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Q2 2023 OraSure Technologies Inc Earnings Call

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## CORPORATE PARTICIPANTS

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

**Jason Plagman**

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

## CONFERENCE CALL PARTICIPANTS

**Jacob K. Johnson** *Stephens Inc., Research Division - MD & Analyst*

## PRESENTATION

### Operator

Good day, and thank you for standing by. Welcome to the OraSure Technologies 2023 Second Quarter Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Jason Plagman, Vice President of Investor Relations. Please go ahead.

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### Jason Plagman

Good afternoon, and welcome to OraSure Technologies Second Quarter 2023 Earnings Call. Participating in the call today for OraSure 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 a 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 the company's SEC filings, including its registration statements, its annual report on Form 10-K for the year ended December 31, 2022, 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. The company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

Please note that we will be discussing certain non-GAAP financial measures that we believe are important in evaluating OraSure's performance. Details on the relationship between these non-GAAP measures to the most comparable GAAP measures and reconciliations thereof can be found in the press release that was posted on our website.

With that, I am pleased to turn the call over to Carrie.

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

Thanks, Jason, and we appreciate each of you joining us today. We are pleased to provide an update on the progress that OraSure is making on the 3 pillars of our strategic transformation that's first, strengthening our foundation, next, elevating our core growth, and also accelerating profitable growth.

A few notable highlights during the quarter include: we generated \$57 million of operating cash flow in Q2 and grew our cash balance to \$186 million. We executed to deliver stronger than anticipated IntelliSwab volumes on our COVID-19 contracts during the quarter. And in July, we received orders under existing contracts for delivery of additional IntelliSwab devices. And these orders are expected to generate at least \$70 million of revenue in the second half of 2023. We unlocked incremental cost savings as a part of our ongoing enterprise-wide focus on driving improved operating efficiencies. We also delivered core revenue growth on both a sequential and a year-over-year basis. And with our stronger balance sheet, we are investing internally and externally to support and enhance our leadership position and grow in our key portfolios. Rigorous portfolio processes are helping invigorate our innovation road map with organic and inorganic

opportunities, including strategic partnerships that we believe can provide additional fuel for growth.

Next, on costs. As we continue to strengthen our foundation, we remain highly focused on delivering greater operating efficiencies, including in cost reductions. The second quarter reflects a full quarter of impact from the headcount reductions we made in February, and we've implemented additional expense reduction initiatives since then that are expected to reduce both our production costs as well as our non-production-related expenses.

During the quarter, we made progress consolidating our manufacturing facility footprint to drive operating efficiencies, including reshoring some of our capacity to the U.S. to leverage innovative automation capabilities that we have developed. We also continued to make progress on the installation and testing of new equipment and manufacturing processes at our Opus Way facility in addition to our existing automated production of our OraQuick platform. As discussed in prior quarters, we expect this phase of Opus Way expansion to be completed in 2023.

Overall, we expect to generate additional operating efficiencies across our enterprise in the second half of this year and into 2024, including further consolidation of facilities, leveraging of automation and controlling our non-production costs. These initiatives, including incorporating Lean Six Sigma training and methodologies across multiple functions of the company, support our efforts to break even in operating cash flow on our core business by the end of 2024, a target which we remain on track to deliver.

InteliSwab volumes were stronger than expected in Q2, and we generated \$47.5 million in revenue from our COVID-19 products during the quarter. As I mentioned earlier, we received purchase orders in July under existing contracts for delivery of InteliSwab devices. Overall, we are really proud of our work with our public health partners, and we believe this additional visibility improves readiness for potential infectious disease outbreaks in the U.S. and beyond. As we've discussed previously, we also believe the cash generated from InteliSwab, plus the cost reductions we have implemented, will help us fund investments in innovation and future growth opportunities in order to elevate sustainable growth in our core portfolio.

