OraSure Technologies Inc. (2025 Q3 Earnings)
November 5, 2025

Corporate Speakers:

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

Participants:

- Steven Etoch; Stephens Inc.; Analyst

PRESENTATION

Operator^ Ladies and gentlemen, thank you for standing by. At this time, I would like to welcome everyone to the OraSure Technologies, Inc. 2025 Third Quarter Earnings Conference Call. (Operator Instructions)

I would now like to turn the conference over to Jason Plagman, VP of Investor Relations. You may begin.

Jason Plagman^ Good afternoon. Welcome to OraSure Technologies' Third Quarter 2025 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, 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, 2024, 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'm pleased to turn the call over to Carrie.

Carrie Eglinton Manner^ Thanks, Jason, and thank you to everyone for joining us today. Today I will discuss some highlights from Q3 and our progress on key priorities for 2025 and beyond. Overall, we continue to significantly advance our strategic transformation and execute with discipline as we position OraSure for a return to growth in 2026. We have

delivered meaningful progress and continued strengthening our foundation. We're also elevating our core growth by expanding and diversifying our product portfolio and customer relationships, plus we're accelerating profitable growth through investments in internal R&D as well as acquisitions and partnerships that leverage our existing capabilities and that offer an attractive risk-adjusted ROI.

Looking at our Q3 results, total revenue was $27.1 million, and core revenue was $27.0 million, which included Diagnostics revenue of $14.5 million and Sample Management revenue of $10.3 million. Broadly speaking, our key end markets remain mixed, and we continue to partner with customers that are navigating an environment with elevated levels of uncertainty related to funding for public health programs and research, as well as the government shutdown in the U.S. That said, we view 2025 as a transition year, and we're excited about pipeline opportunities in attractive markets that align with our strengths to drive growth in 2026 and beyond.

In our International Diagnostics business, we discussed on our last earnings call that we anticipated a slower pace of orders for our HIV test in the second half of the year as our in-country partners work through their existing inventory and national health programs adapt to changes in the funding environment. That trend played out as expected in Q3 and thus far in Q4. For the full year 2025, we now expect that revenue from our International Diagnostics business will be in the low to mid-$30 million range, representing a decline of approximately 20% compared to 2024, which was a record year for International Diagnostics.

Staying with our International business, we are pleased to share that OTI signed a definitive agreement to acquire BioMedomics. This tuck-in acquisition expands OTI's Diagnostic portfolio by adding Sickle SCAN, a rapid point-of-need test for sickle cell disease that is sold outside the U.S. The global sickle cell testing market, particularly in high burden regions in developing markets, is underserved and fragmented. We believe Sickle SCAN addresses this need with a high-quality, affordable rapid point-of-care test, and there is support from government agencies and global health organizations to increase access to sickle cell testing at the point of need. We see an opportunity to expand the reach and adoption of Sickle SCAN by leveraging OTI's strength, including our international sales channels and our existing relationships with national health programs, particularly in Africa and Latin America. Furthermore, many of our international customers and partners have expressed interest in a reliable, low-cost, rapid diagnostic test for sickle cell disease.

Transitioning to our U.S. Diagnostics business. Our public health customers are adapting to significant reductions in staffing at HHS, CDC, SAMHSA and other federal agencies that support public health programs, along with budgetary uncertainty and challenges related to the federal government shutdown. We are continuing, however, to see traction with our syndemic approach that leverages our portfolio of rapid tests across multiple conditions. And we are expanding our customer base in nonpublic health markets, such as urgent care, hospital emergency rooms and correctional facilities for rapid hepatitis C testing plus online channels specializing in consumer-initiated testing.

Overall, for the full year 2025, we expect our U.S. Diagnostics business to generate revenue in the low- to mid-$30 million range, representing a low single-digit percentage decline compared to 2024.

We also wanted to provide an update on Together Take Me Home, a collaboration funded by the federal government that makes HIV self-tests available through the mail in order to advance the President's goal of ending the HIV epidemic. We are pleased to share that this highly effective, life-saving program was renewed by the Trump Administration with strong bipartisan support in Congress. As a result, Together Take Me Home is continuing for program year 4, which runs from October 2025 to the end of September 2026. We expect to recognize approximately $1.8 million of revenue from Together Take Me Home in Q4 and anticipate a similar pace of quarterly revenue in 2026.

Switching gears to our Sample Management business. The overall trend continues to be mixed. SMS revenues increased on a quarter-over-quarter basis in Q3, but we anticipate a sequential decline in Q4, which is consistent with the typical seasonal ordering pattern for this business. For the full year, we expect revenue from Sample Management products in the high $30 million range, which would be approximately flat compared to 2024, if you exclude the impact of the decline in orders from a large consumer genetics customer.

Looking ahead, we are confident that the Sample Management business is positioned to return to growth in 2026 and beyond, as genomic end segments gradually return to stronger growth driven by clinical adoption of precision medicine. Our confidence is also supported by continued scientific and technological advancements such as the increasing utilization of short-read and long-read genomic sequencing, the decline in unit costs for sequencing and analysis, and advancements in areas such as proteomics.

