OraSure Technologies, Inc. (2026 Q2 Earnings)
August 5, 2026

Corporate Speakers:

- Michele Anthony; OraSure Technologies, Inc.; Chief Accounting Officer
- Carrie Eglinton Manner; OraSure Technologies, Inc.; President, Chief Executive Officer
- Ken McGrath; OraSure Technologies, Inc.; Chief Financial Officer

Participants:

- Mac Etoch; Stephens; Analyst

PRESENTATION

Operator^ Good day and thank you for standing by. Welcome to OraSure Technologies, Inc. 2026 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 first speaker today Michele Anthony, Chief Accounting Officer. Please go ahead.

Michele Anthony^ Good afternoon. Welcome to OraSure Technologies' second quarter 2026 Earnings Call.

Participating in the call today for OTI are Carrie Eglinton Manner, our President and Chief Executive Officer; and Ken McGrath, our Chief Financial Officer.

As a reminder, today's webcast is being recorded, and the recording can be found on our Investor Relations website.

Before we begin, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share,

and other financial performance, product development, performance, shipments 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 31st, 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. 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, Michele, and thanks to everyone for joining us. Today I'll discuss some of the highlights from Q2 and provide updates on our key priorities for 2026.

Q2 was another important quarter in OraSure's transformation. We exceeded our revenue guidance, expanded gross margins sequentially, advanced our decentralized diagnostics pipeline in rapid tests and sample management solutions, and continued to position the business for sustainable growth and long-term shareholder value in the second half of 2026 and beyond.

Through our multi-year transformation, we have moved from restructuring and portfolio simplification to execution against a more focused growth strategy.

In 2025, we said that 2026 would be a transition year on the path back to growth. Q2 demonstrated that transition beginning to take shape through stronger revenue, improving margins, and meaningful innovation milestones, including FDA clearance of Colli-Pee Dx with its NucleoPrecision chemistry for use with Roche cobas STI tests, plus FDA emergency use authorization for our second-generation OraQuick Ebola rapid test.

Also, on the innovation front, an FDA update, is our InteliQuick CT/NG test on the Sherlock platform. While we remain very confident in and excited about this first-of-its-kind rapid

molecular self-test, I would like to call out that we are no longer expecting FDA clearance and U.S. launch to occur in 2026.

I'll provide additional details later on this, but want to reiterate our conviction that it's an excellent test that performs very well. Following constructive conversations with FDA, however, we recently elected to withdraw our submission. We are incorporating feedback from the agency and will be working with them on resubmission to bring it to market.

We have positive momentum on multiple fronts, and while we are disappointed in the InteliQuick delay, I want to emphasize this does not change our commitment or ability to deliver on revenue growth in 2026 or cash flow from operations break-even as we enter 2027.

We are strengthening our foundation by leveraging our Pennsylvania manufacturing capabilities, insourcing work previously performed by third-party contractors, and maintaining disciplined cost controls that are visible in our margin performance.

We are elevating our core by diversifying the markets, channels, and customers we serve across rapid diagnostics and sample management solutions, as evidenced in our sequential progress. We are accelerating profitable growth through targeted R&D and partnerships focused on high-value markets where decentralized access, proprietary know-how, scalable manufacturing, and accessible rapid testing and collection solutions can create attractive risk-adjusted returns.

Focusing on our Q2 results, total revenue was $30.6 million, exceeding our guidance range, and gross margins improved sequentially. Lapping the divestiture of our risk assessment testing business and now with Covid almost entirely behind us, we are focused on growing our business, executing launch readiness for near-term catalysts, and progressing toward operating cash flow break-even as we enter 2027.

The accomplishments we will highlight today are important proof points of that strategy. Moving to those highlights. In mid-June, we announced FDA clearance of the Colli-Pee Dx urine collection kit, which enables at-home self-collection of volumetric first void urine samples for STI testing, which can be collected at any time of day.

We believe clearance of OTI's differentiated Colli-Pee collection device with its proprietary NucleoPrecision sample stabilization technology, utilized with Roche's STI tests on its cobas molecular diagnostic platform, can increase access, convenience, and privacy for important STI

testing. It also represents a key milestone in our strategy to decentralize diagnostic solutions and connect more people to care while helping increase SMS portfolio growth.

