OraSure Technologies, Inc. (Q4 2024 Earnings)
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Corporate Speakers

- Jason Plagman; OraSure Technologies, Inc.; Vice President, Investor Relations
- Carrie Eglinton Manner; OraSure Technologies, Inc.; President and Chief Executive Officer
- Kenneth McGrath; OraSure Technologies, Inc.; Chief Financial Officer

Participants

- Jacob Johnson; Stephens; Equity Research Analyst
- Casey Woodring; JP Morgan; Vice President, Equity Research
- Andrew Cooper; Raymond James; Vice President, Equity Research
- Unidentified Participant; Unknown; Analyst

PRESENTATION

Jason Plagman^ Good afternoon. And welcome to OraSure Technologies Fourth Quarter 2024 Earnings Call. Participating in the call today for OTI are Carrie Eglinton Manner, our President and Chief Executive Officer; and Ken McGrath, our Chief Financial Officer.

As a reminder, today's webcast is being recorded, and the recording can be found on our Investor Relations website. Before we begin, you should know that this call may contain certain forward-looking statements including statements with respect to revenues, expenses, profitability, earnings or loss per share and other financial performance, product development, performance, shipments and markets, business plans, regulatory filings and approvals, expectations and strategies. Actual results could be significantly different.

Factors that could affect results are discussed more fully in OTI's SEC filings, its annual report on Form 10-K for the year ended December 31, 2023, its quarterly reports on Form 10-Q, and its other SEC filings.

Although forward-looking statements help to provide more complete information about future prospects, listeners should keep in mind that forward-looking statements are based solely on information available to management as of today.

OTI undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call. With that, I am pleased to turn the call over to Carrie.

Carrie Eglinton Manner^ Thanks, Jason. And thank you to everyone for joining us today. We are pleased to provide an update on the progress OraSure is making on the three pillars of our strategic transformation: one, strengthening our foundation; two, elevating our core growth; and three, accelerating profitable growth.

Today I'll discuss a few highlights from Q4 and our priorities for 2025. A few notable developments during the fourth quarter include: we delivered Q4 revenue that was in the top half of our guidance range for total revenue and core revenue, which grew 10% year-over-year.

In December, OTI acquired Sherlock Biosciences to expand our innovation pipeline with the addition of a molecular diagnostics platform that is expected to provide rapid results with strong sensitivity and specificity in a disposable format that is well suited for over-the-counter usage. Sherlock's first molecular self-test for chlamydia and gonorrhea or CTNG is in clinical studies and is expected to be submitted to the FDA by the end of 2025 for review.

Next, we secured FDA approval in December for a labeling change to our OraQuick HIV self-test that will increase access to HIV testing for adolescents. The change expands the approved age range to include individuals 14 years of age and older in using the OraQuick HIV self-test. Previously the test was approved for use in those 17 and older.

In November, we received an award through the Rapid Response partnership vehicle for the development of a Marburg virus disease rapid antigen test. The initial contract award valued at approximately $7.5 million over multiple years in the base period with a potential value up to $11 million, funds the development to achieve U.S.

FDA 510(k) clearance of a single-use lateral flow immunoassay intended for the qualitative detection of antigens from viruses within the Marburg virus genius. During Q4, we generated positive cash flow from operations for the core business, demonstrating continued progress on our operating efficiency and cost savings initiatives.

Overall, with our healthy balance sheet, we are strong today, and we are well positioned for the future. We do the work required to compete and win. We closely monitor the external environment.

We continue to invest in our innovation roadmap and in opportunities that leverage our existing strengths, all of which bolster OTI's journey toward delivering sustainable, profitable, accelerated growth.

Diving into our core business. Q4 core revenue of $36.5 million grew 10% on a year-over-year basis, which was above the midpoint of our guidance range. Diagnostics revenue grew 9% and Sample Management Solutions revenue grew 14%, each on a year-over-year basis.

Within our Diagnostics portfolio, we continue to have success with multiproduct sales across our portfolio of HIV, HCV and Syphilis tests as health care providers and public health organizations recognize the need for a systemic approach to rapid testing, given the significant overlap in patients at risk for these infections. The commonality and simplicity of the workflows across all of the rapid tests we provide makes our comprehensive offerings appealing to clinicians, lab directors and other customers.

