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VIVO.OQ - Q1 2022 Meridian Bioscience Inc Earnings Call

EVENT DATE/TIME: FEBRUARY 04, 2022 / 3:00PM GMT

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PRESENTATION

Operator

Greetings, and welcome to Meridian Bioscience First Quarter 2022 Financial Results Conference Call. (Operator Instructions) As a reminder, this conference is being recorded.

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

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

Thank you, Doug. Good morning, and welcome to Meridian's Fiscal 2022 first quarter earnings call. With me are Jack Kenny, Chief Executive Officer; and Julie Smith, Senior Vice President, Controller and Principal Accounting 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.

Jack and I expect to participate in at least one conference prior to the next earnings call, but do not have anything to announce at this time. Per usual, details of any events will be announced via press release and posted to our website as they are finalized. Finally, our Q2 fiscal 2022 earnings call is currently scheduled for Friday, May 6, 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, February 4, 2022, and undertakes no obligation to publicly update them.

Additionally, the company's remarks also include market data based on management's knowledge of the industry and good faith estimates of management. The market data referenced 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 in part is derived from management's estimates and beliefs, is inherently uncertain and imprecise and has not been verified by any independent source.

Lastly, throughout this presentation, we refer to non-GAAP financial measures, specifically operating expenses, operating income, operating margin, net earnings and net earnings per diluted share, each on an adjusted basis. A reconciliation of these non-GAAP financial measures with the most directly comparable GAAP measures and other related discussion are included in our earnings release.

And now I would like to turn the call over to Jack.

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

Thank you, Charlie. While disappointed that we are fighting yet another wave of COVID-19 infections across the globe, I am pleased to be here recapping another fantastic quarter for Meridian, one of the best in the company's history.

What is really exciting about this quarter is that the strong result is due to both businesses performing ahead of our internal plan. This dynamic bodes well for the quarters to come.

Diagnostics was up 10% year-over-year, and the Omicron wave of this pandemic drove higher demand for our Life Science reagents relative to our fourth quarter of fiscal 2021.

Julie will elaborate more, but it should be noted that the first quarter of fiscal '21 was a record quarter for the company, and while the metrics will show Life Science down year-over-year, this most recent quarter was one of the best on record, with sales in the first 3 months nearing levels that would have taken us nearly 12 months to achieve pre-pandemic.

Operationally, the company made tremendous progress in the quarter, perhaps outshining the strong financial results. The Life Science innovation engine in London keeps cranking with the launch of the first sample-specific mixes in our Lyo-Ready format, which are designed for use in molecular assays that are lyophilized. These first products were our saliva mixes, and we will be launching more throughout the year.

Enhancements made in fiscal 2021 in our Life Science manufacturing still leave capacity for growth. The team has deftly managed these supply chain challenges plaguing other companies in the industry and we continue to have ample inventory of critical raw materials.

As I have mentioned in the past, our ability to meet the demand of our customers, throughout surges in the pandemic, has won awards from our suppliers and helped us win business from the competition. We are being diligent in staying ahead of this situation to protect our reputation as one of the most reliable suppliers in the industry, in addition to being the leading innovator with our Air-Dryable format and sample specific mixes.

Also in the quarter, 2 diagnostics assays received approval from the FDA, with Curian Campy receiving 510(k) clearance and the Revogene SARS-CoV-2 assay receiving Emergency Use Authorization. The latter is being updated in response to the Omicron variant and we are working closely with the FDA to get this shipping later this quarter.

The LeadCare team in Billerica has made substantial progress in resolving the issues with the third-party components behind the recall initiated last year. The team is in the process of validating the new packaging components and we remain highly confident that we will have this important product shipping again by the end of this quarter. Of course, exact timing is subject to review with the FDA.

The ramp-up of Revogene manufacturing continues its pace. The new line in Quebec became operational in the quarter and the first line in Cincinnati just completed validation and recently began producing kits. As we announced earlier this week, the NIH continues to be a strong believer in the benefits of the Revogene system, awarding us another $2.5 million to support continued manufacturing scale up and the development of the respiratory panel.

