OraSure Technologies (2026 Q3 Earnings)
November 9, 2026

Corporate Speakers

- Mike Vallie; OraSure Technologies, Inc.; VP of Investor Relations
- Carrie Eglinton Manner; OraSure Technologies, Inc.; President & CEO
- Ken McGrath; OraSure Technologies, Inc.; CFO

Participants

- Steven Etoch; Stephens Inc.; Analyst
- John Wilkin; Craig-Hallum Capital Group; Analyst

PRESENTATION

Operator: Good day, and welcome to the OraSure Technologies, Inc. 2026 Third Quarter Earnings Conference Call. (Operator Instructions) Please note, this call may be recorded.

I would now like to turn the call over to Mike Vallie, Investor Relations. Please go ahead.

Mike Vallie (OSUR): Good afternoon, and welcome to OraSure Technologies Third Quarter 2026 Earnings Call.

Participating in the call 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, cash flows 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 OraSure's SEC filings, its annual report on Form 10-K for the year ended December 31, 2025, 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. We undertake no obligation to update any forward-looking statements to reflect events or circumstances after this call.

In addition, the call will also discuss certain non-GAAP financial measures. A reconciliation of these measures to the most directly comparable GAAP measures is included in our earnings press release issued today, which is available on the Investor Relations section of our website.

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

Carrie Eglinton Manner (OSUR): Thanks, Mike, and thank you to everyone for joining us.

Today, I'll discuss some highlights from Q3 and provide updates on our key priorities for the balance of 2026 and our outlook for 2027.

Q3 was another solid quarter of execution and our return to growth. We delivered 14% year-over-year growth and 1% sequential growth, meaningfully expanded gross margins and reduced operating spend, results driven by continued execution of our strategy.

Continuing now with more on each of our portfolios.

In International Diagnostics, our Q3 performance reflected our approach to stabilize, diversify and localize our business. We are building on our long-standing leadership in HIV testing while expanding our portfolio and strengthening partnerships that broaden our reach and enable us to address critical public health needs across Africa, Latin America and other international markets.

Starting with Ebola. As discussed last quarter, in July, we received FDA emergency use authorization for our OraQuick Ebola 2.0 rapid antigen test. The test detects all four Ebola virus species known to cause human disease, including Bundibugyo, the species responsible for the current outbreak. Since the outbreak began, its scale and geographic reach have increased dramatically.

As of November 3, WHO reports that there are now more than 10,600 confirmed cases and nearly 5,200 deaths. Transmission has spread across multiple provinces in the Democratic Republic of the Congo and across international borders, including the first recorded cases in Kenya's history as well as the case in Nigeria.

Against this backdrop, the need for rapid decentralized diagnostic capacity is clear. Rapid testing can play an important role alongside surveillance, contact tracing, isolation and other public health measures to identify cases quickly and help interrupt chains of transmission. Our test is particularly well suited for point-of-need deployment with its low infrastructure needs, speed and ease of use.

Following our FDA EUA, we have quickly fulfilled initial commercial orders for Ebola 2.0. We believe, however, that the more meaningful catalysts for broader adoption are still ahead of us. One important catalyst will be the results of the BRIDGE Access Platform study, which we previously discussed. Led by Africa CDC and WHO with Unitaid support, the BRIDGE Access Study is independently evaluating diagnostic products for the current Bundibugyo outbreak with the evidence intended to inform Africa CDC recommendations as well as national and regional decisions regarding registration and introduction of diagnostic tests.

This is an important example of how the public health environment in Africa is evolving post-pandemic and following the international aid cuts of 2025. African countries are increasingly focused on building greater self-reliance and locally led health security infrastructure.

Africa CDC itself has made local manufacturing, reduced dependency and greater health sovereignty central elements of its health security agenda. That evolution means adoption increasingly occurs through African-led country-specific pathways for evaluation, registration, procurement and deployment.

These include new processes that are taking time even during an urgent outbreak, but they also reinforce the importance of the investments we have been making to localize our presence and capabilities in the region.

To best serve Africa, OraSure has launched local assembly in Uganda, where our partner is already expanding access to our HIV products and has the potential to add Ebola and other products in the future. Nigeria is our next planned market for launching our localized approach in Africa.

We believe we are well positioned as the Ebola response moves into its next phase. CDC currently assesses the most likely near-term scenario as a very large, sustained outbreak with high-intensity transmission in multiple areas, underscoring the immediate and continued need for a range of effective diagnostic tools. Our product can play an important role on the front lines and porous borders of this outbreak.