Our international Diagnostics business also delivered strong performance in Q4, and 2024 was a record year for revenue from that business, surpassing OTI's prior high set in 2023. Shifting to Sample Management Solutions. Revenue increased sequentially in Q4 as it did in the prior three

quarters of 2024 as we continue to see signs of growth, albeit variable across our customer segments. Here in 2025, the market environment is clearly posing elevated uncertainty that I will reiterate, we are closely monitoring in our segments.

For infectious disease testing programs, administrative orders such as freezes on U.S. funding for foreign aid announced in January have caused significant uncertainty for several of our partners that help coordinate programs for HIV testing and treatment in developing countries.

For OTI, the international Diagnostics business generated $41 million of revenue in 2024. And we believe approximately 80% of that amount is associated with programs that are supported by some type of donor funding. Worldwide, the largest sponsor of HIV testing and treatment programs in developing countries including the international programs that OTI works with is the Global Fund, a multilateral partnership to defeat HIV, tuberculosis and malaria that is supported by both public and private donors across numerous countries.

We also work with programs that receive support from the President's Emergency Plan for AIDS Relief, also known as PEPFAR, which is funded by the U.S. government.

In 2024, programs directly supported by PEPFAR represented a portion of business that is in the low teens as a percentage of our international diagnostics revenue or low single digits of our core revenue. Following the initial freeze on foreign aid, PEPFAR has been granted a waiver to continue performing its life-saving work, but operational activities in some countries have been disrupted as the groups that both procure and implement testing and treatment programs in developing countries work to understand the impact of changes on their operations and budgets. Separately, potential reductions to research funding by the National Institutes of Health, or NIH, are also creating uncertainty for some academic and research organizations that utilize our sample management solutions.

Specifically, earlier this month, the NIH announced plans to reduce funding mechanisms that cover indirect research costs. For OTI, the U.S. Academic and Research segment represented less than $10 million of revenue for our SMS business in 2024.

We estimate approximately 75% of that amount is supported by some type of NIH-related grant, and this translates to low single digits of our core revenue in 2024 that was associated with NIH-funded research projects. Clearly, these are fluid situations impacted by the changing dynamics of the federal government and including judicial review in many cases.

While we do not have full visibility right now we wanted to provide a frame of reference for these evolving external factors as we closely monitor them along the way. Overall, we share the view held by many.

Investments in science and innovation support the United States leadership and competitiveness as our country plays a key role in improving public health, work that is supported by OTI. Despite external near-term uncertainty, we remain confident in our strong positioning today and our opportunity for long-term growth.

Over the last few years, we've demonstrated progress in strategically expanding and diversifying our customer base and our product portfolio. In the SMS business, we've deepened existing relationships across segments like clinical diagnostics and added new ones with key innovators in emerging fields such as in oncology and genetic risk assessment, for research programs with pharma and biotech companies, and in animal health as a few examples.

As we described over the last few quarters, we're working to expand our sample management offerings into other important sample types, analytes and applications with active work toward launches in blood proteomics, self-collected urine with Colli-Pee and self-collection of blood samples with Sapphiros. Across OTI, our innovative product portfolios help connect people to care wherever they are.

In the Diagnostics business, the COVID-19 pandemic demonstrated the value of high-quality accessible infectious disease testing at the point of need for health care providers and for the general population. Patients want flexibility and privacy.

They want to be able to access diagnostic insights through rapid, easy-to-use tests like the ones OTI provides that we make available through a variety of channels including private and public health, over-the-counter and home delivery. We have been investing in the drivers for future growth. We believe these opportunities for OTI will increase significantly as we expand our portfolio of tests and build upon OTI's strength, longevity and credibility in serving our customers.

Switching gears to our portfolio innovation with new products and life cycle expansion. The acquisition of Sherlock Biosciences in December represents another step in OTI's innovation strategy and aligns with our focus on expanding our portfolio of rapid diagnostic tests that improve access to care.