Our H. pylori franchise is our most important contributor to the Diagnostics segment and the team keeps delivering results. Integration of both the BreathID and BreathTek acquisitions are now complete. This is a perfect example of the expertise we have built in M&A, seamlessly integrating 2 acquisitions, including a carve-out, in the midst of a pandemic where travel has been greatly limited.

This is a good segue into a new feature that I would like to introduce in fiscal '22. In an effort to provide a better appreciation for the opportunity that lies ahead at Meridian, I would like to take some time to provide further details on important areas of our business. A good place to start is with H. pylori, as that franchise is the largest disease state for our Diagnostics segment, accounting for approximately 45% of our Diagnostics revenue in Q1, and offering a tremendous growth opportunity.

As you know, Meridian was the pioneer in stool antigen testing, introducing the first assay of its kind in 1998. We had patents on that testing method, which expired in 2016 and 2017, that yielded extremely high margins. As new entrants emerged following expiration of the stool antigen H. pylori patents, we took steps to protect that business.

First, we entered into multi-year agreements to annually step down pricing with our largest customers. Second, we entered into a strategic partnership with DiaSorin to accommodate higher volume customers by providing an H. pylori assay on the fully automated high throughput LIAISON platform.

Adding this product to our portfolio allowed us to diversify our volume based market segments and complement the other technologies in our H. pylori franchise. Both of these strategies have been successful in maintaining our leadership in testing volume, albeit at a lower average selling price.

In 2020, we added urea breath testing, also known as UBT for short, to our already strong H. pylori franchise with the acquisition of Exalenz Bioscience, the manufacturer of the BreathID system. Last year, we acquired the BreathTek product line from Otsuka, another urea breath test for H. pylori.

With these products, we are the only company selling FDA approved assays for both stool antigen and urea breath testing for H. pylori. This is an important advantage for our sales force in crafting solutions for our customers. Each test has advantages and challenges, and often clinicians are biased towards one solution over the other.

While both testing methods have good sensitivity and specificity, UBT has superior performance relative to stool. UBT also uses a sample type that is easier to collect and process. The downside to UBT is that patients need to stop taking medications that are suppressing their symptoms for 2 weeks prior to the test.

There is one other minimally invasive approach to detecting H. pylori, which is serology. This was the first method developed for testing H. pylori, and has significant limitations. First, it is dramatically less sensitive than either UBT or stool antigen testing. Second, and most importantly, it does not confirm whether you have an active infection. This could lead to misdiagnosis and the overuse of antibiotics.

Additionally, it cannot be used to confirm eradication after a patient completes a treatment plan which can lead to long-term consequences for the patient. Poor performance of serology testing has led to reduced or, in many cases, no reimbursement for this type of testing.

Further, key medical organizations such as the American College of Gastroenterology and the American Gastroenterological Association have recommended against using serology tests. Despite that, there are still a number of doctors using these tests and we estimate that over 25% of H. pylori testing is done with serology.

Globally, H. pylori prevalence is very high, as well as in the U.S., where it is estimated that on average 25% to 30% of the population is infected, with greater than 50% infection rates in more ethnically diverse areas.

With only an estimated 6 million to 8 million tests performed per year, many people remain undiagnosed and untreated. This results in billions of dollars spent on over-the-counter and prescription medications that only address the symptoms and not the underlying infection.

When left untreated, H. pylori can lead to peptic ulcers and in some cases gastric cancer where H. pylori is the leading cause. So, there are very compelling reasons, both for patient health and efficiency of healthcare spending to increase testing.

One of our strategies to increase testing is to provide education to both patients and physicians on the disease itself, the prevalence, and negative consequences of not properly diagnosing and treating H. pylori. Meridian offers health systems, a solution with options for non-invasive, guideline recommended, active infection tests.

Regardless of the choice in testing method, stool antigen or UBT, we encourage more testing to accurately diagnose patients and reduce cost related to misdiagnosis and treatments.

Lastly, we have noticed that H. pylori testing volume is weighted more towards the large reference labs than other products in our portfolio. On average, most products see 20% of the testing volume performed at the national reference labs. For H. pylori, the volume in roughly triple that. There is an opportunity to shift that testing closer to the patient, enabling a better patient experience and outcome. Additionally, it is possible to obtain a higher ASP that is a win-win for both Meridian and our IDN customers.

