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VIVO.OQ - Q3 2021 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 2021 Earnings 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 2021 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 virtually in the H. C. Wainwright 23rd Annual Global Investment Conference September 13 to 15. Other events may be added as we approach the Fall. Our last earnings call of fiscal 2021 is currently scheduled for Friday, November 12, 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 and post-pandemic outlook 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 including its Delta variant. Meridian makes these statements as of today, August 6, 2021, and undertakes no obligation to publicly update them.

Additionally, throughout this presentation, we refer to non-GAAP financial measures specifically operating expenses, operating income, operating margin, net earnings and net earnings per diluted share each on an adjusted basis. Reconciliations 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 & Director*

Thank you, Charlie. As has been the case throughout this pandemic, predicting the volume of testing has been a challenge across our industry. The impact of COVID-19, particularly due to the Delta variant coupled with the global rollout of the vaccine remains unpredictable and somewhat volatile. We have thus far been directionally correct with what we see things going -- with where we see things going. This quarter is another example of that. From the beginning of the fiscal year, and again in May, we forecasted slowing reagent demand related to the pandemic in the second half. This quarter's performance in Life Science was in line with that forecast.

However, what should not be overlooked is that fiscal year-to-date performance has been exceptional. In looking at this quarter alone, Life Science performed significantly better than a typical pre-pandemic quarter further validating our message that we have a much stronger business coming out of this pandemic. The Diagnostics segment continues to face some headwinds, but continued advancement of our strategy is positioning us well for future growth. Let me expand on some of the operational highlights of the quarter and then Bryan will cover the financial results in more detail.

Consistent with our messaging in May, we concluded the remaining studies for the Revogene SARS-CoV-2 assay and re-submitted our EUA application to the FDA. Unfortunately, we cannot predict when the FDA will review the application, and we eagerly await their response. We finished the quarter with an install base of 343 Revogene instruments. The story with new commercial activity remains the same with customers continuing to wait for the approval of the COVID-19 assay. We expect the pace of installs to return to normal levels once the COVID-19 assay receives EUA clearance. On the manufacturing front, the production expansion in Cincinnati and Quebec are progressing with initial production on track by the end of September.

As you know, when I joined Meridian almost 4 years ago, there were a number of FDA-related issues with our LeadCare manufacturing facility in Billerica, Massachusetts including a warning letter issued in October of 2017. Our regulatory and quality teams have worked tirelessly on improving our quality systems and procedures in Billerica in collaboration with the FDA. In June, the FDA conducted an inspection of our Billerica facility and earlier this week officially closed that warning letter.

Lead testing and demand for new LeadCare II instruments continue to be a bright spot in the recovery from pre-pandemic lows. For the third quarter in a row, installs exceeded our expectations and our Q3 sales this year were on track to post the best quarter in the product's history. However, in May we initiated a recall of specific lots of our LeadCare assays due to, based on our current assessment, an apparent contamination with one of the components supplied by a third party. This recall serves as an example of our quality system at work, identifying an issue, investigating the root cause, and taking active steps to resolve the issue. Unfortunately, the recall and supply related issues resulted in a backlog situation pushing some revenue out of the quarter. The recall is still in process and continues to be a headwind.

In addition to LeadCare, the H. pylori franchise led by BreathID is seeing strong momentum. BreathID had the best quarter in its history and the closing of BreathID orders picked up significantly as our commercial team was able to leverage our broad portfolio of H. pylori testing options. We have leading urea breath tests, stool antigen ELISA and rapid tests, and in partnership with DiaSorin, high throughput stool antigen immunoassays. Whatever testing modality the customer requires, we have a solution and that is reflected in the continued strong commercial performance of the franchise.

In new product development, the team continues to advance the pipeline of products. Clinical trials continue to be a bottleneck for some of our products and during the quarter we redirected resources to the COVID-19 resubmission project. As a result it looks like completing clinical trials and preparing a 510(k) submission for C. diff on Curian and the GI panel on Revogene will be delayed until next fiscal year. There are many exciting products on the horizon in the Diagnostics segment that we look forward to commercializing.

In Life Science, the team had another strong quarter. We continued the expansion of the new Air-Dryable master mix portfolio with mixes optimized for saliva and plant-based samples. The first mix has already been included in an EUA approved COVID-19 assay with saliva as the specimen type, and the second is getting the attention of the AgBio industry because of the simplicity it enables. Inhibitor tolerant properties of our mixes enable lab technicians to bypass a number of typical preparation steps and simply add a plant sample. Additionally, we released both DNA and RNA based versions of our Lyo-Ready mix optimized for LAMP technologies.

