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OSUR.OQ - Q1 2024 OraSure Technologies Inc Earnings Call

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CONFERENCE CALL PARTICIPANTS

Jordan Adler

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the OraSure Technologies First Quarter 2024 Earnings Conference Call. (Operator Instructions). Please be advised that today's conference is being recorded. I would now like to turn the conference over to your speaker today, Jason Plagman, Vice President of Investor Relations. Please go ahead.

Jason Michael Plagman - *OraSure Technologies, Inc. - VP of IR*

Good afternoon, and welcome to OraSure Technologies' First 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, end markets, business plans, regulatory filings and approvals, expectations and strategies. Actual results could be significantly different. Factors that could affect results are more -- are discussed more fully in OTI's SEC filings, including its registration statements in the annual report on Form 10-K for the year ended December 31, 2023 or 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'm pleased to turn the call over to Carrie.

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Thanks, Jason, and thank you to everyone for joining us today. We are pleased to provide an update on the progress OraSure's making on the three pillars of our strategic transformation. And before I talk about the quarter, I just want to frame what strengthening our foundation, elevating our core growth and accelerating profitable growth look like in our business.

Strengthening is our organizational restructuring and cost rebalancing that has improved our balance sheet and cash flow generation.

Elevating is the focus on our core capabilities and leveraging these strengths internally and in strategic partnerships to expand our product portfolio and the market segments we serve.

Accelerating is about investing for profitable mid- and long-term growth while our end segments rebuild momentum.

A few notable highlights during the first quarter include, we delivered Q1 revenue that exceeded our guidance ranges for both core revenue and COVID-19 products. As part of strengthening our foundation and our enterprise-wide focus on operational efficiency, we are taking next steps to streamline our operations, including in-sourcing third-party manufacturing activities into our Bethlehem facilities, exiting our microbiome laboratory and analytical sequencing services business known as Diversigen, and consolidating our Novosanis site in Belgium into other locations.

These initiatives are expected to result in significant cost savings over the next 2 years and are important steps to align around our strengths, right size our cost structure, and achieve our target to breakeven in operating cash flow from our core business by the end of 2024. Next, our strategic partnerships with Sapphiros and Diagnostics Direct that we announced earlier this year are off to a strong start.

And with our healthy balance sheet, we are investing in our innovation road map and partnerships to leverage our existing strengths in order to position OTI for profitable growth. Starting with operating efficiency. We continue to strengthen our foundation. As we've discussed over the last 18 months, we have made tremendous progress in improving our operating efficiency, streamlining our footprint, and establishing an enterprise-wide mindset that delivers continuous improvement.

As part of these efforts, we are taking additional steps to rebalance our cost structure and position OTI for long-term success. First, we initiated steps to wind down Diversigen by the end of the third quarter. OTI acquired Diversigen and CoreBiome in 2019 based on the potential of the microbiome sequencing services market.

Despite early success, the COVID-19 pandemic and other external market factors have negatively impacted the microbiome segment, and we have experienced a decline in services revenue while lacking line of sight to meaningful near-term growth in this segment.

Given our limited visibility to scaling the business profitably and prioritization of our other core strengths, we have decided to exit the microbiome sequencing services business. We are focused on providing continuity for our clients and transitioning them to a leader in the space. Plus, it's important to note, we will continue to participate in and serve the segment with our DNA Genotek microbiome sample management kits and our distribution of Anaerobe Systems' collection offerings.

Second, we commenced projects to in-source production of certain sample management products from external contract manufacturers in Canada into our manufacturing center of excellence in Bethlehem, Pennsylvania over the next 18 months. In-sourcing these activities is expected to improve our operating efficiency and further leverage our existing capabilities and infrastructure.

Third, we are planning to exit our Novosanis site in Belgium by the end of this year and integrate those activities into our existing infrastructure. We will continue to develop and sell the Colli-Pee urine collection device as part of our sample management solutions.

In total, these actions are expected to result in more than $15 million of incremental annual expense reductions following completion and they are important steps in achieving our target to breakeven in operating cash flow from our core business by the end of 2024.

Moving to COVID-19. InteliSwab generated $23 million of revenue in Q1. As we discussed last quarter, we have visibility to order trends that are expected to fulfill the remaining portion of our largest InteliSwab contract with the U.S. government during Q2.

Moving to our core business, which excludes COVID-related products. Q1 core revenue of $31 million was at the high end of our guidance range.