In summary, there are 3 vectors for growth in this disease state: One, converting existing serology volume to one of our better performing alternatives; Two, grow the market through more testing; and Three, drive, higher ASPs through decentralized testing. This makes H. pylori one of the Diagnostics segment's best growth opportunities.

Now I will hand the call over to Julie to provide some additional details on the financials for the quarter.

Julie Smith

Hello everyone. As Jack mentioned, this was a very strong quarter for Meridian that exceeded our expectations in both the Life Science and Diagnostics segments.

Consolidated net revenues were $88 million, down 5% year-over-year, but second only to Q1 of 2021.

Diagnostics segment net revenues grew 10% to $33 million. This growth was driven by strength in gastrointestinal and respiratory product revenues, partially offset by negligible LeadCare revenues.

In the gastrointestinal category, a significant driver of growth was the addition of BreathTek, which we did not have in Q1 of fiscal 2021. In respiratory, the primary driver of growth was increased demand for our mycoplasma, Group A Strep and RSV products. Interestingly, flu demand, while up year-over-year is still very light.

Life Science had a very strong quarter, with net revenues of $55 million. As we mentioned in last quarter's call, we are no longer reporting the portion of Life Science revenue driven by COVID-19. Many customers use our reagents in multiple tests, therefore, it has become too difficult to estimate the portion of molecular reagents that are used solely in the manufacture of COVID-only tests.

That said, it is fairly obvious that the year-over-year decline in molecular is driven by decreased demand related to COVID-19 molecular testing. But, what isn't clear is that there is offsetting growth from respiratory panels and non-COVID assays which are manufactured using our molecular reagents.

On the immuno side, demand for SARS-CoV-2 antibodies, which are used to make rapid antigen tests, were the biggest contributor to growth. However, non-COVID immuno product revenues were also up more than 30% year-over-year. This was led by our blocker product line, which increased by almost $2 million or 113%.

Consolidated gross margin was 56%, with a Diagnostics margin of 48% and a Life Science margin of 60%. While the Diagnostics margin is low by historical standards, it was modestly better than our expectations. The primary driver of these lower margins is LeadCare being off the market, which is a drag of approximately 400 basis points.

Life Science gross margin was down, both year-over-year and sequentially from Q4, due to variation in the mix of revenue between immuno and molecular products. As we have said in the past, due to the nature of the molecular reagent manufacturing process, which benefits more from scale than the immuno business, our molecular products have dramatically higher gross margins than the immuno products.

Adjusted operating expenses were $29 million, up $4 million year-over-year due to increases in consolidated G&A costs, R&D spending in Diagnostics, and sales and marketing expense across both business segments. GAAP operating expenses were also $29 million, up $2 million versus prior year driven by the aforementioned items, and partially offset by a decrease in legal expenses and contingent consideration expense.

Consolidated operating income on an adjusted basis was $21 million, a margin of 23%. This breaks down to an adjusted operating margin of 48% for Life Science, partially offset by an adjusted operating loss of $2 million for Diagnostics. Overall, the biggest driver of operating margin is the lower gross margin for both segments.

Adjusted diluted EPS was $0.35 compared to $0.65 in the first quarter of fiscal 2021, while GAAP diluted EPS was also $0.35 in Q1 of 2022 compared to $0.61 in Q1 of 2021.

If you want to dig deeper into the drivers for the first quarter of fiscal 2022, please refer to our press release and our 10-Q, which will be filed today.

Turning to the balance sheet. As of December 31, we had $73 million in cash. During the quarter, we also repaid $10 million on our line of credit, putting us in a net cash position. This leaves us with a borrowing capacity of $150 million. As we mentioned on the last earnings call, in October, we revised the terms of our existing credit facility to increase the capacity to $200 million, extend the maturity date to 2026, and incorporate other favorable changes in the covenants.

I will now turn the call back to Jack to discuss guidance and offer some closing remarks.