On our core business, which excludes revenue from COVID-related products, we grew 4% sequentially this quarter and 3% on a year-over-year basis. In our HIV franchise, we mentioned during our Q1 earnings call that we saw a strong start to the Together Take Me Home program, which is funded by the CDC. This 5-year program focuses on providing free in-home testing to at-risk and underserved populations nationwide. We believe the early momentum of this program could create additional opportunities for our infectious disease business.

Moving to hepatitis C. Revenue grew on both a year-over-year and a sequential basis, driven by strength in domestic segments. We continue to be encouraged by the increasing recognition among health officials of the need to increase HCV surveillance and data collection through outreach testing.

Shifting to molecular products. Revenue grew 1% sequentially in Q2, representing the second consecutive quarter of modest sequential improvement. While end segments have experienced softness that we've discussed previously, we are seeing some positive signs, including continued momentum in establishing new partnerships and commercial relationships. Fundamentally, we believe in the long-term potential of molecular testing as an enabler of precision health.

On that front, we are very pleased to announce a collaboration to work on a multiyear project with the Regeneron Genetics Center, a wholly owned subsidiary of Regeneron Pharmaceuticals, Inc., that focuses on early gene discovery and functional genomics. RGC has chosen our Oragene device for all saliva collection requirements, along with leveraging our in-house kitting and single order fulfillment services to remodel its DNA collection workflow.

Also in our molecular product portfolio, we continue to make clinical and commercial progress with Colli-Pee. We recently signed an agreement with the International Vaccine Institute, IVI, to utilize our Colli-Pee first void volumetric urine collection kits as part of a research study to understand the burden of human papillomavirus, HPV, among girls and women in low and lower middle income countries. The International Vaccine Institute is an organization with a mission to discover, develop and deliver safe, effective and affordable vaccines for global health. The study will help inform intervention implementation and prioritization of research and

development efforts that have the greatest potential for public health impact. We believe that first void urine has the potential to provide powerful insights through noninvasive sample collection methods that can transform the approach to HPV patient screening, vaccination and treatment strategies, regardless of a patient's geographical proximity to or familiarity with professional healthcare settings.

Effortless at-home sample collection is fundamental to how our offerings can help power the shift in healthcare delivery that connects care with patients and consumers wherever they are. These ongoing and prior studies demonstrate the value of Colli-Pee urine collection as an easy-to-use, noninvasive self-sampling device. And OraSure is committed to delivering an evidence-based, affordable solution with improved patient experience for people around the globe.

Microbiome is another emerging science that has potential to contribute to precision health innovation. Our microbiome collection devices and services are used to advance research, direct-to-consumer and clinical applications in the space. Of note is the pioneering work done by our biotech customers to leverage the power of the microbiome in developing new therapeutics. One such customer is Seres Therapeutics. Seres, a commercial stage company developing novel microbiome therapeutics, and Nestle Health Science, a leader in the science of nutrition, have jointly announced the FDA approval of the first and only orally administered microbiota-based therapeutics, VOWST, to prevent recurrence of *C. difficile* infection, or CDI, in adults following antibacterial treatment for recurrent *C. diff* infection. The FDA approval of VOWST was supported by a robust Phase III development program that included the ECOSPOR III and ECOSPOR IV studies. OraSure subsidiary, Diversigen, provided the microbiome sequencing services for this series of studies and are pleased to see the FDA approval for this important new oral treatment option for *C. diff* infection.

On our innovation road map, in addition to our current product portfolio, we continue to make progress on our initiatives to accelerate profitable growth through investments in our internal product development pipeline as well as potential external investments, partnerships and acquisitions enabled by the strengthening of our balance sheet during the last year. We have discussed in prior quarters that in diagnostics, we are working on opportunities to expand our portfolio of assays in areas where we have existing strong capabilities such as in infectious disease, respiratory influenza and sexual health. We expect to share more on these opportunities later this year.