Our manufacturing capability is ready, and we bring decades of experience and partnerships to readily serve the region's needs. Beyond this outbreak, we believe rapid point-of-need diagnostics can become an increasingly important component of outbreak preparedness and response and that OraSure is ready and able to play a meaningful role as these pathways mature.

Moving to sickle cell disease. We continue to support growing awareness and expansion of newborn screening across Africa, where Africa CDC estimates that 300,000 to 400,000 babies are born with sickle cell disease each year. This momentum is driving increased demand for Sickle SCAN and our successful integration of BioMedomics is enabling us to leverage our international commercial infrastructure to broaden access in markets with significant unmet need.

We are also building partnerships with national and local health programs to expand point-of-need testing. Our recently announced partnership in Nairobi is one example, focused on scaling Sickle SCAN across community health centers and bringing testing closer to patients. At the same time, our participation in the World Coalition on Sickle Cell Disease connects OTI with leaders across government, health care and patient advocacy to advance earlier diagnosis and strengthen testing pathways. We believe these relationships and joint efforts can help create the conditions for broader adoption of solutions like Sickle SCAN over time.

In summary, the ongoing progress of HIV, early momentum of Sickle SCAN, the potential of Ebola plus the launch of our partners' near-shoring operations reflect the continued evolution of our international diagnostics strategy. We are successfully and increasingly pairing differentiated point-of-need diagnostics with localized capabilities and strong partnerships to expand access, diversify our business and unlock new growth priorities. Over time, we believe this approach can continue to broaden our global reach, strengthen our competitive position and enhance the durability of our growth.

Switching to U.S. Diagnostics. We delivered strong year-over-year growth driven by strength in HCV, syphilis and the continued underlying demand for HIV testing. Our syndemic testing strategy continues to be an important differentiator for us. With rapid testing solutions for HIV, HCV and syphilis, we give customers a broader set of tools to reach populations that face multiple interconnected infectious disease risks. We're very pleased with the progress of this strategy and the clinical and economic value it can deliver for our customers and the communities they serve.

Turning to a regulatory process update on our InteliQuick CT/NG test on the Sherlock platform, intended as a first-of-its-kind rapid molecular self-test. We continue to work towards our resubmission with the FDA following our announcement of withdrawal in August. We are currently working within the pre-sub process, the aim of which is to align on the best path to regulatory access.

We have valuable experience and feedback from our prior submission and are leveraging that and this pre-sub process to evaluate a range of pathways that can bring this important innovation to market. We remain confident in the product's performance, the impact it can have on patients and our ability to navigate the regulatory landscape. We will provide updates as we have more to share.

Now moving to our Sample Management Solutions portfolio. Growth from key commercial customers, along with the timing of orders, contributed to a strong Q3 with growth of more than 20%, both year-over-year and sequentially. As announced last quarter, we received FDA clearance for our Colli-Pee Dx urine collection kit in June. We believe this technology can help expand access to STI testing through a more convenient and private approach to sample collection.

We commercially launched the product in the third quarter and have been very encouraged by initial sales. At the same time, we are excited by the pipeline of potential customers who see real opportunities for the technology, both the chemistry and the device, with many evaluating the workflow required to incorporate self-collected urine into their testing programs. This customer engagement reinforces our confidence in the opportunity for Colli-Pee Dx to support expanded access to STI testing over time.

In Q3, we delivered strong growth in our SMS portfolio. Looking forward, our robust portfolio, the increased anticipated contributions from Colli-Pee and its NucleoPrecision chemistry, along with our partnerships with IVD platform manufacturers, reinforce our confidence in the long-term outlook for Sample Management Solutions and its ability to contribute to our return to growth strategy.

Overall, as we've outlined, OTI delivered a solid third quarter. We further demonstrated our return to growth, drove meaningful gross margin expansion and continued to take cost out of the business. These results reflect the progress we are making in executing our strategy and positioning the business for sustainable growth and long-term value creation.

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

Ken McGrath (OSUR): Thanks, Carrie.

Total revenue in the third quarter was $30.9 million, growing 14% year-over-year and approximately 1% on a sequential basis. Diagnostic products generated $16.8 million of revenue in Q3, representing 16% year-over-year growth. The increase was driven by higher international HIV revenue, reflecting stabilization in our African markets and customer order timing, improved HCV performance supported by U.S. funding dynamics and continued growth from Sickle SCAN.