The pandemic highlighted the benefit of quicker, point-of-care friendly molecular technologies, and our new mixes can accelerate product development time for our customers. The pipeline of additional master mixes to be launched in this quarter is robust and it will address critical clinical samples such as stool, urine and blood. Our Life Science business continues to launch solutions that accommodate a broad array of the most common patient sample types and test chemistries while ensuring the performance of the test. We believe this unique approach and pipeline of products provides us a strong competitive advantage in the market by accelerating development of molecular assays.

Lastly, as you know we recently closed the acquisition of the BreathTek business from Otsuka. This is another great example of how we are putting our strong balance sheet to work to drive greater returns to the business. Meridian remains focused on offering best-in-class solutions for GI, respiratory and pediatric point-of-care. Consistent with that strategy, this acquisition is another example of our commitment to the GI diagnostics area. According to the CDC, approximately 2/3 of the world's population is infected with H. pylori. Meridian is a big proponent of non-invasive testing for this highly under-diagnosed infection. If tested and treated, patients see great outcomes, and when not treated it is a leading cause of a gastric cancer.

This is a customer centric acquisition. Otsuka's organization was moving in another direction strategically, and as such Otsuka was looking for the right partner to support the business and their customers. They could see our commitment to H. pylori testing and our reputation for strong customer focus. Otsuka's customers will continue to be able to utilize their BreathTek solutions, but will now have the service and support of Meridian. We look forward to working with these customers in driving awareness and emphasizing the importance of non-invasive testing for this condition. We expect to take the opportunity to introduce Meridian's other H. pylori products including the option to upgrade to the BreathID solution when the time is right for the customer.

Meridian acquired this business for approximately 1x revenue, which is a good value for our shareholders. This business generates over $20 million a year in sales and as Bryan will discuss in more detail, we see this as being accretive immediately. We are able to absorb this product line with our current infrastructure and do not plan a material increase in headcount.

Now I going to hand the call over to Bryan to talk about the financial results for the quarter.

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

Thank you, Jack. As we start to transition from COVID-19 being a pandemic to being endemic, meaningful comparisons to prior periods will be challenging. Despite being down from the pandemic highs, Q3 was a strong quarter for the company relative to pre-pandemic levels. We recorded consolidated revenues of $64 million. Remembering that Q3 fiscal '20 was the peak quarter of that year, revenues are down 25% year-over-year. Looking back to Q3 fiscal 2019, a good example of pre-pandemic performance, we are up 31%.

Consolidated gross profit margin was 58% in the quarter down from 66% in the third quarter of the prior year and roughly flat to Q3 of fiscal '19. The year-over-year and subsequent quarter reduction in consolidated gross profit margin is primarily a result of a change in business segment mix. This quarter was nearly 50/50 between the Diagnostics and Life Science segments versus 25/75 in favor of Life Science for Q3 2020.

On an adjusted or non-GAAP basis, third quarter operating income was $13 million with a margin of 20%. Adjusted operating expenses were $24 million, down approximately $1 million year-over-year. Also, on an adjusted basis, net earnings were $10 million and diluted EPS was $0.22. Again, while down year-over-year this represents a greater than 37% increase over the $0.16 generated in Q3 of fiscal '19. The year-over-year decrease in adjusted operating expenses was driven primarily by lower Diagnostics R&D spending and corporate-wide G&A expenses, partially offset by 1 additional month of expense from the Exalenz acquisition that closed last year on April 30.

On a GAAP basis operating income was $16 million with operating expenses of $21 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses include a credit from an adjustment to lower the fair value of our contingent consideration obligation for the GenePOC transaction. GAAP net earnings were $12 million and GAAP diluted EPS was $0.26.

Now let's look at the details of our 2 operating segments. Diagnostics delivered revenues of $31 million, up from the pandemic low point by 44%. Unfortunately, this was down sequentially by approximately 2% due to the backorder situation that Jack mentioned in his opening remarks. We

estimate the Q3 impact of the LeadCare backorder to be $1.5 million and expect to be working through the backorder situation through the end of the calendar year. Respiratory as a category continues to lag the recovery, while both GI and Blood Chemistry continue to post strong gains. While we did have 1 extra month of BreathID revenue in this quarter versus the prior year, both our H. pylori and foodborne product lines are performing very well contributing significantly to the 86% year-over-year growth in the category.

