple of ones here that are all kind of non-related sort of one-offs. But just to start, when you think about Life Science and the revenues there that you're guiding to, I appreciate all of the commentary on all of the percentages that you ran through, Jack. I mean, I have to go back to the transcript to get all this down. There was a lot of stats. But I'm just curious, as you look at that guide for next year, how much do you guys see as kind of like repeat ordering, where you guys have visibility versus new business that you need to go out there and try and have to win at this point?

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

So I'll start and, Bryan, you can chime in. So first of all, Brian, I would say that from a guidance standpoint, we're kind of taking a similar approach that we had to last year, which worked for us, which was don't try to go way out in the future, go to where we have some line of sight, and then try to use what we think is good business judgment with historical perspective to finish the longer-term part of our guidance.

And so we have a pretty good idea of kind of what's going on in the business as we head into respiratory season with COVID and non-COVID-related stuff. And so part of the reason we expect fairly strong Q1, and then as we work into the later part of the year, Q2, 3 and 4, we really kind of viewed it more like what does our business -- what does it look like. You still had COVID testing going on, but more of an endemic type of volume likely, like we had in Q3 and Q4 of last year, or Q4 of 2020 and Q3 of 2021, right?

And so that's kind of the way that we look at it, which is how we got to the [$140 million] to [$150 million]. And so it is -- look, we have well over 100 customers that are running our products in COVID or respiratory and other types of tests that are tied to this endemic, if you will, and there are recurring orders that we anticipate there. The question comes down to how severe are those -- how large are those orders? And that really depends on the progression of the disease as COVID as it goes kind of more towards endemic. Bryan, do you want to add?

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

The other thing that I would add to that is that when you talk about like the 40 customers that were referenced in Jack's comments earlier on, we have a lot of those same customers in our guidance assumptions for 2022, Brian. Varying degrees of revenues, but certainly, there's what we would say, COVID, but there's also non-COVID growth embedded in those customers as well. There's a balance. There's a balance between the two.

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner, Group Head of Life Sciences & Healthcare Analyst*

Got it. That's understood. Okay. And then for the recent authorization for Revogene, just can you tell me how impactful that is? You talked about placements being a little bit on the softer side as customers were waiting for this. Can you give us some idea or some scale on what that funnel looks like? And just how impactful this can be relative to your guidance that you put out there for the Diagnostics side?

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

So Brian, I'll start with -- Bryan and I just got back from our sales meeting. We had our team in the U.S. altogether for a sales meeting, and while we would have liked to have had the EUA earlier, the timing of getting it early this week was great in that we have the entire sales force together this week for some training. A couple of different notes. First of all, the energy from the sales team was off the charts. They were incredibly excited. They have a large number of customers that they work with, existing customers of the 359 placements we have that have interest in looking at COVID. There's still strong need. And remember, we're in a lot of these smaller hospitals that don't have all of these other solutions molecularized, and they really like the Revogene.

So we do think that in our existing customers, there's a desire for it. We also have a lot of other customers, Brian, that for us to financially make a Revogene work for them and financially work for them, tending a broader menu is important. So they may not run enough now for us to financially have made it make sense to convert them from Alethia over to Revogene. And now when you have COVID EUA and you bring that in, it can make great sense financially for us and for the customer works as well. So we would anticipate that this puts us back into the kind of volumes that we had in previous quarters, the 20-plus instruments a month or more type of range for instruments related to that.

And then following that up with the GI panel and then following that up with further respiratory, that's why we do believe that this will help us to kind of reignite the revenue. So we're looking for kind of like the performance we were having before on a quarterly basis. And I think that we fully expect that going forward, and we'll have a lot more line of sight to that at our next call because we'll see what -- sales rep energy has to equate into sales rate effectiveness. Sales -- they have to be effective and that -- we'll start to see that as we get through this next quarter.

Brian David Weinstein - *William Blair & Company L.L.C., Research Division - Partner, Group Head of Life Sciences & Healthcare Analyst*

Okay. And then the last one for me is just around the LeadCare situation. Obviously, it's been a thorn in your side for a while now. You're qualifying a bunch of different options here, which is great. But what gives you the confidence that April is the right time frame here? And how much specifically do you have embedded in your guidance for LeadCare just in case this were to extend beyond that time frame?

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

So I'll start, and then Bryan can work around it. A couple of comments first, Brian. I want to make sure I'm really clear to you and to other investors that we have, this is a COVID casualty. The reality of this whole thing is that plastic tubes that are used in our kits, we've been using them for a number of years. They work fine. We have a quality system that kind of keeps track because you want to make sure you're not having interference.

In the summer of 2020, and ultimately, we started to see in the fall, the plastic tubes that we were getting, there were changes to their performance, and that's what led to this recall. Ultimately, some changes occurred in the resins, and we don't know what those changes are. And quite frankly, I'm working with the FDA. They also were like, don't keep looking for that, let's work -- figure out a different path. You're looking for a needle in the haystack scientifically, but ultimately, changes to resins were made probably related to COVID when they were trying to make more plastic or something on those lines, and ultimately, our quality system caught it. So we are proud of the fact that our quality systems did what they were supposed to do here. Unfortunately, with these changes that happened due to COVID that's happened.