Sherlock's CTNG test, which is currently in clinical trials, is expected to further bolster our strength in diagnostic testing for infectious diseases and sexual health following regulatory approval for which we plan to submit by the end of year.

We believe there is a significant opportunity to provide an innovative instrument-free OTC test that can serve a large addressable market that has significant unmet need through improved access and affordability.

We are off to a great start in welcoming Sherlock's talented team to the OTI family and working with them to advance our priorities. From day one, our newly expanded team has been working well together, leveraging the unique expertise in developing and clearing novel diagnostics that existed in both organizations to accelerate the planned launch of the Sherlock device and its first assay.

Looking forward, we expect that the combination of our pre-analytical sample prep expertise and our now widened assay development capabilities has the potential to drive breakthrough innovation in point-of- need rapid diagnostic testing.

Additionally, we are also demonstrably advancing our efficiency agenda including leveraging automation, consolidating our facility footprint and in-sourcing certain production activities into our Bethlehem, Pennsylvania Center of Excellence.

Our enterprise-wide focus on continuous improvement is expected to deliver further productivity gains in 2025 and beyond, which Ken will detail in his discussion of our financial results and guidance. Ken?

Kenneth McGrath^ Thanks, Carrie. I'm happy to discuss our results for the fourth quarter of 2024 and provide updates on our financial outlook. Total revenue in Q4 was $37.4 million. Core revenue, which excludes COVID-19 products and the molecular services business that we exited, was $36.5 million and increased 10% on a year-over-year basis.

Within core revenue, our diagnostic products generated $18.8 million of revenue in Q4 and grew 9% year-over-year, driven by strong order trends in our international HIV business as we previewed last quarter.

Sample Management revenue in the fourth quarter was $14.8 million and increased 14% year-over-year. COVID-19 products contributed $1 million of revenue in the fourth quarter, which was consistent with our expectations.

Revenue from the risk assessment testing business that we are exiting was $2.1 million in Q4. As we discussed last quarter, we decided to exit our risk assessment testing business in order to focus our resources on segments that offer attractive growth opportunities. During Q4, we made significant progress in exiting the operations related to this business, and we determined that it would be beneficial to extend our support of our customers and continue the process of winding down our remaining inventory through the first half of 2025.

Shifting to margins. Our GAAP gross margin in the fourth quarter was 36.2% and includes a $1 million inventory reserve related to discontinuing the risk assessment testing business. Non-GAAP gross margin was 40.1%, which was slightly below our expectations, primarily due to the mix of lower-than-expected gross margins in the risk assessment business as well as higher-than-expected scrap expense related to raw materials, which we do not expect to recur. GAAP operating expenses in the quarter were $26 million.

During Q4, we had $2.7 million of noncash stock compensation expense, $849,000 for severance expense and $1 million of transaction expenses related to the Sherlock acquisition. Our GAAP operating loss in Q4 was $12.4 million, and our non-GAAP operating loss for the same period was $6.7 million. Moving to our balance sheet.

We ended the fourth quarter with zero debt and total cash and cash equivalents of $268 million. During Q4, we generated operating cash flow that was slightly positive, driven by solid performance in our core business and we deployed $5 million through the acquisition of Sherlock in December.

Turning to guidance. We are guiding to first quarter total revenue of $27.5 million to $31.5 million. We expect core revenue in Q1 to be $27 million to $31 million, and this range includes

$1 million of risk assessment testing revenue as we work toward our exit from that business. Revenue from COVID-19 products is expected to be approximately $0.5 million in the first quarter.

The midpoint of our core revenue guidance range is approximately flat on a year-over-year basis after adjusting for our decisions to exit the molecular service business and risk assessment testing. The wider guidance range for Q1 factors in a variety of scenarios regarding the impact of elevated uncertainty associated with HIV testing programs and U.S. academic and research budgets as well as expected ordering patterns from a large customer in the consumer genomics industry.

We expect our gross margin percentage in Q1 to be in the low 40s and then to expand significantly throughout 2025, driven by growth in volumes and the realization of incremental operating efficiencies from our initiatives to leverage automation, consolidate our facility footprint, and in-source certain production activities.