Performance in both core diagnostics and core molecular sample management markets were consistent with the outlook embedded in our guidance.

Within our Diagnostics business, March 2024 wrapped up the initial 12-month period for the Together Take Me Home Program that includes HIV at-home test kit distribution. As you may remember, Together Take Me Home is a collaborative effort across the private and public sector, with the goal to provide free HIV test kits in all 50 states and Puerto Rico.

Initial plans were to distribute 200,000 test kits per year during the 5-year program for a total of 1 million tests deployed. However, the demand for tests has far exceeded expectations. According to data collected by the program, 27% of orders were people who reported they had never tested for HIV before.

The program success demonstrates how reducing barriers to care empowers individuals to learn about their health, combat stigma, and positively impact access to HIV testing prevention and care services. We are proud to play a role in this important program and look forward to a successful second year.

Since our last call, we successfully launched the sales and distribution partnerships that we announced previously. We delivered our first sets of orders for Diagnostics Direct syphilis health check test and for Anaerobe System's Biome Preserve, amongst others. These launches demonstrate how partnerships allow us to enter new market segments, expand the portfolio of comprehensive products we can provide to our customers, and leverage our existing capabilities.

Shifting to molecular sample management solutions. The market environment remains muted as the industry emerges into the post-COVID environment, In addition to factors such as regulatory uncertainty for diagnostic labs, evolving research priorities and funding environments for life sciences and academic organizations, and a few customers working through short-term uncertainty related to corporate structures.

Even with these near-term headwinds, however, we remain confident in the mid- and longer-term opportunities for our sample management solutions while we continue to reinforce our market leadership position. As our end segments begin to recover, we are confident in our position as an industry-leading provider of sample management solutions for a number of reasons.

We continue to demonstrate the quality and consistency of our sample management solutions, including our 510(k) cleared collection and stabilization devices in several categories. Also, we believe our track record of collaborating with our partners and successfully navigating complex regulatory approval processes will become even more important for diagnostic labs as they contemplate FDA regulation of LDTs.

And we have developed very strong customer relationships as a result of our consistent execution, reliability, and our experienced sales team. We continue to reinforce our leadership position by onboarding new customers as well across multiple segments, including clinical reference labs, biopharma companies, global research, as well as nonhuman segments.

While the orders from these customers represent a small percentage of our revenue today, they represent future growth opportunities as they're offerings scale and their discovery work progresses.

In addition to onboarding new customers, we are proud to hold long-standing relationships with the pioneers and innovators in the genetic testing space. On this note, we are pleased to share that we've recently signed a multiyear deal with 23andMe to continue to provide our 510(k) FDA-cleared Oragene collection device to be used in their health and ancestry services. 23andMe provides individuals with genetic insights and tools to empower them to take action on their health.

From an innovation standpoint, we continue to make investments in our product pipeline and evaluate potential investments that can accelerate our growth. This includes both internal and inorganic opportunities through strategic partnerships and potential acquisitions.

Our strong balance sheet and positive cash flow generation continue to be important differentiators in the current market and economic environment as we look for opportunities to accelerate our growth and profitably scale our business.

Before I conclude, I'd like to highlight that we recently published our 2023 to 2024, OraSure Cares ESG report on our Investor Relations website. This report highlights our progress in advancing sustainability and governance-related initiatives that are meaningful to our internal and external stakeholders and our efforts to create value for our customers, employees, shareholders, and the global communities that we serve.

With that, I'd like to turn our call over to Ken to discuss our financial results and guidance.

Kenneth J. McGrath - *OraSure Technologies, Inc. - CFO*

Thanks, Carrie. I'm happy to discuss our results for the first quarter of 2024 and provide updates on our financial outlook. In Q1, we delivered total revenue of $54.1 million. Core revenue, which excludes COVID-19 products, was $31 million in the first quarter. Within core revenue, our diagnostic products generated $16.4 million of revenue in Q1 and decreased 4% year-over-year.

Looking at molecular sample management solutions. Revenue in the first quarter of $10.8 million decreased 16% on a year-over-year basis, which was consistent with the expectations embedded in our guidance range. COVID-19 products, predominantly in InteliSwab, contributed $23.1 million of revenue in the first quarter.

Purchasing patterns under our contract with the U.S. government were slightly stronger than forecasted. We expect to fulfill the remaining $17 million of our largest contract with the U.S. government during the second quarter.