In molecular, over the past few quarters, we have shared our progress in new collaborations in precision health. It's great to see those partners, such as Quest Diagnostics, Grifols and Ziwig launching their new offerings across a broad range of use cases, such as consumer-initiated testing and genetic counseling services as well as disease-specific testing. Overall, we believe OraSure is well positioned to be the partner of choice to help power precision health due to several important differentiators: 1, the quality and reliability of our offerings and the expanded patient reach they enable; 2, the consistency of our delivery and execution; and 3, our track record of collaborating with our partners and successfully navigating complex regulatory approval processes for segment access and expansion.

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

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

Thanks, Carrie. I'm happy to discuss our financial results for the second quarter of 2023 and provide updates on our financial outlook.

We delivered total revenue of \$84.5 million (sic) [\$85.4 million] in Q2, representing 6% year-over-year growth. COVID-19 products, including IntelliSwab, contributed \$47.5 million of revenue in the second quarter and grew 10% on a year-over-year basis.

Purchasing patterns under our contracts with the federal government were stronger than expected during the quarter. Total core revenue, which excludes COVID products, was \$37.9 million in the second quarter, representing 4% sequential growth and 3% year-over-year growth. Within core revenue, our core diagnostic products generated \$19.8 million in Q2 and grew 41% year-over-year. The strong growth was driven by significant domestic HIV sales, bolstered by the Together Take Me Home program, as well as growth in international HIV sales.

Looking at our core molecular products. Total revenue of \$13.1 million decreased 26% year-over-year. On a sequential basis, molecular products revenue grew 1%. As we expected, we continued to see muted purchasing patterns from a few large customers during the quarter. That said, we are seeing some signs of stabilization with current customers as well as opportunities in new areas.

From a gross margin perspective, our GAAP gross margin in the second quarter was 30.9%. GAAP gross margin declined significantly compared to the prior quarter, which was primarily attributable to the impact of accelerated depreciation and inventory reserves related to the winddown of our manufacturing operations in Thailand.

Non-GAAP gross margin was 42% in the second quarter and declined slightly compared to the prior quarter, which was previewed last call. The decline was primarily attributable to the fact that a larger portion of our IntelliSwab volumes during Q2 were through our contract with a lower selling price. The impact of this pricing headwind was partially offset by savings from IntelliSwab packaging redesign that we discussed in prior quarters as well as other cost reductions we implemented this year. Looking ahead, we are focused on driving efficiencies across our entire portfolio of products and services, including site consolidation, product standardization, procurement savings and further leveraging our automation capabilities at our Opus Way facility.

Shifting to operating expenses. Our GAAP operating expenses in the quarter were \$32.8 million, which decreased by \$8.7 million compared to Q1. Our non-GAAP operating expenses were \$29.1 million in Q2, which decreased by \$4.5 million compared to Q1, primarily due to our headcount reductions in February. We are focused on driving additional efficiencies in our non-production expenses in the coming quarters. These savings are important as we look to utilize cash for growth investments and as we are committed to achieving breakeven operating cash flow in our core business by the end of 2024.

This quarter, our GAAP operating income was a loss of \$6.4 million, which compares to GAAP operating loss of \$21.5 million in last year's second quarter. Non-GAAP operating income was a positive \$6.7 million in the second quarter. Non-GAAP operating income in last year's second quarter was a loss of \$1.2 million.

We ended the quarter with zero debt and total cash and cash equivalents of \$186 million, which is up from \$112 million last quarter. The increase in our cash balance was primarily driven by strong collections on accounts receivable as well as receipt of \$18 million from the U.S. Department of Defense related to the achievement of milestones at our Opus Way facility. The majority of the cash expenditures tied to this expansion have been completed, and we have \$31 million remaining in milestone payments from the government.

Turning to guidance. We are guiding to third quarter revenue of \$72 million to \$77 million, which includes core revenue of \$37 million to \$39 million and IntelliSwab revenue of \$35 million to \$38 million. As Carrie discussed, in July, we received purchase orders under one of our existing contracts with the federal government for delivery of IntelliSwab devices. These orders are expected to contribute at least \$70 million of revenue in the second half of 2023. Additionally, as part of our ongoing focus on enterprise-wide operating efficiency, we are on track to exceed the \$15 million of annualized cost savings announced in Q1 2023.

