OraSure Technologies (2025 Q4 Earnings)

February 26, 2026

Corporate Speakers:

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

Participants:

- Steven Etoch; Stephens; Analyst
- Unidentified Participant; Citi; Analyst
- Andrew Cooper; Raymond James; Analyst

PRESENTATION

Operator^ Good day. And thank you for standing by. Welcome to the OraSure Technologies' 2025 Fourth Quarter 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 for today Jason Plagman, Vice President of Investor Relations.

Please go ahead.

Jason Plagman^ Good afternoon. And welcome to OraSure Technologies' Fourth Quarter 2025 Earnings Call. Participating in the call today for OTI are Carrie Eglinton Manner, our President and Chief Executive Officer; and Kenneth 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, 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 am pleased to turn the call over to Carrie.

Carrie Eglinton Manner^ Thanks, Jason. And thank you to everyone for joining us today.

I'll discuss some highlights from Q4 and our key priorities for 2026 and beyond.

As we've discussed previously, 2025 was a transition year, and we supported our customers in navigating a challenging and uncertain funding environment.

As we enter 2026, we are seeing increasing signs of stability in key segments, including improved visibility to funding for important testing and research programs, and we are excited by several near-term catalysts for growth including our two product launches planned for midyear.

One, our rapid molecular self-test for chlamydia and gonorrhea, also known as CT/NG; and two, our Colli-Pee at-home urine collection device for sexually transmitted infections.

Our submissions of these two separate applications to the U.S. FDA in December represent significant milestones on our innovation roadmap as we move into the next phase of our multiyear strategic transformation to deliver profitable growth and to create value for our customers and shareholders.

Looking at our Q4 results, total revenue was $26.8 million and core revenue was $26.7 million, which was above the midpoint of our guidance range.

In our International Diagnostics business, order trends are stabilizing as national health programs adapt to revised funding structures including framework agreements that have been signed between the U.S. and more than a dozen countries in Africa that incentivize greater levels of local investment in order to build more resilient and durable health systems.

To that end, we are well underway establishing closer relationships with some of our existing distribution partners in Africa including their in-country value-added assembly and manufacturing, also known as nearshoring.

We believe that this trend represents an important opportunity in rebuilding health program momentum in countries around the globe and expect these expanded local relationships in Africa to begin to contribute revenue in Q1 and throughout 2026.

We also expanded OTI's presence in Canada with the recent launch of our OraQuick HIV Self-Test following its receipt of a license from Health Canada. This test is Canada's first oral HIV self-test, and we are excited to work with St. Michael's Hospital, Unity Health Toronto, as the exclusive distributor of this test in Canada.

Continuing with our international business. Our integration of BioMedomics is off to a good start following the close of the acquisition in November. We are seeing strong demand from existing customers for the Sickle SCAN Sickle test which is a rapid point-of-need test for sickle cell disease, or SCD.

Our team is also building momentum with our initiatives to expand the reach and adoption of Sickle SCAN by leveraging our international sales channels and our existing relationships with national health programs, particularly in Africa, where more than 385,000 babies are born each year with SCD, as well as in Latin America with its moderately high incidence of SCD and lack of newborn screening programs.

In our U.S. Diagnostics business, demand for our rapid test from public health customers is stabilizing as those organizations adapt to the current funding environment at the federal and state level. We are also seeing consistent demand for our over-the-counter HIV self-tests from telehealth and direct-to-consumer online platforms that want to offer a reliable FDA-approved self-test that is authorized for use with oral fluid and is designed to meet the needs of individuals who wish to test themselves privately and painlessly at home.

Switching gears to sample management. We remain confident that the sample management business is positioned to deliver growth in 2026 and beyond as genomic end segments continue to stabilize and gradually return to stronger growth, driven by clinical adoption of precision medicine. We also anticipate modest contributions to SMS revenue growth from the academic and government segment as NIH funding returns to a more regular cadence, from international markets, and from progress with our blood proteomic solution that we launched in mid-2025.

Next, I'll transition to our innovation and product pipeline which includes several important near-term catalysts for growth in attractive markets as well as our pipeline of earlier-stage opportunities in high-value growth markets that we discussed last quarter.

Starting with Sherlock. We submitted our rapid molecular self-test for CT/NG to the FDA in late December. As we've discussed previously, OTI's rapid self-test for CT/NG is built on the Sherlock molecular diagnostics platform and is designed to provide the results in approximately 30 minutes in a disposable over-the-counter format. The test uses a self-selected swab and results are intended to be read directly on the handheld testing device without the need for an electrical connection, enhancing accessibility and ease of use.