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

Thanks Julie. As you can see, fiscal 2022 is off to great start and we have even more optimism than we did at the outset. As such, we are raising our guidance. We now expect consolidated net revenues of between $315 million and $330 million, which includes between $145 million and $150 million of revenue for our Diagnostics segment, and between $170 million and $180 million for our Life Science segment.

You will notice that the Diagnostics revenue guide remains unchanged. Our current view is that the modest outperformance in the first quarter, coupled with the increased demand we are seeing for our partner SARS-CoV-2 rapid antigen test will offset any lost revenue from the delay in shipping the Revogene SARS-CoV-2 assay.

We still expect Diagnostics revenue in the second half to be moderately higher than the first half, as LeadCare production comes back online and we have contribution from the Revogene SARS-CoV-2 assay.

The increase in Life Science revenues reflects the level of demand we are seeing for our reagents, driven primarily by the Omicron wave. As such, you should allocate this increase more to the second quarter than the later quarters.

Adjusted operating margin is expected to be between 21% and 23%. This reflects inflationary pressures on wages and other operating costs, 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.

This all equates to an EPS range between $1.10 and $1.30 based on a fully diluted share count of 44.5 million shares. It's really great to be able to present a quarter with both business segments performing above expectations and, yet again, being on a trajectory to exceed the guidance set at the beginning of the fiscal year.

The rest of Q2 still requires some strong execution from our Diagnostics R&D, regulatory and operations teams, as well as both commercial teams, but the progress to date is promising and I remain highly optimistic that Q2 will be another quarter with great accomplishments for both segments.

I wanted to close with some brief comments on the governance changes we announced coming out of the Annual Shareholder Meeting last week. After 21 years, our Chairman, Dave Phillips retired from the Board. His contribution to the Boardroom over that time was tremendous and we will miss his presence.

Fortunately, we have developed a strong bench on our Board and did not need to look externally for Dave's successor. We are excited to have John McIlwraith assume the role, and with the depth of talent of the rest of the Board and my management team, we have the leadership to continue this tremendous run that we've experienced in the last 24 months.

Now Julie and I are here for your questions you may have.

QUESTIONS AND ANSWERS

Operator

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

Unidentified Analyst

This is actually [Griffin]. Brian, [Andrew] and I, we'd love to know how you guys are modeling and taking into account what we think will be multiple days the City of Cincinnati kind of been shutting down on the Super Bowl with the parade. I mean is that contemplated in this guide?

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

We are very hopeful that we have that problem here in Cincinnati. Obviously, it's been, what, 31 years since the Bengals have been in this game. And we are cautiously optimistic that we are going to be highly unproductive on Monday, the 14th of February.

I'd also just tell you real quick. I am a little conflicted. I'm a Bengals fan. You live in Cincy, you have to be a Bengals fan. I'm a little conflicted, however, because I'm from Detroit and we have Matt Stafford in the Super Bowl, and we have M&M at half time. So I kind of have it both ways. It's the closest Detroit is ever going to be in this Super Bowl. So in either way, I'm going to have a good Sunday on the 13th.

Unidentified Analyst

That's good stuff. Just on the -- to start on the quarter and the guide for Life Science, I mean, understanding that breaking out COVID specifically. But just directionally, any sense of how we should think about that where COVID revenue in Life Sciences came in this quarter versus last quarter?

And then on the guide, appreciate the color on Q2 being a little bit more heavily weighted. But can you just talk about the overall COVID assumptions? I mean, are you assuming any other surges or sort of a sequential decline throughout the year there?

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

Yes. So we -- what we've done throughout the whole -- this whole process, [Griffin], because we are -- it's hard to predict exactly what's going to happen with COVID is really try to make sure where we have line of sight that we bring that into our guidance. And we, clearly, have line of sight through this quarter with activities that are going on. We definitely see strong performance. We had a good performance in Q1, and I think you can take from our guide that we see similar type of performance in Q2 on the Life Science side.

Our guide doesn't really -- we kept our guide the same for the back half of the year that we've had historically, which is our off seasons are of a certain size, and we say off-season like the non-respiratory season. So we are -- we have not modeled in our forecast that Omicron continues to rage up and down. We viewed it more like what happened in 2020 and 2021 where in the spring and summer, it kind of gets a little quieter, and goes into more of an endemic type of situation. And there's -- the revenue that we had in those other quarters is -- we envision a similar type of revenue in that quarter.