Gross profit margin for the segment was 51% down approximately 150 basis points from Q2, and down approximately 140 basis points from the same quarter last year. The decline in margin from Q2 was driven by a lower level of royalty revenue in the current quarter. In addition, the year-over-year decrease was driven by pricing pressure in our H. pylori stool antigen products that we have mentioned in previous quarters.

Diagnostics had an operating loss on an adjusted basis of less than $1 million. Similar to prior quarters, this is a result of our continued investment in new product development and commercial excellence programs despite the lower level -- despite the lower sales levels. Diagnostics adjusted operating expenses for the quarter were down $0.8 million year-over-year driven by lower R&D spending and incentive comp.

Our Life Science segment recognized revenues of $32 million, a decrease of 49% year-over-year. This was more in-line with what we saw in Q4 of last year when we saw the first break in the pandemic demand. This level of sales is still dramatically above our pre-pandemic averages and we are seeing good growth in non-COVID product sales in addition to the continued contribution from COVID-related sales. Also of note, we had a backorder of approximately $1 million affecting our Life Science segment revenues at the end of the quarter related to core immunoassay blocking-reagent products. We estimate that revenue from COVID-19 products was approximately $14.5 million. This estimate suggests our core revenue was up approximately 15% year-over-year and would have been even higher had it not been for the backorder.

Gross profit margin was 66% in the quarter, down 500 basis points from Q3 of last year. Margins continue to be strong at this level of sales despite the year-over-year impact of product mix changes. Adjusted operating income was $16 million a margin of 50% demonstrating that this business still produces strong margins even off the peak revenue levels realized during the pandemic.

Turning to the balance sheet. As of June 30, we had $70 million in cash and a borrowing capacity of $110 million under our $160 million line of credit. As you know subsequent to the end of the quarter, we closed the acquisition of the BreathTek business funding it with approximately $20 million of cash on hand.

Turning to guidance. As Jack said in his opening remarks, predicting the impact of the pandemic is very challenging. Going into the quarter we knew that the second half of the year was going to see slower demand for products used in COVID-19 assays. While demand was lower than we would have liked, it was still consistent with our range of expectations. As such, we are holding the low end of our guidance and simply tightening the range and layering in the impact of the BreathTek acquisition.

We now expect consolidated net revenues of between 308 and $314 million, which includes Diagnostics revenues of between 128 and $130 million and Life Science revenues of between 180 and $184 million. We anticipate adjusted operating margin to be between 30% and 31% resulting in adjusted net earnings per share of between $1.61 and $1.67.

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

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

Thanks, Bryan. Meridian has delivered a strong 9 months and we are on pace to have another record year, eclipsing $300 million in revenue. We have made significant investments to reinvigorate our Diagnostics segment, and our Life Science segment has solidified its strong position with key Diagnostics customers during the COVID-19 pandemic. Meridian emerges from this pandemic much stronger. In the last 18 months, Diagnostics has submitted new products to the FDA and has advanced a robust pipeline expected for submission in the coming months. Life Science has established new relationships with the largest IVD customers and grown relationships with existing partners while pioneering new master mix technology with a focus on what diagnostics customers need in this new environment. Exciting times in each of our business segments.

Before I finish up, I want to acknowledge and thank our team in Billerica and our regulatory and quality teams. They have worked very hard over the past 4 years to remediate our quality system. As you know, you're never done working on quality and we will continue to invest in the improvement of our quality system, but the closure of the warning letter is an important milestone for the team. We remain committed to our strategy and laser focused on execution. We appreciate our shareholders' continued support of VIVO as we transform our business. We're proud of the progress we made but confident that our best days remain ahead of us.

And now, Bryan and I would like to take any questions you may have. Shelby, can you open it up for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question is from Brian Weinstein of William Blair.

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

I know that we're very much focused on kind of this quarter and still in '21, but I kind of wanted to get a little bit of a thought process at least on some high-level thoughts as it relates to how we should be thinking about next year recognizing there is a lot of uncertainty of course, but just conceptually you've talked about Life Sciences being $100 million business kind of coming out of this, you just did $30-something-million here this quarter, so annualizing well over that, but should we be thinking about Life Sciences as a $100 million plus business next year. And on the Diagnostics side, low to mid-single digits, is that still kind of the way to think about that? You had a couple of delays on some R&D, I'm just not sure kind of what high level we should be kind of thinking about on that side for growth?