OTI estimates the testing for CT/NG represents a total addressable market of more than $1.5 billion. Today the vast majority of CT/NG Tests in the U.S. are processed in centralized laboratories, creating an opportunity for meaningful market expansion through the introduction of a convenient, private and affordable rapid self-test.

Also in December, OTI submitted a separate application to the FDA for clearance of our Colli-Pee device for sexually transmitted infections, or STIs. The Colli-Pee device, which includes its proprietary stabilization chemistry, is designed for at-home urine collection and is aligned with patient preferences for private and convenient diagnostic testing. The

submission covers multiple STI indications and is being pursued in collaboration with a leading diagnostics platform provider. Receipt of clearance for the Colli-Pee device for these indications would be in addition to the research use-only products and is expected to expand access to testing while further strengthening OTI's leadership position in novel collection devices and chemistries.

We anticipate that revenue from our product launches will ramp in the second half of the year. And these two submission milestones reflect meaningful progress on our innovation roadmap and demonstrate how we are advancing our vision to help decentralize diagnostics and connect people to care that is more accessible, convenient, affordable and private.

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 fourth quarter was $26.8 million. Core revenue, which excludes Covid-19 products, was $26.7 million. Diagnostic Products generated $15.1 million of revenue in Q4, and Sample Management Solutions revenue was $9.1 million, and both were consistent with our expectations.

Our GAAP gross margin in the fourth quarter was 41% compared to 36.2% in Q4 2024, and non-GAAP gross margin was 41.4% compared to 40.1% in Q4 '24.

Looking at GAAP operating expenses in Q4, R&D expense was $11.4 million, sales and marketing expense was $6.6 million, and general administrative expense was $9.8 million. Noncash stock compensation expense in the fourth quarter was $1.5 million, and depreciation and amortization expense was $2.4 million.

Our GAAP operating loss in Q4 was $20.1 million, and our non-GAAP operating loss was $15.2 million.

Moving to our balance sheet. We ended the year with zero debt and total cash and cash equivalents of $199 million.

During the fourth quarter, we deployed $5 million to repurchase 1.9 million shares of our common stock. For the full year 2025, we returned $15 million of capital to shareholders through the repurchase of 5.3 million shares. Consistent with our balanced capital deployment strategy, we also continue to evaluate organic and inorganic opportunities that can accelerate our growth.

As we discussed in November, we invested approximately $4 million during Q4 to acquire BioMedomics in order to expand our portfolio of rapid diagnostic tests that we can sell to our international customers.

Operating cash flow in the fourth quarter was negative $9 million which was consistent with our expectations given our investments in the Sherlock platform, clinical trials for our molecular CT/NG test and Colli-Pee, and other innovation projects.

We expect to return to breakeven from an operating cash flow standpoint as we enter 2027, driven by our expected return to revenue growth including contributions from our anticipated product launches as well as our continued focus on delivering incremental cost savings through operating efficiencies.

For the first quarter, we are guiding to revenue of $26 million to $29 million which includes a negligible amount of revenue for Covid-19 testing.

We expect our gross margin in the first quarter to be in the low 40% range. On a sequential basis, we expect that our Q1 gross margin will improve slightly compared to Q4 2025.

Overall, we remain focused on disciplined execution that aligns our organization and cost structure with our revenue growth and continued profitability improvement. Recently, we eliminated a number of non-production roles and continue to take actions that increase operating efficiencies, which are partially offset by targeted commercial investments supporting anticipated product launches as well as onetime costs related to severance and other nonrecurring items.

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

Carrie Eglinton Manner^ Thanks, Ken. A year ago, we entered 2025 with the strength to withstand what turned out to be multiple external headwinds, and we are proud to have supported our customers in navigating that environment while we continued to invest in our future and further streamlined our business. We made significant progress in advancing our innovation pipeline and ended the year with two major product submissions to the FDA. Now, here in 2026, we are already seeing signs of market stabilization, and we are also well positioned to capitalize on the growth opportunities that our near-term product roadmap can unlock.

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

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question for the day will be coming from the line of Mac Etoch of Stephens.

Steven Etoch^ Maybe just a couple for me.