Julie, do you have anything? Does that make sense or any addition?

Julie Smith

Yes. No, that's exactly what we're looking at. And I think the other thing that also has happened repeatedly throughout the pandemic is, when we have these spikes, customers stock up. And so then sometimes after that we will see a little bit of a dip. So I think we would -- right now, there's a lot of demand. And if demand wanes, then customers will have stock on hand, so that can impact our results.

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

Yes. And we've definitely seen that. It's better now. In the early days, they were hoarding everything they could get their hands on supply chain. But because we've proven more reliable, they aren't ordering in as big a batches at a time, but we still have some of that, that carries over. We historically have called our Life Science business a little bit lumpy, and there's that same factor here with regards to COVID.

Julie Smith

Yes. I think that's the primary driver of why we're down this year, Q1 versus last year Q1, because there were a lot of customers stocking up last year.

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

Major stock as last year. Yes, I agree.

Unidentified Analyst

Okay. And then just another on Life Sciences. As we think about kind of post-pandemic, you talked about the strength in that business and how it's changed pretty significantly. But can you just talk to any additional proof points about how we get through the acute phase of the pandemic? What it looks like on the other side, what's sort of a normalized Life Science business? And any kind of proof points you have there?

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

Yes. I would tell you that we -- in the Q4 quarter that we did, we provided a little bit more guidance to try to give some people some reason why we have such confidence for what our Life Science business looks like on the other side of COVID, and other side being more of an endemic environment. So we see the world that COVID is not going to go away. That it will be endemic, and that we're going to have testing that's ongoing.

And when you have a significant share of COVID, people using your products that will continue, just at lower volumes in more endemic environment. And so we really do view that we have a business that, going into the pandemic was a $63 million Life Science business, and we feel confident that we have a $150-ish million business now that we can grow from.

I would also tell you, [Griffin], that we've had -- we had a chance to shine for these companies. We got our chance. We were new in the molecular space, because we had pivoted from selling to researchers. And so this was our chance to shine, and we delivered very well for our customers over the last couple of years and those customers are actively working with us on their new product pipelines and portfolios. So we have -- none of those tests have the volume that a COVID would, because that was so overwhelming to the world, but you just get into this regular cadence of new tests that are coming with these folks, and we have a strong pipeline of that that's occurring.

So the longer this pandemic goes on, the more entrenched we're getting with these customers as well. So we find ourselves, here we are 2 years into the pandemic, and it's a completely different environment with us and our customers on the Life Science side. And so, we're really strong believers that a $150 million business that is growing double digits is what we have in this whatever post-COVID world looks like.

Unidentified Analyst

That's really helpful. And then just 2 on Diagnostics. A number of FDA submissions, I think, 4 expected this year. But can you just kind of generally characterize the conversations you're having with the FDA? I know they've been a little slow. Review times have been pushed out on some of the non-COVID stuff? And then any sense of -- any more specific time lines for those for the Shiga Toxin and C. diff for Curian, and then respiratory and GI for Revogene?

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

So there's no doubt that the FDA was dealing with backlogs and dealing with challenges, and that hasn't necessarily led up. An example would be Campy. We put it in the Spring and really took several months before we even were able to kind of get them to really look at that with all the things that they had in their plate. And it seems to go in waves. When the Omicron stuff hit again, their activity level goes up. So we do anticipate that it's going to be a continued grind to get things through the FDA.

Hard for us to say if it frees up. At some point you have to believe that it will. But we haven't seen it free up. It's still been pretty -- FDA is working incredibly hard, but they got a lot on their plate right now. And so we have kind of been assuming that it's going to take us longer than normal for things to get approved. And so as we model out the business, we are planning for a little bit longer periods of time before a product does get through final approval and start shipping.

So I don't know if that completely answers [Griffin]. But our dialogues with the FDA are good. The question is getting the FDA at the table, because they can't get you, because you're kind of in line. It's like you're waiting in line in the queue and you're waiting for your chance to get to the person to help you. Once you get to them, they work with you and they work effectively, but it's been hard to get to them at times.