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

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

Thanks, Ken. And just to clarify, our second quarter revenue was \$85.4 million, not \$84.5 million. And in summary, during the second quarter, we delivered significant progress on our strategic priorities. We strengthened our foundation by generating significant positive cash flow and continued driving operating efficiencies, discipline and accountability across our enterprise while executing on our IntelliSwab contract. We delivered positive core growth, which was due to the dedication of our team members providing value for our customers, partners and patients. And we continued to make investments to strengthen and expand the leadership position of our products and services in order to accelerate our profitable growth in the coming years.

Overall, we are confident that OraSure's foundational capabilities and current strength position us for success as we aim to help power the shift in healthcare delivery, meeting people, patients where they are to increase access, affordability and quality of care.

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

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**QUESTIONS AND ANSWERS**

**Operator**

(Operator Instructions) Our first question comes from Patrick Donnelly with Citi.

**Unidentified Analyst**

This is [Brendan] on for Patrick. Congrats on the quarter. First off, I apologize if you guys already went over this. But I wonder if you can go through the cadence for the second half of the year for the IntelliSwab revenue. So I know you said that there were around \$70 million of new orders left and around \$30 million left in your older contracts. How should we think about that in the second half of the year?

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

Yes. So our guidance -- and thank you for the question. Our guidance for second half is \$70 million of IntelliSwab revenue. And then what we guided in our guidance for the Q3 was \$35 million to \$38 million. So you can imagine another \$35 million for Q4 as we go forward. Is that the rest of your question there?

**Unidentified Analyst**

Yes. And then one follow-up. For the Let's Stop HIV Together program, I know you guys have talked about that program expanding. I wonder if there's been any movement and possible expansions of that program and when may we see that.

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

Yes. We continue to have great relationships with the CDC when it comes to this program. And we've had a lot of success where they want to continue it, and in a time, potentially accelerate it as we go forward. So really pleased with the efforts. And what they're learning there is the importance of this channel to get out to underserved populations as we go forward.

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

So I'd just say, off to a really good start. And we will continue to update everyone on the strength of HIV in the core. But we do think that the momentum of that program has potential to help our infectious disease business overall as we're reaching underserved populations and really increasing access to the HIV diagnostics.

**Unidentified Analyst**

Congrats again on the quarter.

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

Thanks, Brendan.

**Operator**

Our next question comes from Jacob Johnson with Stephens.

**Jacob K. Johnson Stephens Inc., Research Division - MD & Analyst**

Maybe Ken, just first on the third quarter guidance. The base business revenues grew sequentially this quarter, but if my math's right, I think the third quarter guidance implies the base business was kind of flat to down a bit. Can you just talk about anything we need to consider from a seasonal perspective as we're thinking about the base business in the third quarter?

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

Yes, we did, to your point, we saw a very strong Q2 in some of our lines of business. We are expecting -- we feel in the molecular business, we did see some solid stabilization in the core, in the business. And as far as diagnostics, we are seeing some strong growth, what we saw in Q2 around our domestic and international business. We believe that, again, the molecular, we are maintaining that stabilized position as well as in diagnostics business.

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

Yes. So it is flat. We're sort of guiding in that flat to sort of slight growth range.

**Jacob K. Johnson *Stephens Inc., Research Division - MD & Analyst***

Okay. Makes sense. And then Carrie, maybe just on molecular products. You talked about some of the headwinds you faced there. But you've announced a variety of partnerships as it relates to that segment. Can you just talk about how we should think about the revenue contribution from these partnerships maybe kind of near term versus long term and what the ramp from some of those relationships could look like?

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

Yes. As we continue to say, we believe in the long-term potential of molecular and that it really is a foundation for precision health. While we don't call out specific guidance, I think what we've been trying to do is show the momentum where molecular collection is increasingly expanding from what has been kind of a direct-to-consumer historically, into the clinical space and into other applications where, again, Jacob, where we will share more specifically as we have it. But fundamentally, I think, think about that as this increasing pipeline of opportunities that as molecular end markets, you see those recoveries, that we fully expect to grow with those end markets as they grow. So good news across the board, and I think we're all looking for those continuous signs of recovery with the big players, and you know who they are.