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

So I'll start this Bryan and you can wrap around. So first of all, Brian, as you saw we were in the low-30s, if you will, in the quarter. We have talked consistently over the number of quarters that our Life Science business is a much different business coming out of this. It was a $65 million business going into the pandemic and we have very high confidence that it is certainly $100 million plus business. And when we talk about that, we believe that the core business in and of itself with no COVID impact is approaching that $100 million range, in the $90 million plus range. And then as you know there will be some level of COVID testing next year. I would say that we're -- I think we're pretty clear that COVID is not going away, but the reality of it is we don't anticipate it's going to be like it was this year. So we're going to provide much fuller guidance as we -- in Q1 we'll provide that, but I think your question in regards to $100 million plus, we have very high confidence that it is above $100 million business as you head into next year. Bryan, any comments on that?

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

Yes. I will just reiterate we are actively going through our modeling processes as we speak. We'll certainly have more to say in the fall when we issue guidance for 2022, but I think Jack is spot on in his comments.

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

Brian, we're really confident we have a strong Life Science business and it's going to continue to show its strength over the coming years. I don't think we have any concerns on that front. On the Diagnostics front, we have been talking about a mid to high single digit kind of growth for that business and we still have very high confidence in our ability to do that. I think our number next year is going to look more than that because you've got some acquisition revenue that comes in from the acquisition and also some of the recovery of COVID. So we are certainly expecting a higher performance in mid to high single digit next year. It will be a double digit type of growth year for sure and we'll provide much more guidance

on that as we get to the end of Q1. Our Diagnostic business, Brian, we have been grinding in that business for a number of quarters. We're making a lot of progress and our confidence continues to build with that business. So we feel very good about both of our businesses as we head into '22.

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

Yes. I would just add to that, Brian, we are encouraged by the volume increases we're seeing on the Diagnostics side in our gastrointestinal line of products. We have foodborne products as you know, we've talked about H. pylori, the volumes increasing even beyond what we've talked about from an acquisition standpoint encourages us that we're starting to see the other side of this pandemic effect.

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

Got it. Okay. I want to also talk about cash a little bit here and use of cash. We're still kind of in that same kind of range on R&D where you've been for a little while now, and there are opportunities that are out there. I'm just curious how you're viewing kind of any kind of acceleration in R&D to fuel future growth. I mean you obviously have programs in place but are there other opportunities, are there inorganic opportunities? Obviously, this one over the last month or so was kind of a special situation where it was kind of a perfect fit and the holder of that asset was hoping to get out of the business, but I mean how aggressive should we be thinking about these other ways of kind of accelerating the top line here, be it increased R&D or more M&A?

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

So I'll start and Bryan you can wrap around again. so, first of all, Brian, we're going to continue -- I think the investment you've been seeing on the Diagnostics side in that high-teens 17%, 18-type of percent of revenue, that level of spending is what we're anticipating generally speaking going forward. The percent will start to come down as our revenue dollars increase, right? So it will be a lower percent of sales, but we'll be continuing to invest similar amounts of money into R&D and we do believe with that pipeline we can build a robust organic growth in the future from that. As you alluded to before, we -- as you know, a couple of years back, we eliminated the dividend and thanks to our Board for the support of doing that, that enabled us the opportunity to really begin a more aggressive investment into the business organically and inorganically. The cash that we generated through COVID, we've deployed that, we made the Exalenz acquisition and now the BreathTek acquisition, both of those were really done to strengthen our position in a post-COVID type of environment. And so, I think what you'll continue to see from us is continued internal investment on the Diagnostics. You will also see increased investment going forward in R&D on the Life Sciences side. We have a very efficient organization, it's done amazing work on the Life Science side organically, but we're going to increase some of those investments with that team as well. There is planned investments on the Life Science side organically. From an inorganic standpoint, we hired Charlie 1.5 years ago for a couple of different reasons. One of them was IR but also really from a business development standpoint. And so we have a working pipeline and a process that we are using to really assess opportunities. We have been very committed to staying on the strategy that we have. So in Diagnostics, it needs to be GI, respiratory or pediatric point-of-care related or in the Life Sciences side I think you're starting to see us build our funnel on the Life Science side as well. So I think our intention is to use the cash we have to strengthen it and really to get this thing firing on all cylinders. Life Science has been firing. We're going to get Diagnostics firing next but we want to keep putting gas on that fire. Bryan?