We are also seeing early signs of positive trends in some international markets, such as the Middle East, that are planning to invest in population health studies using novel sample collection devices in order to accelerate precision health and life sciences research in the region.

We're also pleased to share that the ENDO 1000 project has selected multiple kits from our OMNIgene and Colli-Pee product lines for the collection and stabilization of a variety of sample types, including saliva, urine, stool and vaginal swab. The ENDO 1000 project is a United Kingdom wide initiative aimed at accelerating discovery and advancing data-driven research into the diagnostics and personalized treatment of endometriosis. By collecting biological samples and lifestyle data from participants over 2 years, the study seeks to uncover patterns that can inform more effective individualized care strategies. The inclusion of our sample collection kits in this landmark study underscores their value in enabling high-quality research and positions us for continued growth in the Precision Health and Clinical Research segment.

Now I'll transition to our exciting pipeline of innovation, including an update on several products targeting attractive markets. Mid-year, we launched a blood collection tube with stabilization chemistry for research use only, or RUO, markets in the burgeoning field of

proteomics. We also anticipate near-term milestones for Colli-Pee urine collection, initially for sexually transmitted infection, or STI, indications and future expansion into liquid biopsy. And our Sherlock Molecular Diagnostics Rapid Test platform, whose first assay is expected to serve the large and growing chlamydia and gonorrhea, or CT/NG, segments of STIs.

As we discussed last quarter, our HEMAcollect PROTEIN product launched in July 2025 in the RUO market, like I just mentioned. Since this launch, we've received positive and insightful feedback from our customers and early adopters that will help inform our roadmap as we enhance our proteomics product line and build additional momentum in 2026. Additionally, OTI is presenting at the upcoming Human Proteome Organization World Congress to highlight HEMAcollect PROTEIN's proprietary stabilization capabilities and its performance across a range of proteomics technology platforms.

Moving to our Colli-Pee device, which is designed for first-void urine collection. We plan to submit clinical trial data to the FDA for STI indications by late 2025 or early 2026. Receipt of approvals for these applications subject to regulatory review would be in addition to our existing Colli-Pee RUO product and is expected to further strengthen our competitive position in novel urine collection. Our analytical and clinical studies are demonstrating strong performance and flexibility across multiple target analytes. We're in advanced discussions with leading diagnostics platform providers that are interested in enabling self-collected, non-invasive testing across large and growing markets, including STIs, HPV and other disease states.

Next in product innovation. Regarding our Sherlock over-the-counter Molecular Diagnostics self-test platform and its first assay for CT/NG, we are making good progress in our clinical trial and our plan for submission to the FDA in late 2025 or early 2026.

We anticipate gaining momentum for our product launches through innovation, and it's the work we've done in transforming our enterprise that also allows us to invest in creating a pipeline of earlier-stage opportunities in high-value growth markets that fit well with our strengths and our product platforms where we can compete and win. Examples include categories where we already have a presence like in infectious disease and STIs, plus in newer ones like liquid biopsy or anti-microbial resistance, where rapid tests and differentiated chemistries have outsized potential to create and add value. We look forward to sharing more details as new product opportunities progress through our development process.

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

Kenneth McGrath^ Thanks, Carrie. Total revenue in the third quarter was $27.1 million. Core revenue, which excludes Covid-19 products and the molecular services and the risk assessment testing businesses that we exited, was $27 million. Diagnostic products generated $14.5 million of revenue in Q3, and Sample Management Solutions revenue was $10.3 million. Excluding the headwind from the consumer genetics customer, Sample

Management revenue from the rest of our customer base grew on a year-over-year basis in Q3.

Our GAAP gross margin in the third quarter was 43.5% and non-GAAP gross margin was 44.2%, which was slightly better than our expectations due to lower scrap expenses. GAAP operating expenses in the third quarter were $27.9 million, which includes $2.8 million of non-cash stock compensation expense and $376,000 of expense related to an increase in the estimated fair value of acquisition-related contingent consideration. Depreciation expense was $2.6 million in the quarter. Our GAAP operating loss in Q3 was $16.1 million, and our non-GAAP operating loss was $12.7 million.

Looking at our balance sheet, we ended Q3 with zero debt and total cash and cash equivalents of $216 million. Operating cash flow in the third quarter was negative $10 million, which was consistent with Q2 and our expectations, given our investments in the Sherlock platform, the CT/NG clinical trial as its first assay, and other innovation projects.

We deployed $5 million during the third quarter to repurchase approximately 1.5 million shares of our common stock. Consistent with our capital deployment strategy, we also continue to evaluate organic and inorganic growth opportunities.

As Carrie mentioned, we have signed a definitive agreement to acquire BioMedomics as a tuck-in commercial stage acquisition for $4 million upfront and potential contingent consideration upon achievement of revenue milestones. BioMedomics is currently approaching $1 million of annual revenue, and we believe OTI has the potential to grow that to several million dollars of annual revenue over the next few years.