I appreciate all the color on the call. Given that you've submitted this application for Colli-Pee and the CT/NG test, I think on average, you were calling out roughly $7 million to $8 million a quarter for R&D associated expenses. How should we anticipate R&D tapering off or continuing from here? And do you anticipate redeploying those funds towards other R&D efforts?

Kenneth McGrath^ Yes. Thanks, Mac. Great question.

We are anticipating over the full year, lower R&D expense for the full year, referencing kind of what you talked about in clinical trials.

However there is some continuation of clinical trials to capture some additional data that supports our performance claims in support of the launches.

So there will be some continuing in Q1, but we will see lower R&D throughout the year to reference what you pointed out around clinical trial spend.

Steven Etoch^ Appreciate that. And then I think international HIV was a little bit more of a record in 2024, then slightly disrupted in 2025 due to the PEPFAR and USAID implementation issues. So I just kind of wanted to get a clear picture of maybe the -- whether or not the ordering cadence is normalized at this point?

Carrie Eglinton Manner^ Yes. You described the history in '24 and '25 accurately. And what we are seeing is improved visibility to countries within Africa figuring out not only their funding, but also the implementation. So you'll remember that in many cases, both the U.S. and the countries themselves said these are the most important test to treat life-saving programs we have. We're totally committed to the testing and consumables, we still have money for, but they had removed all of the people on the programs to implement them.

What we're seeing is -- at least what we're looking at into Q1, Q2 is a recovery where those countries are figuring out the funding and the programs, they're investing more themselves. We mentioned 14 countries in Africa that have signed MOUs with the government, and it really is about your targeted focus, local investment that matches in these bilateral agreements and what we're seeing as part of the encouraging signs of stabilization.

Kenneth McGrath^ Yes. In addition to build on that, Carrie mentioned during the scripted remarks around nearshoring opportunity and that we're excited about that opportunity. It's an opportunity for us to partner with some of these countries starting in Africa which we think can be meaningful dollars -- revenue dollars in the future.

Carrie Eglinton Manner^ And that's really -- I'm sure folks know the term nearshoring, but it's really for local manufacturing assembly in country that makes that available in a more meaningful way with the local demand.

Operator^ And our next question is coming from the line of Patrick Donnelly of Citi.

Unidentified Participant^ This is Brendan on for Patrick.

I want to ask a little bit about the two product launches in midyear. What’s kind of the latest you've heard from the FDA, visibility into launching into the second half? And I know you guys only typically guide quarterly, but any additional insight we can get on potentially what that ramp in the second half could look like?

Carrie Eglinton Manner^ Yes, Brendan we're still working toward that midyear launch and the revenue ramp in the second half, exactly as you described. What we'd say is that there's always uncertainty in the regulatory review process. To give you anything -- in terms of timing, we'd be giving you false precision, but we'll clearly keep the -- provide that information as we have more to share.

But I'd just reiterate, still working toward midyear launch, still working toward a revenue ramp. And as you noted, we don't do guidance beyond the quarter, but we'll share more when we do.

Unidentified Participant^ Appreciate it. And then I believe on the last call you guys talked about expanding beyond the public health setting into more like the clinical such as like the urgent cares and hospitals, specifically for the Hep C test. Would you be able to talk about how traction has kind of evolved since the call? And any other opportunities really come about since then?

Carrie Eglinton Manner^ Yes. We are both encouraged by the progress in our expansion of customer segments. That's part of the stabilization that we've been encouraged by is the pickup in not just public health, but that clinical setting. And so we have seen in the syndromic approach, we've talked about a number of times, but that's the occurrence of the sort of the synergy of epidemics amongst HIV, HCV and syphilis that there is a focus on that in emergency rooms, there is a focus on that in urgent care and we do have -- we are encouraged by the progress. We love the public health funded space, but we're encouraged by the market and segment expansion beyond it.

Operator^ And our next question will be coming from the line of Andrew Cooper of Raymond James.

Andrew Cooper^ Maybe start with Sample Management. I would love if you could share to some degree, how you view the growth when you look back at '25 ex the large customer headwind that you've talked about, meaning what does that underlying look like? And when you talk about a gradual improvement there, just a little more color for what that looks like and what some of the drivers are as we move through 2026 and beyond.

Kenneth McGrath^ Thanks, Andrew. When you look at the full year for Sample Management and to your point, when you exclude that one large customer, for the full year, we did see growth year-over-year, and that encourages us, driven by a lot of things, right? Some could be driven by market, but also driven by our diversification of our customer base which we think now starts paying off benefits as we look at multiple customers and multiple avenues for growth.