Sample Management Solutions revenue in Q3 was $12.5 million, a 21% year-over-year increase, driven by key commercial customer growth and timing of specific commercial orders. Our Q3 GAAP gross margin increased 173 basis points to 45.2% from 43.5% in the third quarter of last year. And non-GAAP gross margin in Q3 increased to 45.9% from 44.2%. The gross margin expansion was driven by operational efficiencies, resulting in improved overhead absorption, partially offset by geographic mix. While margins may move quarter-to-quarter based on product mix and order timing, we believe the absorption gains we have built this year will continue to further improve as we scale the business.

Turning to operating expenses. As expected, we saw a material sequential improvement in our operating spend. In the third quarter, R&D expense was $7.6 million, down $1.8 million sequentially as a result of the tapering of development-related spend. At the same time, we continue to invest in innovation, including advancing the early development of HPV testing as a potential future application for Colli-Pee in collaboration with leading global molecular diagnostic partners.

Sales and marketing remained relatively flat at $6.6 million as we leverage our existing capabilities to invest in new growth within our portfolio. And finally, as expected, G&A expense declined to a more normalized level in the third quarter. Total G&A was $12 million, a significant $2.4 million reduction coming as a result of lower nonrecurring items, including legal and professional service costs.

Noncash stock compensation expense in the third quarter was $2.3 million, and depreciation and amortization expense was $2.2 million. And our GAAP operating income in Q3 was a loss of $13 million, and our non-GAAP operating loss was $10.2 million.

Moving to our balance sheet. We ended the quarter with zero debt and total cash and cash equivalents of $148.2 million. Operating cash flow in the third quarter was negative $10.9 million. Consistent with our balanced capital deployment strategy, we continue to evaluate organic and inorganic opportunities that can accelerate our profitable growth in high-value markets and leverage our existing capabilities.

On the partnership front, Sapphiros KKR announced last week that it combined with Hildred-backed binx health to form Onvaro. Through our existing investment in Sapphiros, OraSure remains a minority investor in the combined company, and our strategic agreements with Sapphiros remain in place.

Next, moving to guidance. In the fourth quarter, we expect revenue between $30 million and $32 million, which would represent year-over-year growth of approximately 12% to 20% in the quarter. This guidance represents full year revenue between $119.5 million and $121.5 million and implies a full year growth rate between 3.8% and 5.6%, with 4.7% at the midpoint and as we expect gross margin in Q4 to be similar to or slightly below Q3.

As I mentioned earlier, while quarterly margins may fluctuate due to revenue mix, improved manufacturing efficiencies and continued focus on our underlying margin profile are driving fundamental improvement and providing a stronger base to build from going forward.

Looking ahead to 2027. Regarding cash flow from operations. At the beginning of the year, we laid out a path to achieving cash flow from operations breakeven, entering 2027. That plan contemplated a combination of continued improvement in the underlying business and contributions from several growth opportunities. As the year progressed, the timing and mix of those growth opportunities have changed. Our original plan included a meaningful contribution from CT/NG molecular self-testing.

Following our decision to withdraw that submission, we had identified other opportunities, including significant potential demand for Ebola rapid testing that we believe could offset much of the contribution within the original time frame.

As Carrie discussed, we continue to see attractive opportunities in Ebola and across the broader portfolio. But as the timing of these opportunities has evolved, we have decided to take a more conservative approach to our estimates, and we now expect to reach cash flow from operations breakeven in the second half of 2027.

Continuing our conversation on 2027. In alignment with the execution of our strategy, we expect full year revenue growth to accelerate in 2027 compared with 2026, and we'll provide additional insights into our 2027 outlook on our fourth quarter earnings call.

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

Carrie Eglinton Manner (OSUR): Thanks, Ken.

Looking to the balance of 2026 and into 2027, we are focused on continued execution of our strategy and our return to profitable growth. During the third quarter, we demonstrated the results of our strategy, supported by our simplified portfolio, operating discipline, strengthened production and manufacturing capabilities and advanced innovation pipeline. Together, these drivers translate to revenue and operating margin expansion, positioning OraSure to deliver sustainable long-term value for our customers, partners and shareholders.

Thank you for your continued support and confidence in OTI. We look forward to updating you on our progress next quarter.