Examples of projects we've completed whose benefit will ramp up in 2025 include: first, smaller HIV packaging with less plastic and lower shipping costs; second, new real-to-real automated manufacturing, which we translated from COVID-19 to the rest of our portfolio; third, ongoing in-sourcing of contract manufacturing; and fourth, in-sourcing of critical reagents, further reducing product costs. As a result, for the full year 2025, we expect adjusted gross margin to increase from the 44.4% we reported in 2024 towards our target of 50% gross margin.

Moving to operating expenses. In Q1, we expect core operating expenses in the low $20 million range plus $10 million of investments in innovation, which includes $7 million to $8 million of investments related to Sherlock. With that, I'll turn the call back to Carrie to conclude.

Carrie Eglinton Manner^ Thanks, Ken. As we've discussed, we've made meaningful progress in our strategic transformation in 2024. We have done the work that built a strong foundation today, one that is well-positioned for the future, even in light of external uncertainty, and we plan to deliver additional proof points in 2025.

Our core business delivered positive cash flow from operations during Q3 and Q4. Core Diagnostics revenue grew 3% year-over-year after delivering very strong growth of 41% in 2023. We continue to streamline our operating footprint and our cost structure in order to focus our resources in markets that offer the most attractive opportunities for profitable growth and that align with our core strengths in rapid diagnostics and sample management solutions.

We significantly advanced our innovation pipeline through multiple pathways including internal investments in R&D and product development such as blood proteomics and Colli-Pee, the acquisition of Sherlock in December, which we expect will allow us to enter the molecular testing space with a versatile diagnostics platform for assay development including its initial disposable rapid molecular CTNG self-test, and launching strategic partnerships early in 2024 with Sapphiros and Diagnostics Direct that are expected to contribute incremental revenue growth in 2025.

Overall, we believe OTI is in a strong position to return to growth in our core business. Our differentiated products are well suited to compete in attractive, durable end markets that are gradually rebuilding momentum.

While some of our customers are facing elevated uncertainty in the near term, OTI remains focused on strengthening and diversifying our customer relationships, investing in our innovation roadmap to expand our product portfolio, and operating with disciplined execution and accountability. And we are confident that the progress we are making positions OTI to drive profitable long-term growth and create value for shareholders. With that, I'm pleased to turn the call over to the operator for Q&A. Brianna?

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from Jacob Johnson of Stephens.

Jacob Johnson^ Maybe, Carrie, just starting on the global uncertainty. I appreciate the comments you made there. If I were to kind of summarize them, it seems like the low single-digit exposure to PEPFAR and the low single-digit from academia, maybe are the two you're really keeping an eye on right now.

Is that a fair characterization? Or is this global fund something we should monitor as well? And then maybe along the same lines, it seems like maybe you've seen some impact from the PEPFAR funding to this point. What have you seen from the academic end market to date, if there's anything you can share there?

Carrie Eglinton Manner^ Yes, Jacob, you got it in the right order. PEPFAR is where there's most uncertainty in spite of that waiver that they and we have in hand. So I'd say PEPFAR and the sizing of that is the one that we're monitoring most closely and the one that we've included in Q1 guidance. The academic is much more of a monitor situation where we've not seen a significant slowdown of any kind.

But there's obviously a lot of talk and a lot of concern. We think that our sample management solutions are a part of direct costs, not the indirect cost. But as everybody is gauging how to respond and what they need to do with the NIH changes.

I think you got that in the right order. And we can expand on PEPFAR, but yes, that's the right order. And less of an impact on any other donor, but really PEPFAR alone is U.S. funded, and we incorporated just under $1 million of that into the Q1 guidance.

Jacob Johnson^ Okay. That's helpful. And maybe as a follow-up, maybe I'll just ask a question on Sapphiros. Just the blood collection device there and potential approval this year, any update on that?

Carrie Eglinton Manner^ Yes. Still in the works. We still anticipate Sapphiros self-collected small volume blood through the regulatory process, dependent on the regulatory process, but we

still see that timing here in 2025. No update to provide beyond that, but it is still in process, and we still anticipate it this year.