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

Yes, I would just to add to that, Brian, that on the Diagnostics side of the business we feel very good that we have the right instrumentation platforms available to us now and you're going to see us building menu content from an internal R&D perspective. And then on the Life Science side, you've seen a number of press releases from us over the last several months. We think we're being pretty innovative in the new products we're coming out with on the Life Science side, particularly the Air-Dryable mixes that you hear us talk about. From an M&A perspective, as we said before, the transactions that we would do need to be on strategy. They need to fit very well within -- to what we're trying to do strategically. Things are a little rich right now, I would say, in terms of valuation. So that's always a consideration but I think the deal we just did with Otsuka is a good example of something that works not only well for the business but works well for our shareholders as well. So we're trying to make sure we're thinking about both of those things as we filter through acquisition opportunities.

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

Okay. And the last one for me is on cost pressures. Obviously, everybody is talking about them. Can you just talk about the impact of increased costs whether it'd be on the labor, freight, materials, kind of what you're seeing in the availability of the materials throughout the supply chain. Thanks, guys, and we'll see you in about 10 days I guess.

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

I'll start that. So first of all, Brian, we definitely are seeing some level of pricing pressure with some of our supplies. I think we're no different than anybody else on that front. We've been working hard with other cost saving programs really with the intent of trying to make sure that we contain any risk that we have from a pricing standpoint. I don't think that we've seen anything that's overly material at this point in the data that we've got and from a hiring standpoint certainly wages are challenging. There's higher wages that are being out there, but we're also having a hard time hiring even at higher wages. I think like most companies, it's been a challenge to try to hire people on. So at this point from my perspective, there are some pressures on that, it's not overly material to our numbers at this point. Bryan, would you?

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

I would absolutely agree with that. And some of the supply chain things we've alluded to isn't necessarily a price issue, it's more of being able to secure the volume that we need from a manufacturing standpoint.

Operator

Your next question is from Steven Mah of Piper Sandler.

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

So my first question's on the -- your Air-Dryable master mixes. So it seems like if you can do saliva and plant, which my understanding is plant is a pretty hard sample to get it working properly. So how hard is it to move into the different sample types, blood, urine, et cetera. And the second part to the question is for these different master mixes for different samples, how materially different are they? Are they just small tweaks or are they completely different?

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

So, by all means, Bryan and I are not the most scientific individuals to answer this but I think I can get you at least on the path Steven and if not, we'll get the right people to take it further. I'd start first of all by saying, our team in London has really built a strong expertise in how do you use excipients and how do you dry down what reagents to make them air-dryable and ultimately enabling high performance and the great benefits of shipping. So we kind of figured that out over the last couple of years and built some strong expertise. After we figured that out, we really started to then work on these different sample types because every sample type has a different type of inhibitors that basically can impact the performance of that sample type. Stool is completely different than saliva which is different than blood than urine, et cetera. And so I would describe the expertise we have in the dry down capabilities and the excipients along with the expertise because we have been working with sample types and we know what inhibits them. So we brought those 2 capabilities together and it's really kind of working our way through these. So we don't have any that we have discomfort that we can get to build a great mix on, it's really kind of like the next one up and working your way through the pipeline. And so we have really high confidence and all the mixes that we have, have been working very, very well and in many cases the customers were happy and we were great. In a few cases, we do a couple of extra tweaks as we work with those customers to really optimize that performance but we feel very, very, very good about that.

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

The only thing I would add to that is that the way I would think about this, Steven, is we have an underlying development process or system to where this is maybe a little bit similar to when you think about menu development on a diagnostic instrument. So in this case, we have a mixed process, if you will, that we can think about different samples to kind of plug into the same development process, if you will. So kind of a standardized process of how we do things that makes it a little bit easier on the development side.

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

And it's certainly been very exciting for us on the molecular front to make all these different mixes. It's a very unique approach. Competitors are not doing that and so we do believe it's a very significant competitive advantage for us as we're helping our customers to build new molecular tests. But we also believe that our expertise can take us into some other areas in the future like next-gen sequencing and providing some capability or skill sets into that area as well. So that's an area that we're starting to look at as well with our capabilities.