We also recently shared that we received FDA emergency use authorization for our OraQuick Ebola 2.0 Rapid Antigen Test.

Building on our Ebola 1.0 Rapid Antigen Test, for which we received authorization in 2019, our version 2.0 test was also developed in partnership with BARDA. The test detects all four Ebola virus species known to cause human disease, including the Bundibugyo species driving the current outbreak in Central Africa.

This authorization underscores OTI's strength in public health, including our R&D expertise, our regulatory capabilities, manufacturing scale, global reach, and long-standing partnerships with governments and global health organizations.

Together, these capabilities enable us to respond quickly to emerging and ongoing health threats with accessible rapid diagnostic solutions. While this outbreak is a stark reminder of the devastating impact of infectious diseases, it is another reminder that our mission and expertise matter.

We are proud to contribute to the response and remain committed to applying our strengths where they make a meaningful difference for communities in need while creating value for our shareholders.

In international diagnostics, our Q2 progress reflects an approach to stabilize, diversify, and localize. We continue to serve long-standing HIV testing customers while also expanding the portfolio and deepening relationships with partners that support public health needs from Africa to Latin America and in between and beyond.

While Ebola is our latest example of the strength of our capabilities to serve global markets, another is our work on nearshoring and in-country value-added assembly programs for our OraQuick HIV self-test, which we discussed in Q1.

These partnerships are increasingly important as national health programs adapt to evolving funding structures and as customers seek more resilient local supply models. We expect to share more on localization later this year.

A third strong global example is in the progress following our acquisition of BioMedomics with Sickle SCAN. We are seeing encouraging progress integrating Sickle SCAN into our international commercial channels and pursuing opportunities with national health programs in geographies where point-of-need Sickle cell testing can address significant unmet need.

In the hands of our international sales team, Sickle SCAN revenue is growing twice as fast in 2026 as it did in 2025. Taken together, Ebola 2.0 Rapid Test access, OraQuick HIV nearshoring, and Sickle SCAN expansion reflect the strategic evolution of our international diagnostics business.

By addressing critical public health priorities with increasing localization while diversifying our revenue base, we are creating new avenues for growth and reinforcing the capabilities that differentiate OTI globally. We believe this approach positions us to serve customers more effectively, strengthens long-term partnerships, and creates durable value for shareholders.

Switching to U.S. diagnostics, we saw stronger public health demand in Q2, including customer purchasing patterns tied to fiscal year cycles. Even with continued federal funding pressure, HIV testing programs remain an important public health priority, and demand for our market-leading OraQuick HIV self-test was strong in the quarter.

We also continue to benefit from the syndemic testing approach we have discussed on prior calls. By offering rapid tests across HIV, HCV, and syphilis, we can help customers address overlapping populations while delivering both clinical and health economic value.

In addition, our consumer and B2B2C channels for the OraQuick HIV self-test continue to grow, including through telehealth and other digital access points. These channels provide a strong foundation for future OTC and decentralized STI testing opportunities and reinforce the growing demand for convenient, private access to diagnostic testing. That demand is also reflected in the opportunity we see for InteliQuick CT/NG molecular self-testing.

As I mentioned earlier, I want to provide more detail on the withdrawal of our FDA submission and our regulatory path forward.

Our studies demonstrate a strong performance compared with centralized laboratory molecular diagnostic methods, and we remain encouraged by the product's performance and its potential to address an important public health need.

Based on the strength of our data across all elements of performance, the demonstrated patient and provider need for this test, and the value of InteliQuick's differentiated profile, we had anticipated FDA clearance around this time.

Following constructive interactions with the FDA and in consultation with them, we are building our plan for resubmission. While we are disappointed by the delay in obtaining regulatory clearance and broader market access for InteliQuick CT/NG, our confidence in the quality, performance, and clinical value of the test has only increased.

We will provide additional updates on our progress in future quarters as we move quickly to complete the work we think is necessary for regulatory clearance and full market launch. Moving to sample management solutions, we are seeing varied levels of improvements across key customer segments, including commercial, advanced diagnostic testing laboratories, and other precision healthcare applications, including microbiome collection, along with early signs of recovery in academic and research channels.