Operator^ Our next question comes from Casey Woodring of JPMorgan.

Casey Woodring^ The first one is just on the BARDA contract. Can you just elaborate on how you expect that $7.5 million to burn and just timelines there to get to FDA 510(k) to unlock that additional $11 million? And I have a follow-up.

Carrie Eglinton Manner^ Yes. So in general, on Marburg and the BARDA funding, the $7.5 million, we do expect it sort of back-end loaded and work with them based on those milestones for the potential access to the full $11 million.

So more to come, Casey, on that, but I think it builds on the expertise we have in Ebola and other hemorrhagic viruses. It builds on the relationship that we have with them. And I think it's just another great proof point of our mantra is we're big enough to deliver and small enough to care. And did you have another part post? Is that it, Casey, on BARDA?

Casey Woodring^ Yes. No. No. That's helpful. I guess, yes, my follow-up is just the scrap expense you mentioned in the quarter on the gross margin line. Can you just elaborate why that's a one-off? And then the progression through the year to get to that kind of exit rate towards 50%? Kind of just walk us through some of those moving parts there on the gross margin line that Ken mentioned.

Kenneth McGrath^ Yes. So for the first question around the scrap that we think is one time it was really related to some expired materials that we had that were related to one of our product lines.

So we don't think that will continue going forward. Our normal run rate that we've experienced is anywhere between 300 and 500,000. This was in excess of that. As far as drivers that give us confidence for gross margins working towards that 50% gross margin range. It's the drivers a little bit the ones that I mentioned during the prepared remarks.

Our HIV Self-Test, our packaging, our version two, we call it packaging, significantly reduces the materials, both that gets you obviously savings in cost, but also savings in shipping costs and freight costs related to that.

So that we're really excited about that. The other is our reel-to-reel, which is an automation process that we developed with COVID during COVID-19, and now we're applying to our other product lines, in this case, HIV.

The other is our continued in-sourcing of our contract manufacturing, where we see some improvements in operating efficiency there. And then another area is insourcing our critical reagents where we see some improvements there in our margins. The good news is these aren't technologically constrained anymore. We've done the work for it. Now it's just rolling it out as you kind of transition the volume utilizing these new capabilities.

Operator^ Our next question comes from Andrew Cooper of Raymond James.

Andrew Cooper^ Maybe just following up on the gross margin and inventory dynamic. I just want to make sure. Can you confirm that scrap or inventory expiration you mentioned there isn't the reserve that you are backing out of the non-GAAP adjustment.

I just want to make sure those are two separate things. I know one says product line discontinuance, but I just want to confirm that those are separate and distinct, and the scrap piece is not being backed out of the adjusted metrics.

Kenneth McGrath^ Correct. You are correct. That is separate. The risk adjustment testing inventory write-down is separate from what I'm describing here.

Carrie Eglinton Manner^ Based on winding down the business.

Kenneth McGrath^ Based on winding down the business.

Carrie Eglinton Manner^ Separate from the expiration of inventory.

Andrew Cooper^ Perfect. I just wanted to confirm that. And then thinking about the 1Q noncore guide, I know you kind of laid out, hey, here's why this range is a little bit wide.

But maybe just help us think the high end versus the low end, what's going on across each of these pieces? I know it sounded like, Carrie, you're not necessarily assuming substantial headwind in sample management.

And I think you said $1 million in PEPFAR headwind. So what's kind of the rest of that range that we should be thinking about and the difference between, again, that high end and the low end there?

Carrie Eglinton Manner^ Yes. The other thing we called out, Andrew, in addition to the PEPFAR is ordering pattern for a large consumer genomic customer. So we've shared a number of strong strategic relationships we have good visibility with our customers.

But in a matter of timing and the visibility that we have in Q1, I'd say that's one of those other factors. The international ordering with PEPFARÊ I mentioned it, and again, we have very ongoing discussions with the implementation teams in country.