From a gross margin perspective, our GAAP gross margin in the first quarter was 44.5%. Non-GAAP gross margin was 45.2% in the quarter, which was consistent with our expectations. While we anticipate some quarterly fluctuations in gross margin percentage during 2024 related to the timing of the restructuring initiatives we've discussed and the tapering of InteliSwab volumes, we continue to believe we can drive additional gross margin expansion over the coming years.

And we remain focused on delivering efficiencies across our enterprise, including consolidating facilities, driving procurement savings, and further leveraging our automation capabilities.

Shifting to our operating expenses. Our GAAP operating expenses in the quarter were $31.2 million, which includes $2.8 million of noncash stock compensation expense, $3.3 million for impairment of assets related to Diversigen and Novosanis, and $173,000 for reduction in workforce severance.

Our GAAP operating loss in Q1 was $7.1 million and non-GAAP operating loss was $300,000. As Carrie discussed, as part of our transformation journey, we initiated several additional actions to rebalance our cost structure, consolidate our operational footprint, and streamline our portfolio of offerings, while we focus on our strengths.

To that end, we plan to wind down and exit Diversigen by the end of the third quarter. This business, which comprises our molecular services offering, generated $4 million of revenue over the last 12 months, a decline from the prior 2 years.

From a cost savings perspective, our exit from the microbiome sequencing services business is expected to reduce our annualized expenses by approximately $10 million, which includes both cost of goods sold and operating expenses.

In our Sample Management Solutions business, we are in-sourcing manufacturing of certain products into our Bethlehem facilities. We expect to transition production for a majority of the volume by the end of 2024, with the remainder in 2025. In-sourcing these activities is expected to result in approximately $5 million of annualized cost savings upon completion of the transition.

Additionally, we initiated steps to close our Novosanis site in Belgium by the end of 2024 and integrate those activities into our teams in the U.S. and Canada.

In total, these three initiatives are expected to result in more than $15 million of incremental annual expense reductions following completion, which is an important step in our plan to achieve our target to breakeven in operating cash flow from our core business by the end of 2024. These actions are in addition to our ongoing enterprise-wide focus on operational efficiency and continuous improvement.

Moving to our balance sheet. We ended the first quarter with 0 debt and total cash, cash equivalents and short-term investments of $264 million. During the quarter, we generated $7 million of operating cash flow and we deployed $28 million for our investment in Sapphiros.

Turning to guidance. We are guiding to second quarter revenue of $50 million to $55 million, which includes core revenue of $33 million to $36 million and InteliSwab revenue of $17 million to $19 million. Our Q2 guidance includes $650,000 of revenue from the molecular service business that we plan to exit.

Looking ahead to the second half of the year, we expect slight sequential improvement in core revenue in Q3 and Q4 compared to our Q2 outlook.

This view is influenced by several factors, including our expectation for de minimis revenue contributions from the Diversigen molecular services business after the second quarter, and a muted pace of recovery in genomics and other 'omics segments, consistent with the current market environment.

With that, I'll turn the call back to Carrie to conclude.

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Thanks, Ken. As we detailed today, we are taking important steps to continue to strengthen our foundation by rightsizing our cost structure, streamlining our operations into our centers of excellence, and focusing our investments in areas that leverage our existing strengths in order to accelerate our core growth in the mid- to long term.

Overall, we are confident that OTI is well positioned to execute on our vision of transforming health through actionable insights, powering the shift that connects people to health care wherever they are.

And our mission of improving access, quality and value of health care with innovation and effortless tests and sample management solutions is aligned with where health care is headed in the U.S. and globally over the coming years.

With that, I'm pleased to turn the call back over to the operator for Q&A. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Our first question comes from the line of Jordan Adler with Evercore ISI.

Jordan Adler

Maybe for the first one, you guys have mentioned the strengthening of your balance sheet as a priority. Can you talk to some of the opportunities that you've been targeting, whether it be for partnerships and/or inorganic opportunity?

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Yes. We have announced 7 partnerships, Jordan, that I know you're aware of, but that we're really excited about. So we've talked every quarter about this journey and I love that you asked about it. But starting with that strengthening the foundation, the point really is to position us for investing in the future.

That's internal and as I just reiterated, the sort of strategic partnerships that we've talked about with Sapphiros that span our portfolios, with Diagnostics Direct that launched and allows us to enter the U.S. Syphilis Testing Market, and other opportunities.