We are encouraged by increasing utilization of genetic insights to assess disease risk, inform diagnoses, and guide patient care. For example, the U.K.'s National Institute for Health and Care Excellence, also known as NICE, its recent draft guidance recommending Ziwig Endotest marks another important commercial validation of saliva-based diagnostics in women's health and expands access to non-invasive testing for endometriosis within the U.K. healthcare system.

We've talked about Ziwig before, and Endotest, it incorporates DNA Genotek's OMNIgene ORAL saliva collection and nucleic acid stabilization technology, underscoring the capability of our collection solutions to support advanced testing.

This adoption demonstrates the versatility of our technology beyond genetics into high-value diagnostic applications, and it reinforces our position as a trusted partner for innovative developers.

As demand grows for similar accessible, patient-friendly testing, we believe our broad portfolio of collection technologies are well-positioned to support the next generation of women's health, wellness, and molecular diagnostic programs worldwide.

Additionally, in SMS innovation, we were excited in Q2 to announce the important milestone we achieved with Colli-Pee Dx Urine Collection Kit receiving FDA clearance. The kit solution comprises the Colli-Pee Dx collection device, which enables volumetric self-collection of biomarker-rich urine, enabling a broad range of testing solutions, and our NucleoPrecision chemistry, which is proprietary and non-toxic, for the stabilization and storage of biomarkers.

The recent FDA clearance applies to eight STI indications. That's four types of Roche cobas tests, chlamydia, gonorrhoeae, trich, and m. gen, for both male and female self-collected urine on the Roche cobas molecular diagnostic platform.

The Colli-Pee Dx launch is off to a nice start as customers are expressing strong interest in the innovation and its potential to expand access to STI testing that is more convenient and private.

Overall, SMS revenue increased sequentially in Q2. Combined with the anticipated contribution from Colli-Pee and its NucleoPrecision chemistry, we remain confident in the long-term outlook for sample management solutions and its ability to help drive growth in 2026 and beyond.

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

Ken McGrath^Thanks, Carrie. Total revenue in the second quarter was $30.6 million and grew 9.7% on a sequential basis. Diagnostic products generated $19.4 million of revenue in Q2, with U.S. revenue higher than international revenue.

Diagnostic revenue grew 14.7% on a sequential basis, reflecting stronger public health demand, including customer purchasing tied to fiscal year cycles, as well as higher syphilis revenue and the addition of BioMedomics' Sickle SCAN sales.

Sample management solutions revenue in Q2 was $9.9 million and grew 9% on a sequential basis, with growth across segments.

Our Q2 GAAP gross margin increased 120 basis points sequentially to 43.5% from 42.3% in Q1 2026, and non-GAAP gross margin in Q2 increased to 44.2% compared to 43.4%. Gross margin expansion was driven by lower scrap and operational efficiencies, partially offset by revenue mix. Looking at GAAP operating expense in Q2, R&D expense was $9.4 million, sales and marketing expense was $6.6 million, and general and administrative expense was $14.4 million.

R&D expense declined both sequentially and year-over-year, reflecting the tapering of launch preparation and production readiness spending for our Colli-Pee device. The year-over-year increase in G&A was primarily driven by non-recurring items, including higher legal and professional service costs related to our proxy and stockholder activism.

As we stated last fall, we expect G&A expense to decline to more normalized levels beginning in Q3 as these non-recurring items wind down. Included in the Q2 financials, the company recorded a reduction in its contingent consideration liability as a result of updating our submission plan to incorporate feedback from the FDA for the CT/NG test on the Sherlock platform.

Non-cash stock compensation expense in the second quarter was $2.3 million, and depreciation amortization expense was $2.4 million. Our GAAP operating income in Q2 was $5.4 million, and our non-GAAP operating loss was $14.7 million.

Moving to our balance sheet, we ended the quarter with zero debt and total cash and cash equivalents of $161 million. During the second quarter, we deployed $2 million to repurchase 647,000 shares of our common stock.

Since initiating the program last year, we have returned $22 million to shareholders through the repurchase of 7.7 million shares, representing nearly 10% of our outstanding shares and utilizing approximately 55% of the $40 million authorization.

Given the commercial opportunities ahead, we paused additional repurchase activity during the quarter and are prioritizing balance sheet flexibility to support launch-related investment across the portfolio, including Colli-Pee and Ebola 2.0 Rapid Tests.