They feel like that will ship I'm sorry, that will be implemented. It has already shipped, but just a matter of being able to recognize the revenue, I think, again, a matter of timing. So it's more right now about timing in terms of what we have visibility to. And that sample management large genomics customer was the second one. And Ken?

Kenneth McGrath^ Yes. No, as we sized it, I think Carrie sized it earlier, international orders and academic, that combined is about $1 million. And then the other one, the expected ordering patterns of a large customer, you could size around a couple of million dollars as well.

Andrew Cooper^ Okay. Helpful. And then I know your kind of refraining from full revenue guide for the year. But as we think about some of these headwinds progressing through the year, I mean it sounds like you're telling us this is timing, but how do we think about what if PEPFAR continues to be challenged.

I know we've heard from at least one other that folks in some instances were sort of let go and standing back some of these efforts on the ground could be disrupted a little bit longer. So how do we think about the pacing that those can recover and what that means specifically to the Diagnostics growth later this year and even into '26?

Carrie Eglinton Manner^ Yes. I'll start, Andrew, with the direct answer in terms of sizing and PEPFAR, we framed around that low single-digit core amount.

What we're confident in is the bipartisan support for PEPFAR as a life-saving test and treat program for the most important infectious diseases in HIV, TB and malaria. And a lot of reiteration for the millions of lives that have been saved by the program. And the test and treat has specifically been called out.

So we sized PEPFAR kind of more broadly in this low single digits of core to give you a feel for that. But again, we're holding the waiver. Our partners are holding the waiver. Like I said, we already have orders that are in country. And we've served this market long enough.

We fully anticipate that there becomes movement, but we just don't have good enough visibility right now to tell you what looks like that's within year versus what could push. So what we've done is incorporate what we have the best visibility around. That's really Q1. We're sharing that that's around $1 million.

But the full year is kind of the best that we have just in kind of scoping it overall is in that low single-digit potential range, but with test and treat, waived, super important programs, and we're optimistic for the year. And we'll provide more when we have better visibility, but that's kind of the best we have right now.

Operator^ Our next question comes from Patrick Donnelly of Citi.

Unidentified Participant^ This is Brendan on for Patrick. First, I want to touch on the possibility of tariffs being put in place in Canada, Mexico or even China.

So I was wondering if you guys could walk through what the possible exposures are in those areas, both from a revenue standpoint and manufacturing. And then more so on the manufacturing standpoint, what steps can you guys take to try to offset any of those impacts?

Carrie Eglinton Manner^ Thanks, Brendan. Yes. You'll remember that well before tariffs were a discussion or there was even an administration change. We began reshoring into the U.S. and started talking about it over 18 months ago. In earnest, we made significant progress in 2024. We reshored from Thailand, significant operations. We closed Belgium, and we have already moved significant contract manufacturing from Canada into the U.S., which will largely complete here in 2025.

So this was a strategic benefit, leveraging all of the capabilities and capacities that we built during COVID. And the great news is we had a really good jump on that because it was just the right thing to do for our business. That means when the tariff discussion started and our exposure being that remaining portion of Canadian contract manufacturing, it's part of what we closely monitor. We had scenario plans in place.

We had communications with customers when we got to the 6:00 p.m., maybe it was 11th hour of the last discussion around tariff implementation. And with that 30-day pushout, we're doing exactly what you'd expect, which is have our scenario plans be ready for whatever may occur. And it is directly in that closely monitoring.

But part of the reason we talk about the consolidation and leveraging our automation is that we are well ahead of moving operations into the U.S., and that well positions us overall. And Ken, maybe I don't know if you want to add any sort of.

Kenneth McGrath^ No well captured that. One thing around is that given the uncertainty in the timing, the amount and the scope, we haven't baked that in tariffs into our outlook at this time.

Carrie Eglinton Manner^ Yes. That's a good call out.

Unidentified Participant^ Got it. And then one quick one, if you guys wouldn't mind kind of reiterating the OpEx expectation for this year, especially in regards to the Sherlock acquisition. I believe if I remember correctly, I think there were some expenses related to trials and different regulatory processes, if you won't mind going through that again.