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

Okay. Great. Yes. I think that's pretty exciting, the Air-Dryable master mixes, yes. So maybe just pivoting over to COVID, we've been hearing a lot that there is potentially going to be a flu season and there's some spikes of RSV as well. Could you update us on the status of the Revogene respiratory panel clinical trial. I know that you guys are having some difficulties enrolling patients but just wondering if that changed now with the kind of the recent Delta variant emergence?

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

So the first test that we will have will be the COVID-only test and that's really what we would like to have as we enter into fiscal 2022. We do have active programs on the respiratory panel. As you noted before, Steven, you couldn't get any flu or RSV specimens, any fresh specimen last year so it was very challenging. We anticipate that you know that we would be able to get more of those specimens, but it's going to be more likely in any kind of quantity more along the time frame of when the flu season starts to hit when you can really get any reasonable amount of those specimens. So as far as a respiratory panel, it is unlikely that we would have it in this flu season. Now there is a chance for it Steven, but we are not counting on that and any of the numbers that we have, we're really only looking toward the COVID-only product into our portfolio in the '22 flu season. Bryan, do you have anything to add to that?

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

The only other thing I would add, Steven, is we're trying to make sure we've got flexibility built into our clinical processes and what I mean by that is, if for some reason we have trouble with getting fresh specimens, how do we think about from a regulatory standpoint going and getting frozen specimens that are archived or something like that. So we're trying to think of all different angles to help us through this process here as we go through.

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

And that's one of the things that it's really a little unclear with how the FDA will work, do they contract specimens versus fresh specimens and so that's a little bit of an ongoing active type of dialog that you'd have with the FDA. I would say for now, Steven, as we look at 2022 it's really about the COVID stand-alone test for us. The other thing if it does happen would be an upside but I would say that we are not materially counting on that as we head into 2022.

Operator

Your final 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 given the current data showing that the Delta variant can transmit and affect -- infect both the vaccinated and the unvaccinated individuals, do you think in the near term in the current quarter or the following quarter that there could be an uptick in COVID-19 related revenue?

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

So Yi, it's a little bit hard -- it's a hard thing to predict. I mean I think as we all look out in the press today, clearly there is a lot more COVID activity now than there was 60 or 90 days ago, right? I mean if you look in our last quarter, there was not a -- life was fairly normal and there wasn't a lot of COVID talk. I mean it was still out there. It is certainly surging a bit more with regards to the Delta variant. So even if you look in our implied guidance, we are anticipating a bit of a stronger Q4 than Q3, but we are not planning on a huge COVID impact. Certainly if it does occur, we're prepared for it. We have the ability with our capabilities from a scale standpoint to handle it, but our approach has been to really look at it kind of what's in front of us and so that's what's led us toward the guidance we have. I would say our business, we do have ordering pattern things that come into play, but it does kind of follow what happens with the overall COVID trajectory around the globe. And so that would be the other comment I would make.

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

The other thing that I would say to this on the Life Science side of our business is we are still monitoring how much inventory is in the supply chain and that can be a factor at least in the near-term as manufacturers are working through inventory that they have on hand throughout this process.

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

Got it. And if we just strip away the COVID revenue and obviously the Life Science segment is growing quarter -- year-over-year but do you think this growth rate could be maintained going forward without any COVID revenue or do you think it may continue to drop a little bit, the growth rate?

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

So our non-COVID business is growing robustly. And so we have very high confidence that, that will continue going forward. We had -- as COVID hit, we were quick to respond and had helped our customers build great tests, but then we also were able to supply them. So what happened is we built a lot of loyalty with some of these key customers and certainly it's been a positive impact for our business during COVID but ultimately now we're working with those customers in their post-COVID activities. And so we have strong confidence in a very robust double digit growing business for our Life Science business outside of COVID. What we don't know is what happens with COVID right? Is it huge like it was last year? Is it here but not as big? And so -- but part of -- Brian asked the question earlier about $100 million business, take $65 million business and we're approaching $100 million kind of core business over this next year without any COVID. And I think we'd all agree that COVID may not be what it was last year but it's not likely to go away. And so I would describe to you that we have a lot of confidence that we have a robust growing Life Science business for a number of years going forward.

Operator

There are no other questions.

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

Okay. Well, first of all, I want to thank you for joining today. As you heard from Charlie, we look forward to speaking to you as we have some upcoming conferences, and again in November at the conclusion of fiscal 2021. Thank you very much, and have a great day.

Operator

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