Andrew Cooper^ Okay. That's helpful. And then maybe just another one for you, Ken, on the guide. Presumably, on the gross margin side, there's a pretty big difference in absorption at least between the bottom end of the revenue range and the top end of the revenue range, just given the kind of breadth of the guide.

So just would love how we should think about gross margins, both in 1Q, but also as revenues hopefully ramp, what that trend can look like on the margin side?

Kenneth McGrath^ Yes. So what we did say is that in Q1, we expect sequentially some improvement, and we guided to the low 40s. But you're right on as far as the absorption part of it. What we said before is that we're probably operating at around 30% capacity. So you can imagine, as we add volume -- as we add revenue and add volume, we get the benefit from not having to add the fixed costs associated with that volume. So you will see a natural improvement in gross margin.

The other thing you may recall is we had a project where we were consolidating some manufacturing to our Bethlehem facilities. And all of that has been done at this point. And we had two areas. One was moving some of our HIV testing from Thailand to our Opus Way facility in Bethlehem and to leverage, like you said, some of that absorption -- overhead absorption. And actually, it was cheaper because when you run it on automation, it's actually cheaper than what we were getting in Thailand.

The other aspect was consolidating or internalizing some of our volume from our sample management business from contractors that we had in Canada. And we've essentially completed all but some cats and dogs, like 95% or 97% of all that volume has been brought into our Bethlehem facility. So as you can imagine, as we kind of ramp up that, we will get the benefit as well. There is some initial -- the reason you don't see the benefit initially is there is some initial kind of transaction transfer costs that are associated with that transition. But once you get that through and you start getting at the same efficiency rates, you will see that benefit.

Andrew Cooper^ Okay. Helpful. And then if I can sneak maybe just one last one in.

I guess when we think about '26 and the comment at least in the press release and I think some in the call here, this expectation to get back to better growth, how much of '26 is just normalizing from a 2025, where you saw spend come out of the system versus end market growth that you would expect to be more durable as opposed to comp oriented?

Kenneth McGrath^ Yes. That's a great question.

I think -- I'll say what we know and then we can elaborate as we go from there. And what we do believe is that our core business, we will be seeing some growth in the core business. And then we think we expect to accelerate that growth with the product launches in the second half of the year.

So kind of start with that framework. Then as far as that core growth, we are seeing stabilization, right? Like we said, we saw stabilization and some growth in sample management in 2025. And we are seeing stabilization, both international as well as U.S. when it comes to funding.

The area where we do, we are getting excited in international, and Carrie mentioned it was around this nearshoring opportunity, where we are partnering with -- and we're starting in Africa with some African countries, and then we'll expand it beyond that into Latin America and Central Asia. But we're partnering with these countries as they become more self-sufficient, we're partnering with them to help them be able to on-site, be able to do some assembly where we can work with them and be their provider going forward. And we think that's an exciting opportunity. And it's not an opportunity that's cannibalizing existing. It's in addition to existing sales.

Carrie Eglinton Manner^ Yes. And Ken provided a nice overview of that. Just giving thoughts to your distinction around what sort of recovery from where funding came out versus what's growth in end markets. I'd say it's obviously different by portfolio and segment. And SMS is sort of more driven by end market growth, where the core of diagnostics, where you're talking HIV, HCV syphilis, I do think it is more about recovery. The huge impact in '25 was public health funding cuts. So part of that growth is -- it's not necessarily that the funding is completely coming back, but it's that this type of testing is so critical in test-to-treat life-saving program that people are figuring out how to provide those services because they just save lives.

So I think it's different -- sample management is more about end market recovery. Diagnostics is more about a return to core growth based on those segments figuring out funding, figuring out the programs and making trade-offs. And then we layer in product launches onto both portfolios. We layer molecular into diagnostics. We layer Colli-Pee into sample management, and those are organic growth drivers that I think very much align with trends that are clear customer-driven trends around self-collection, around privacy, access that's affordable.

Kenneth McGrath^ Then you factor in our ability to win in those markets like syphilis, where we drive -- we've been driving good growth over the years.

Operator^ And this does conclude today's Q&A session. I would like to go ahead and turn the call back over to Carrie for closing remarks. Please go ahead, Carrie.

Carrie Eglinton Manner^ Thank you, Lisa. And thank you for everyone who participated in our call today and for your continued interest in OTI. Thank you so much. Bye, bye.

Operator^ This does conclude today's program. You may all disconnect.