Kenneth McGrath^ Yes. I start with the good news is that we've, all good news, but we've dramatically reduced our OpEx over the last couple of years. We reduced it year-over-year by quarter, millions of dollars. So we've made a lot of progress in this area.

For what we've said on the call for Sherlock, we said that we expect to spend between $20 million and $25 million, the majority of that being in the clinical trial development for the approval of the CT/NG product.

Operator^ Our next question comes from --

Carrie Eglinton Manner^ And sorry, Brianna.

Kenneth McGrath^ And Brendan, if you were looking for the Q1 amount, we expect for innovation spend in Q1 related OpEx, about $10 million, about $7 million to $8 million of that coming from Sherlock.

Carrie Eglinton Manner^ Sorry, Brianna, he's probably moved on, but we can provide more detail.

Operator^ No worries, of course. Our next question will be from Vijay Kumar of Evercore ISI.

Unidentified Participant^ This is Daniel on for Vijay. My first one, I know you called out consumer genomics customer timing in 1Q. Can you discuss the dynamics there? Is this really just pure lumpiness with timing? Or is it related to the broader market softness? And then also, was there any impact there on the fourth quarter?

Carrie Eglinton Manner^ Hi, Daniel, yes, it is a single large customer who has some significant strategic alternative process underway. I would say it's not indicative necessarily of a broader sort of market other than the fact that genomics and consumer genomics as an end market has remained soft through COVID. That's part of the reason.

These are great partners for us. We have very strong relationships and good visibility into things they're doing in Q1. That's what we've guided to. But sort of more broadly, we've been talking for the last at least 2.5 years on the diversification and expansion of our customer base from really concentrated customer composition to real expansion into clinical diagnostics.

We've talked a lot in the past 18 months about the green shoots of a number of new customers, the types of segments. That's why in the scripted remarks, we highlighted areas like research and pharma and biotech, animal health.

But maybe just to repeat for the third time, clinical diagnostics with big clinical customers where that transition has been a really important diversification and expansion of our customer base.

So you asked specifically, is it representative of something more broader going on? I would say we don't believe so that sort of why we called out a single large customer and uncertainty around their environment but we think they have a path for the year, and we'll provide more as we understand or get better visibility to that specifically. We've guided to Q1 because that's what we know.

Unidentified Participant^ Got it. That's really helpful. And then my follow-up, how do you frame the potential downside from the international government-funded end markets you serve over the longer term beyond the first quarter? Can you help us frame like a potential range of outcomes? And how do you think about operating the business through this type of uncertainty?

Carrie Eglinton Manner^ Yes. I mean I think that's part of the tough part of the uncertainty, right, is that I mentioned even in the U.S., there's bipartisan support for life-saving test and treat programs, data that shows tens of millions of lives saved due to like a test and treat for HIV.

I'd expand that through HCV and beyond. I think, Daniel, what we tried to do is tell what we've incorporated in our Q1 guidance and then kind of frame the sizing of those afterward. And look, there were changes by U.S. federal government prioritization kind of in four-year terms, there have been changes along the way.

What we've seen is consistency in the desire to end the HIV epidemic and the value of test and treat in public health. And we've played a significant part of that, both internationally and in the U.S. So we tried to frame the $41 million of international business, 80% of it donor funded, a large portion of that, that is multilateral. And multilateral, meaning from multiple countries, public donors, private donors, countries themselves within that.

And because of that, we believe in that public health is key to global health and is key to the quality of life in communities. And while there is uncertainty and maybe cycles, kind of that's the framing that we provided and to say that multilateral support has been a more durable support for international programs.

So that's sort of a lot of trying to kind of pull together what we shared in the call. And I just conclude with that and repetition of we incorporated in guidance what we know. We'll keep everybody posted as it evolves, and we're monitoring it as closely as anyone.

Operator^ I am showing no further questions at this time. I would now like to turn it back to Carrie Eglinton Manner for closing remarks.

Carrie Eglinton Manner^ Well we thank everyone for their interest and for participating in today's call. We'll look forward to talking to you again. Thank you, Brianna. With that, we'll close.

Operator^ Thank you for your participation in today's conference. This does conclude the program. You may now disconnect.