We have five others. I won't list them all, but opportunities like that, that allow us to plug directly in our strengths today, our strong commercial team, the great customer relationships we have and provide more comprehensive product offerings.

So we are very interested in the M&A opportunities, but we think partnerships are a really good way to create that momentum and build on the success that works while being very open, we're investing internally, but also being very open to other M&A that makes sense for our business.

Jordan Adler

Understood. And maybe one quick follow-up. You mentioned the restructuring initiatives that are expected to result in a $15 million of annualized expense reduction. You also mentioned some additional operational efficiencies that you're looking to utilize over the course of the midterm to longer term. Can you talk about some of the additional levers that you have left to pull following these three actions that you mentioned this quarter.

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Yes, absolutely. So thematically, you'll hear the site consolidations in those three actions, right, really bringing into our centers of excellence, some -- our facilities globally and even from in-sourcing third-party manufacturing. Some of the other operating efficiency we get in the centers of excellence are things like the automation that we -- capabilities we built during COVID in our government-funded Opus Way facility that we can translate to other platforms.

So we talked about the three actions. Site consolidation, then you get those next steps like automation. Another example, and I'll just list this one because it's another big deal, is like repackaging and the redesign for smaller packaging. We had announced those significant gross margin improvements in our InteliSwab product last year. We're making those types of changes into our HIV product line as well.

So it's those types of operational efficiencies, we use site consolidation and then we leverage the capabilities we've built, and we extend that into the rest of our portfolio. And we've said this, but since we've only -- looks like we've got two questions this time, I'll just add. We've also brought a process improvement mindset across the business.

Implemented a Lean Six Sigma methodology, have trained well over 100 people in the organization as white belts and every function now has expertise in process improvements. And so we're really thinking about this holistically, planning for the future so that we can invest in innovation for the long term.

Operator

Our next question comes from the line of Jacob Johnson with Stephens Inc.

Unidentified Analyst

This is Mac on for Jacob. Just a few quick ones for me as well. With regards to the wind down of Diversigen, it appears this is mainly a cost decision. But can you discuss why this offering was no longer strategic, and will it have an impact on anything else within the broader portfolio?

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Yes, we were excited in acquiring Diversigen and CoreBiome 5 years ago with the potential of microbiome. As we talked about in the scripted remarks, COVID -- after a really good start and growing the revenue in the beginning, COVID really put a lot of pressure on microbiome as an industry. And we did not see that sort of path to a scaling that we think is necessary in sequencing services.

So while our core strength really is in the device side, on diagnostic devices, and sample management collection devices, the sequencing services at the scale we were at just meant that we were losing significant dollars and that path to a build was far enough out that we have -- are just so focused on our core strengths. We think it makes more sense to wind that down, save the operating cost and overall expense, and focus on our device strength.

So what it means, Mac, is microbiome kits, we're trying to emphasize are still very much within our sample management strategy and the customers will serve in that space. So we do not think it has negative impact on other parts of the business. In fact, we think it allows us to invest in our core, leverage our core strengths, that includes microbiome kits, but it just means the sequencing services that require scale, we can take that savings and invest it in stronger parts of the business.

Unidentified Analyst

I appreciate the color there. And just in light of everything that's -- all the moving pieces within the portfolio at the moment and your expectations for growth at the end of the year, how should we think about cash flow trending as you complete the wind down of inventories and accounts receivable.

Kenneth J. McGrath - *OraSure Technologies, Inc. - CFO*

Yes. We mentioned on a previous call that we think there is upside for cash flow when it comes to our accounts receivable and inventory. We saw some of that in Q1, and we'll continue to see more. I think what we stated in the past was we expect our inventory and accounts receivable to be in that 30, 35, mid-30s range on an ongoing basis from a cash flow perspective.

And then also, our goal is to get -- and our target is to get to our core business being cash flow from operations breakeven. And with that, we think we're in a pretty strong position from a cash wise. Where we would then deploy the cash, if there's any opportunities to invest, as Carrie mentioned, both internally and externally in opportunities for growth.

Operator

I'm currently showing no further questions at this time. I'd like to turn the call back over to Carrie Eglinton Manner, for closing remarks.

Carrie Eglinton Manner - *OraSure Technologies, Inc. - President, CEO & Director*

Thank you. Thank you to everyone for joining, for your interest, and we look forward to our follow-up. With that, we'll close.

Operator

This concludes today's conference call. Thank you for your participation. You may now disconnect.