As far as confidence goes, we -- there's -- this is a grinding process. You have to validate tubes and it takes time because you have to prove that you don't have any issues with lead being affected and it takes time. It's not that it's hard work to do, you have to validate these tubes, but it's the time to run it over a period of time so you can be confident that you don't have interference substances coming out of these tubes. So it is more of a time game than a risk game, but we are actively looking at different suppliers to try to find some that -- either the resins did not have the changes that occurred with the resins -- many of the resins that we've looked and other folks had the same issue. So there's a broader resin change that went on here. That's why we're also exploring glass tubes as well.

So Brian, we don't know the answer to that. I don't want to get over my skis. We felt that the April time frame was a conservative estimate. We certainly would like to be earlier than that, but we don't -- it's a little bit of an unknown still. I would just say, in general, we try to be conservative. We would -- it'd be included in our guidance for that.

So Bryan, I don't know if you want to comment on that.

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

Brian, I can speak to that. I think if you were to look at our LeadCare business on a normalized basis, it's an $18 million to $20 million business. So if you think about us starting to ship products again at the midyear point, that kind of gives you an idea from a guidance perspective what that means.

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

We also -- we didn't assume anything like that the channel has completely been empty. You got to fill your channel back up. We didn't make any of those assumptions. We tried to be very black and white to this, to these amounts as we do the guidance.

Operator

Next question is from the line of Yi Chen with H.C. Wainwright.

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

So the COVID-19-related revenue in the fiscal fourth quarter bounced back from the previous quarter. So can you comment on the trend of COVID revenue going forward?

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

So we definitely started to see -- if you were following the press when the world started talking about the delta variant and the surge of delta, we definitely saw that and we started to see increased orders in our Life Science business. And that's really what happened in the quarter. So it's kind of exactly when the press started -- come August time frame when the world started talking about delta surge and what they felt was going on, we started to see the increase of that, and it has maintained.

What I would also say is that we are seeing different parts of the globe or different places with regards to COVID right now. And so we're seeing different hotspots in different parts, whether it's Europe, it's in a different place than the United States right now from how the COVID is affecting them. And so we are still seeing demand for that.

The one other thing that I would say, and then I'll have Bryan make a comment, is -- the other thing that's different for us is, before supply chains didn't know how to order for this. So they'd order a ton of it at a time just because they were trying to hoard anything they could. We are in a little bit more of a normal mode where we're getting good size orders, but they're not stocking up for 6 months at a time, at least that's not the feeling that we're getting. So we do feel that it's still a lumpy business in Life Science, but less lumpy than it was a year ago.

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

I think that's a fair characterization, Jack, because I think the hotspots lead to some of the lumpiness in the order patterns. That's still resident out there. It's just a little less so than what it's been over the last 18 months.

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

Last thing I would say is, part of our thing is we do think that you'll see a good Q1 from a Life Science standpoint because we do believe there's still a good amount of activity with regards to COVID. And we do think that as we head into the winter season that there's -- you're going into respiratory flu season. It would be silly to think that we're not going to have some kind of return of COVID during that window of time. So we -- that's part of the reason why we felt Life Science would be bigger in the first half than the second half as well.

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

Got it. And so based on your guidance for fiscal 2022, is the projected decline in Life Science segment solely based on the COVID-related revenue? Or there are some other factors playing into this?

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

It is solely based on a decline in COVID-related revenue volumes.

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

Yes, we have not lost any customers. Those customers continue to order. It's the assumption as you move from pandemic to endemic that volumes overall are lower, and that's really what drove the difference. That's being offset by new business that we've been picking up in regards to non-COVID related. So the COVID stuff slows down a bit. We pick up millions of other dollars of new business and that's how we kind of got to the $140 million to $150 million range for Life Science.

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

Got it. And lastly, how many new products do you expect to launch during fiscal 2022?

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

The Diagnostics side, we're expecting to release 3 to 4 -- excuse me, to send into clinicals and the FDA. I don't want to get in the game of predicting FDA timelines. I don't think that would be good for my career predicting. So -- but 3 to 4 tests that would be submitted to the FDA. I guess COVID EUA is one of them that we're talking that's coming through. So you've got another 2 to 3 more in addition to that.

On the Life Science side, there is a -- we have a steady stream. We seem to be doing 5 or more products a quarter. And I would say that we anticipate that to continue as we go through this fiscal year.

Operator

We have reached the end of the question-and-answer session. I will now turn the call back to Jack Kenny for closing remarks.

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

Thank you, Rob. As we close this call, I want to thank our team for their hard work this year. They helped deliver another record year and have positioned us to establish the new post-pandemic base from which we expect continued growth. Thank you all for joining this call today, and we look forward to speaking to you again next quarter. Have a great day.

Operator

This will conclude today's conference. You may disconnect your lines at this time. Thank you for your participation.