The authorization remains in place, and we will continue to evaluate repurchases over time. 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.

Operating cash flow in the second quarter was negative $9.9 million, which was consistent with our expectations.

As Carrie stated, we expect to return to breakeven in cash flow from operations entering 2027. This view is supported by our outlook for revenue growth, including anticipated contributions from new product launches, as well as our continued focus on cost savings and operating efficiencies.

Moving to guidance, we expect revenue in the third quarter of $29.5 million to $32.5 million, and we expect our gross margin in Q3 to be similar to Q2. With that, I'll turn the call back to Carrie to conclude.

Carrie Eglinton Manner^Thanks, Ken.

As we enter the second half of 2026, OraSure is a more focused and operationally disciplined company with a stronger innovation pipeline. We've simplified the portfolio, strengthened our production capabilities, and consolidated our manufacturing footprint.

We advanced important technology and product milestones while also demonstrating a return to growth and preparing for revenue contributions from the launches of Colli-Pee Dx and our Ebola 2.0 Rapid Test. These achievements reflect the discipline of our operating model, the strength of our innovation engine, the differentiation of our products, and the commercial value and execution of our decentralized diagnostic strategy.

Looking ahead, we remain focused on converting our pipeline into growth, expanding our portfolio across attractive markets, and leveraging our manufacturing capabilities and global partner relationships. Together, these drivers position 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 Ari for Q&A. Thanks, Ari.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from the line of Mac Etoch of Stephens. Your line is now open.

Mac Etoch^ Maybe just a couple of questions for me. Just given the CT/NG update, I'd love to get a sense of how you're thinking about the timing around a resubmission and then potential approval past that.

Then secondly, how is that affecting your cost structure moving forward?

I know there were some lingering costs around the post-approval studies that were going on as well.

Carrie Eglinton Manner^ Yes, Mac. I'll just start with our confidence in the InteliQuick test and the performance that it demonstrated. While we are working to incorporate FDA feedback, we plan to resubmit it.

This is a recent discussion. In terms of timing, we plan to come back to share more on that. We're obviously moving quickly in collaboration with them. This is a -- this is a priority. But we will update you -- we'll update our investors with more on timing as we have that.

Ken McGrath^ And, Mac, as far as the cost, this will not -- this will not incrementally add to our overall cash flow from operations usage. There's an offset here related to the milestone payments that will be reduced.

And obviously you can imagine as we go forward with our plan, there'll be some incremental dollars to support that, but that will be lower than the expected reduction in milestones.

Carrie Eglinton Manner^ So in terms of how we think about the total year, Mac, we're clearly disappointed in that delayed timing. Obviously we were -- we were working hard to toward a to work toward clearance and launch.

But in terms of our expectations for the year, I want to reiterate, it does not change our outlook on growth for the year. And in an unanticipated way, we expect that to cost less.

We had every intention of that clearance. We believe it's a matter of timing, and this is all about working toward the resubmission.

Mac Etoch^ Got it. Maybe just to -- just to clarify on that point, Ken, it sounds like maybe any incremental cost that might be incurred from whatever it might be will be offset by a reduce or a reduction of that $20 million contingency payment.

Ken McGrath^ Correct.

Mac Etoch^ Awesome. Then maybe in terms of SMS, I think I heard -- my connection is a little spotty today, but can you -- can you speak to what you're seeing in terms of the advanced genetic testing lab demand?

Carrie Eglinton Manner^ Yes. So we're seeing the continued, not only green shoots in other labs that are growing, but we're seeing a fairly consistent recovery amongst the advanced genetic labs more broadly.

So we delivered that sequential growth. I'd say this has remained muted post-Covid, but there is progress, and we see not only advanced genetic testing labs, we see areas like microbiome collection that had been somewhat soft. In the last couple of years, we see -- have seen some uptick there as well.

Operator^ I am showing no further questions at this time, so I would like to turn it back to Carrie Eglinton Manner for closing remarks.

Carrie Eglinton Manner^ Great. Thank you to all of you for your engagement and support. Ari, thank you for the facilitation. We look forward to providing updates in the next quarter.

With that, we'll close the call.

Operator^ Thank you for your participation in today's conference.

This does conclude the program. You may now disconnect.