BioMedomics is expected to be cash flow breakeven with a path to a very attractive ROI as revenue grows over the next few years. We anticipate minimal incremental operating expense for OTI, given that BioMedomics can be plugged into OTI's international commercial organization and leverage our administrative and regulatory capabilities to expand availability and adoption of the Sickle SCAN rapid test.

Turning to guidance. We are guiding to fourth quarter revenue of $25 million to $28 million, which includes less than $100,000 of Covid-19 testing revenues. Our guidance also assumes continued disruption in ordering patterns from our SMS customer in the consumer genetics industry. This customer represented approximately $4 million of revenue in Q4 last year. We expect our gross margin percentage in Q4 to be in the low 40% range, which is slightly lower than third quarter due to typical seasonality and a greater mix of international revenue as a percentage of total revenue in Q4.

Moving to operating expenses. In Q4, we expect core operating expenses of approximately $20 million, 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. We'll plan to exit the transition year of 2025 and head into 2026 with important near-term catalysts for growth as we advance into the next phase of our multi-year strategy. We've done the work in the last 3 years that gives us the confidence and the capabilities we need to achieve our goals. We have delivered cost productivity at the business level and product level, developed our people and infused new talent in the organization, leveraged our commercial strength to diversify our customer base, implemented enterprise-wide rigor and built a strategic innovation roadmap, strengthened our cash flow profile while maintaining a strong balance sheet that has allowed us to invest in attractive innovation pipeline opportunities, including internal product development along with M&A.

We've also refreshed our Board with the addition of three new independent directors over the last three years, including last week's announcement adding Steven K. Boyd as a Director and appointing Jack Kenny as Chair of the Board. Also, we'd like to thank Mara Aspinall, who has decided to step down after over 8 years of service to pursue new opportunities. We're grateful for her many contributions and wish her the very best.

Our foundation is strong, but our work is not done. We recognize that in order to capitalize on the many opportunities ahead of us, we must continue to execute on our priorities and deliver more innovation. Our entire team is working with urgency and is aligned in purpose: to decentralize diagnostics and connect people to care that is more accessible, convenient, private and personalized to create long-term value for customers and shareholders. We're confident in the path ahead.

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

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from Mac Etoch from Stephens Inc.

Steven Etoch^ I appreciate you all taking my questions. just a few for me, and I'll let others ask some. But maybe could you just discuss this bio -- sorry, apologize if I am pronouncing incorrectly, BioMedomics acquisition and what attracted you to that asset, just to start, and I'll follow up on that?

Carrie Eglinton Manner^ Yes. It's a really nice tuck-in that aligns precisely with our portfolio internationally. So rapid diagnostic testing for underserved markets -- the strength we have in Africa including -- we don't talk as much about Latin America. But for low-cost tests that identify pressing healthcare challenges, whether it's the infectious disease success we've had in HIV or HCV, sickle cell is one of those opportunities where the populations in those underserved regions are often undiagnosed.

So we had heard that need. We've been talking with BioMedomics for many years and working with them. So the opportunity to bring that -- to tap that into our portfolio, leverage the strength of our relationships, our commercial distribution and reach, and just put it right

into the portfolio made a ton of sense. So a very promising potential for what we think is smart capital deployment.

Kenneth McGrath^ And Mac, we also -- we think it has a strong return on invested capital. You noticed in the deal structure, we said it's a small upfront with some contingent considerations if they achieve certain milestones, 3 to 5 years out. We believe that structure allows us to really deliver value. We mentioned also that it will be breakeven cash flow. What that -- as Kerry mentioned, it's leveraging a lot of our capabilities. So we really don't need to add a lot to deliver this and to put it into our channel. Then as we grow the revenue, we'll be able to leverage and be accretive going forward.

Steven Etoch^ I appreciate the context there. Then secondly, pretty good cost management on your part, both at the gross margin level and in terms of OpEx. Just given where revenues fell, can you just highlight some of the puts and takes around gross margins and then given the in-sourcing was completed in 2Q, are there any lingering costs that might have fallen into the quarter?

Kenneth McGrath^ Yes. That's a great question. Yes, for gross margins, we did do a little bit better than guided, than expected. A lot of that was driven by our lower scrap than expected, which is really a complement to our operations team and their continued automation and operational efficiencies. As far as OpEx, that was in line with our spend. And really, our core business essentially is breakeven and what we -- where we do choose to spend our dollars beyond that are on innovation. And in this case, innovation focused on delivering our Sherlock CT/NG clinical trial submission as well as internal innovation.

Then a little bit other benefits of gross margins, there was a little bit of a mix benefit in Q3. We did mention we guided in Q4 that will be a little bit below Q3. Part of that is the mix, seasonality and the mix change where we expect to see a little bit more international revenue in Q4 as a mix, which will lower the margins a bit.

Operator^ (Operator Instructions) There are no further questions at this time. I would now like to turn the call back over to Carrie Eglinton Manner for closing remarks.

Carrie Eglinton Manner^ Thank you, Mac, for your questions, and everybody for participating today. We appreciate your continued interest in OTI. With that, we'll close the call. Thank you.

Operator^ This concludes today's conference call. Thank you for joining. You may now disconnect.