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

QUESTIONS AND ANSWERS

Operator (Operator Instructions): Our first question comes from Mac Etoch with Stephens. Your line is open.

Steven Etoch (Stephens): Hey. Good afternoon, and thank you for taking my questions. I guess I got a handful here. Maybe just starting on the CT/NG test. I know it's kind of a moving target, and there's only so much you can say at this point, but I'd love to just get a feel for how you're thinking about the resubmission time line and the costs that are being factored into the model within your estimates at least to start.

Carrie Eglinton Manner (OSUR): Yes. Hi, Mac, we'll start with just following on from our prepared remarks. We are in the pre-sub process on CT/NG. We think there's really a range of potential paths forward. We obviously would like for that to be a shorter, less expensive path, but I think we've talked about the -- not having to pay out the milestone payments on the deal structure based on FDA approval within -- or clearance within the year, it does provide us the opportunity to spend less of that if we do have to continue some of that clinical trial.

So again, timing, TBD. We'll share more as we have it. We're working in scenario planning every range of options. And the punchline is we're prepared to execute on any of those. We are confident in the performance of this product and the path forward, but it really depends on that regulatory process, and we'll share more as we know more.

Ken McGrath (OSUR): Yes, and one thing -- go ahead, Mac.

Steven Etoch (Stephens): No, that's fine. Go ahead.

Ken McGrath (OSUR): Yes. I was going to say one thing to think about for Q4, you could expect OpEx to be similar to Q3 overall. And one thing that may fluctuate a little bit in R&D, we were talking a little bit about it in the prepared remarks around some of our investments and spend related to HPV.

Steven Etoch (Stephens): Got it. I appreciate that context. I guess I'm trying to understand the OCF guidance for the second half of 2027. I'm just trying to triangulate how you're thinking about that within your own expectations and reinvestment.

Ken McGrath (OSUR): Yes. I mean, so I think we've made significant progress, as you saw this quarter. And as we talk about it, we talk about several levers, right? We talk about the improvement in gross margin, and you saw 170 basis point -- 173 basis point improvement in margins, and we continue to drive our operational efficiency through our consolidation and leveraging of our existing manufacturing capabilities.

You also saw the OpEx spend reduction, and we think that should maintain going forward. And then the final leg on that, as Carrie mentioned in prepared remarks, is around building out our portfolio and the revenue growth. So as Carrie mentioned, we think it's a combination of those that will drive us towards that guidance for cash flow breakeven in the second half of 2027.

Steven Etoch (Stephens): Okay. I appreciate that. And then maybe just following up on the guidance for 2027. The press release mentions reacceleration of growth. You're about to do, call it, 5% to 6% in 2026. And factoring in Colli-Pee as well as the Ebola test, I just want to understand how you're thinking about 2027 from a core revenue business perspective and then also within those two product lines as well.

Ken McGrath (OSUR): Yes. Well, we'll be prepared in the Q4 earnings to give more insights into growth. But overall, to your point, we have talked about accelerating growth coming from a combination of core and then our new product launches will drive that acceleration of growth.

Steven Etoch (Stephens): Okay. I appreciate it. I'll jump back in the queue.

Ken McGrath (OSUR): Thank you, Mac.

Operator: Our next question comes from John Wilkin with Craig-Hallum.

John Wilkin (Craig-Hallum): Hi, guys. Thanks for taking the questions. A couple of points I wanted to touch on and maybe for starters, just could you walk through some of the moving pieces in the Q4 guide? I think at the midpoint, it implies revenue about flat sequentially. I know you called out some order timing and sample management driving some of the growth in Q3. So if you can just help us understand how much of that is being pulled forward from Q4 and what the offset to that is?

Ken McGrath (OSUR): Well, one of the things we look at -- and thanks for the question, John.

One of the things we look at here is the strength of our portfolio and the breadth of our portfolio. And as you've observed and noticed, right, over quarter-to-quarter, we do have a revenue mix kind of fluctuation, whether it's timing of large orders that we've talked about in the past from international that may come at the end of a quarter, at the beginning of a quarter as well as sample management.

So there is some seasonality with that. But what we leverage is the strength of the overall breadth of our portfolio that allows that to balance out over time.

You did see it in Q2 to Q3, right, where you saw some increase in sample management. You saw some -- a little bit of a decrease, right, in diagnostics. And even that was part of that was timing in Q2 where in Q2, we called out that our domestic diagnostics due to timing of state fiscal budgets and when the cycles end, had some ordering at the end of Q2. So you do see that.