**Jacob K. Johnson *Stephens Inc., Research Division - MD & Analyst***

Got it. All right. I'll leave it there. Thanks for taking the questions, Carrie.

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

Thanks, Jacob.

**Operator**

Our next question comes from Brandon Couillard with Jefferies.

**Unidentified Analyst**

This is Matt on for Brandon. Maybe one for you, Ken. Gross margins at 42% in the quarter, down slightly as you've previously spoken about due to the IntelliSwab mix. Curious how that 42% came in relative to your expectations or any of the tailwinds you called out from the cost reductions, the package redesign, freight costs better than expected in the quarter? And then any color on how to think about gross margins here either in 3Q or the back half of the year? And you listed some additional efficiencies you're kind of focused on. Will those show up here in the back half, or are those more 2024 and beyond benefits?

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

Great question. I hope we all get to all your answers here. Yes. So for Q2, we did see better than expected margins. It came from 2 areas, as you described. We had earlier implementation of our version 2 packaging, where we saw a better benefit than expected. In addition, what we saw was a better mix or a stronger mix and stronger volumes in our IntelliSwab business, which drove it. Going forward, we do expect the IntelliSwab volume going forward and the remaining volume to be at the higher price. I think we quoted in the past about a \$5 price, and we expect that going forward. So that should see a solid improvement to our margins. As well as what you described. We're seeing improvement from the efficiencies we put in place, whether it's the packaging efficiencies, the operational efficiencies, the footprint consolidation efficiencies. Carrie mentioned the reshoring of our Thailand facility into our Opus Way. As well as driving automation and leveraging automation, not just on IntelliSwab, but leveraging it on our other segments and other platforms.

**Unidentified Analyst**

That's helpful. And I guess another one for you, Ken. You guys ended the quarter with \$186 million of cash. I think you've previously talked about some working capital benefits as we move through the year around IntelliSwab, both from an inventory standpoint and then accounts receivable that were in total north of \$100 million. Obviously, AR saw a pretty big swing here in the quarter. Inventory is relatively flat. Do you expect to still see that full unwind and the benefit from that to cash? Or is there some change, just given this \$70 million of order, and maybe how you're thinking about inventory for IntelliSwab here in the back half of the year and maybe even into 2024.

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

Yes. Great question and thank you for asking that. Yes, so in Q2, we saw 3 areas through the hard work of the team improved. We saw, like you said, an improvement in accounts receivable, a slight improvement in inventory, and then we got some milestone payments from the government to the hard working team. We expect to see those areas improve going forward in the second half as well. We expect to continue to receive -- of our remaining accounts receivable, still a big portion of it is IntelliSwab-related and government-related, as well as we expect to see inventory drawdown as we go forward in the second half. And then we do expect to have -- we mentioned about \$31 million of remaining milestone payments related to the government. And we have spent most of the expenses related to that program. So now it's a matter of proving it out and getting government approval for those milestones and then receiving those payments.

**Unidentified Analyst**

And then just one last quick one. I think you guys said on the incremental IntelliSwab orders, it's at least \$70 million. Should we think about that as a floor? And is it possible that there could be potential upside to that moving to the back half of the year?

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

Yes. Great question. And the way we're looking at it is that's what we have visibility to right now. You can imagine there's sometimes seasonal ordering patterns that could change that. So we wanted to provide a number that we have visibility to at this time for the second half. And as you can -- in our guidance, you saw we split that roughly evenly between Q3 and Q4.

**Operator**

(Operator Instructions) I'm showing no further questions at this time. I would like to turn the call back to Carrie Eglinton Manner for closing remarks.

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

Great. Thank you. We appreciate everyone participating in our call today. We appreciate your continued interest in OraSure. And we'll talk to you next quarter. Thank you.

**Operator**

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

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