Unidentified Analyst

Okay. And then just the last one on Hp. I appreciate the color in the prepared remarks. I mean if could you talk about how disproportionately more of that testing is done references labs than diagnostics and the pandemic has certainly accelerated decentralized test. But I think the focus on our side has been on respiratory. Do you feel that the decentralization trends in respiratory are being similarly felt in GI based on the conversations you're having with customers?

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

So I would say that all customers -- the customers are faced with 2 challenges right now. Obviously, they're trying to support the COVID testing, but they're also quite frankly supporting -- trying to figure out how to survive with light staffs. So it is less active right now than it will be when COVID goes back in a more normal state, and when our supply chain and, like, hiring gets back to a little bit more normalcy. So there is strong interest from customers to look at things such as urea breath tests that are being sent to reference labs and considering to bring them in. The challenge is a little bit like the FDA is to get their attention when they're trying to survive.

So we knew that when we made these acquisitions. We knew that the time frame to get some of these conversions could take longer. But we plan for it, because we're building our Diagnostic business for the long haul. So we see strong interest from customers, but the reality of it is that it's slower right now, because quite frankly, labs are trying to survive between the COVID testing and the shortage of staff that they have.

Operator

Our next question comes 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 you mentioned that the revenue from the -- the mix from the molecular products is -- there was a decrease and the mix from the immunological products there was an increase. Could you give us additional color behind that change?

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

Yes. So I'd be glad to do that, and then Julie, you can wrap around if there's additional things. So if you look at last year, when we had our $63 million-ish quarter in Life Science. We had a very, very strong molecular sales. And we did again this quarter, it was in the low 30s. I don't have the exact number in front of me, but we did have, but it was lower than last year.

The main difference, Yi, from last year was we had some customers in the United States that were ordering like multimillion dollars, because they were stocking their supply chain because there was still the fear of, can I produce the test. And so ultimately, we did have lower molecular sales. Still very high levels.

And the ordering patterns -- I'll give you an example. A customer last year could say, I want $5 million worth of this product. And that happened in some cases. Those customers didn't know how quickly they were going to use it, but they were trying to get their hands on anything that they could.

We have an environment now where that same customer is more likely to come to us for a $1 million order than a $5 million order, because they know that we've reliably been able to produce. We've got more confidence that they've built in us. So that is a factor here and that specifically showed up in our United States business. That's why you saw the U.S. Life Science was lower significantly than last year.

And then the second factor here, Yi, is, if you look at what's going on in the world for all of us, all that we hear about are rapid tests and people want rapid test. Whether they're shipping them to your house, whether you're going to the doctor, but they want to do a rapid test. That area has been an area that has scaled up to be able to handle the COVID challenges around the globe, and we had a good market position.

So we have seen exploding growth in regards to the rapid antigen testing area. So we sell the antibody pairs that are used to do the rapid antigen test, and that volume is skyrocketed versus last year. It was a fraction of what it was last year versus what it is right now.

So it's -- the molecular is still doing great, it's just per probably ordering patterns and some of those things. And then it's really the acceleration on the immuno side, specifically with the antibody pairs is what the difference is. Julie, I think that covers it.

Julie Smith

Yes. I mean those are the 2 main drivers. The -- yes. Really, the market is shifting towards the rapid testing right now.

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

Yes. Yi, the last thing I'd say is, we've seen some countries like the U.K. that at one point was doing all molecular testing and they came out and said, now, we're going to switch and start doing all rapid, immuno. And so they kind of have bounced around a little bit. So that's also affected what's going on with the demand in general, with some countries and stuff making decisions like that.

Julie Smith

Yes. And a big piece of that is definitely the at-home test, because those weren't available last year.

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

That's true.

Julie Smith

And that's our another whole market.

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

That's true.

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

Got it. So you raised the 2022 fiscal year guidance for Life Science segment, was that primarily because you expect more revenue or more COVID-related revenue or non-COVID related revenue.