But overall, that -- we think it's a strength of our portfolio of kind of having that revenue mix that can drive overall. But we did see strong growth, obviously, from -- on a year-over-year basis, and we expect to see strong growth on a year-over-year basis in Q4 as well.

Carrie Eglinton Manner (OSUR): And just to put maybe a little bit finer point on Q3 and Q4. We -- you saw a real strength in sample management that -- I would say that helped offset a little bit of movement from international orders. Ken was hitting that from a Q3 perspective. International, we had some that we expect to see that international volume in Q4, and we consider that more of a -- sort of a mix shift, then I wouldn't refer to it as pulling that forward, John.

I'd really just sort of refer to that as a mix shift where SMS was maybe a little bit stronger than you would have expected. And I'd say you'd expect that to be not as strong in Q4, but that international portfolio strength that Ken was referring to, that's where you're going to see that come back in Q4.

John Wilkin (Craig-Hallum): Got it. Okay. That's helpful. And I'm wondering if you're able to, whatever extent you're willing to disclose, if there was a meaningful contribution yet in terms of revenue from either Ebola or Colli-Pee and if there's any meaningful contribution from either of the two factored into the Q4 guide?

Carrie Eglinton Manner (OSUR): We appreciate the deeper dive. We don't -- we're not guiding by product. What we would say is what we had shared, which is we're really encouraged by the initial orders. Product ramp-ups, you know how these go. There's adoption and really trying to move into those repeat orders. So we're very encouraged by the initial orders, enough -- encouraged enough to talk about them and to -- I think that's part of the confidence in what we shared on 2027, which we've often just sort of shared quarterly.

I think what we're trying to indicate is that we do feel like that momentum is strong enough for us to point to that -- those increases for a return to growth this year that we believe we're demonstrating and a commitment that following Q4 earnings, we plan to give more visibility, though we are sharing that we see an acceleration of that growth.

And I'd reiterate what Ken had said. To your point, while we're not going to talk specifics on the guide, we are encouraged to say it's a part of the acceleration of growth that we're referring to for '27 in total.

John Wilkin (Craig-Hallum): That makes sense. Fair enough. And then lastly, I just want to ask you, if you're able to delve any more into just what the contracting process is looking like for Ebola. And I know you mentioned a couple of countries in the pipeline that you're going to be launching into. Maybe just any -- if you can size like the magnitude of those opportunities at all or what the time lines look like for getting those in place and getting the products starting to sell through?

Carrie Eglinton Manner (OSUR): Yes. Part of the reason we shared more of the Ebola background is that that major catalyst that I talked about, the BRIDGE Access Study, obviously, we were hoping that you have seen the results of that sooner. That study was announced in May. Inclusion in that was in June. The descriptions of it were moving at the speed of the outbreak. And considering that this is the fastest-growing outbreak to date, the need for diagnostics and rapid testing is so clear that I think everybody is expecting that to be a major catalyst to drive that contracting.

So quite frankly, I would have expected that already. We are not unusual in waiting for this. I mean I know the U.S. government is -- we work with BARDA and CDC, and we're all waiting on that as a catalyst to sort of open up the regional ordering. What I would say is that like we've emphasized, we've got decades-long relationships. We will serve needs that are already contracting. But this is a matter of new processes in place that were not sort of well defined. But fundamentally, we feel very well positioned to work with these partners who we support, who we partner with today.

And we've been very encouraged. They've been figuring out funding and implementation paths for all of the rest of their diagnostic needs. We believe that, that will be the case with Ebola as well. And there are really strong partnerships that we plan to continue to build on. So while we don't know the timing precisely, we do expect that before the end of the year. And as soon as we know more, we'll be sharing that.

John Wilkin (Craig-Hallum): Perfect. Thank you guys for taking the questions.

Carrie Eglinton Manner (OSUR): Great. Thanks, John.

Operator: Thank you. I'm showing no further questions. I'd like to turn the call back over to Carrie Eglinton Manner for any closing remarks.

Carrie Eglinton Manner (OSUR): Thank you. Thank you for your interest and participating in our call. We look forward to our offline discussions as well as following up next quarter. Thanks so much. With that, we'll close.

Operator: Thank you for your participation. You may now disconnect. Good day.