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

We are seeing very good growth in non-COVID, let me be clear. I would say that's been more consistent with what we planned. The increase in our guide is truly for this activity that's going on. We're not breaking out COVID sales. But yes, it's activity that's related to the aggressive nature that Omicron has been. I mean, I think it took over the world, and we felt that in our business.

So that's why we basically said you had a $15 million beat or so in the first quarter, kind of versus what people thought. And we've kind of guided towards it would be similar type of performance in the second quarter versus that. So we do see that.

If COVID keeps continuing on, our guidance would change, but we really try to not get over our skis and really try to make sure that we can guide to what we have good confidence in versus just us trying to predict the waves of COVID between now and the end of the year.

Julie Smith

And I would add that prior to the pandemic, we didn't really see a lot of seasonality in our Life Science business. We would get big orders here and there and have some inconsistency between quarters, but it wasn't necessarily due to seasonality. I mean, with COVID, that's seasonal, and we're probably going to continue to see seasonality in our business on the Life Science side.

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

We would expect to see a higher seasonality. That's correct.

Julie Smith

It's the nature of the --

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

Respiratory season, if you will.

Julie Smith

The [products], yes.

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

Some European countries -- actually, multiple European countries just recently announced that they plan to lift all COVID-related restrictions in the near term. So I'd like to have your perspective on how that's going to impact the volume of COVID testing?

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

So we -- my personal opinion is that, we're in a respiratory season. Omicron is raging. There's people -- everybody has been getting it around the globe. We fully would expect that it's going to come down peak and start coming down. I think you're starting to see signs of that. I think we'll get into Spring and things are going to feel more normal. But the difference is going to be, because everybody is going to open up more, there will be higher levels of testing.

So I do think that there's going to be ongoing testing, whether it be rapid testing to be able to go to dinner in New York City or in Los Angeles. You won't have to do that in Ohio, by the way, come to the Bengals game. You don't need to be tested, just come to the game. But I do think that there will be a strong testing environment as we go forward.

So we would expect that this is going to be something that will turn to a very seasonal thing, whether we get some bumps along the way is questionable. But I do think that you're going to see more and more people opening up. You can't stay closed forever. You've got to have your businesses open up and have a market that's flowing. So we do expect that. We think testing is one of the hedges to help them to do that.

Julie Smith

Yes.

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

Got it. So lastly, what is the current status of LeadCare?

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

Of, I'm sorry, what? LeadCare?

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

LeadCare test. Yes.

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

Yes. So we gave some color on that. What I would tell you is that we worked very hard. We had a third-party supplier that made some changes in some materials. And ultimately, it started creating a situation where our quality system picked up that we were having a detection of suppression of lead results. And so we identified that. We worked with them. We worked with the FDA that led to the recall. So the quality system worked. We feel good about that. We've been working directly with the FDA.

The challenge was trying to figure out the root cause and trying to figure out what happened. And so it was a very challenging thing to go through. We did figure out the source of the contamination being related to cardboard. And ultimately, as bizarre as it is, it diffusing into the tube, so there was an impact that was occurring to the tubes. We've been able to prove that we can fix that, and we're working through the process to validate that and to work with the FDA to get this product back on the market as quickly as we can.

So we are very optimistic that you'll see this product back in shipping and in the hands of much-needed customers who need this point-of-care testing here before the end of the quarter, and we'll provide updates as we go. But all things are looking very positive, and we're extremely optimistic about that.

Julie Smith

Yes. And I'd also like to point out that demand for that product has not waned. Customers are still ordering instruments and asking us to install them so that they're ready when the product is back on the market, it's very encouraging.

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

There's a strong need for point-of-care lead testing, because if not, you're drawing blood from a baby that people don't want to do and you have to wait 2 weeks for results. So having that result on the spot is critical. And clearly, the market is interested to get this product back as quick as we can, and the FDA is working collaboratively with us towards doing that safely.

Operator

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

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

Doug, thank you very much for your help today. We truly appreciate all of you who joined us for the call today. If you can't tell, we're pretty excited about the state of our business and we think that our best days are still ahead of us. And we look forward to sharing more with you about that in the coming weeks and months. Have a great day. And go Bengals.

Julie Smith

Who Dey?

Operator

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