OraSure Technologies Inc. (Q2 2025 Earnings)

August 05, 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:

- Unidentified Participant; Citi; Analyst
- Noah Lewis; Raymond James; Analyst

PRESENTATION

Operator^ Good day. And thank you for standing by. Welcome to the OraSure Technologies Second Quarter 2025 Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. I'd now like to hand the conference over to Jason Plagman, Vice President of Investor Relations. Please go ahead.

Jason Plagman^ Good afternoon. And welcome to OraSure Technologies' Second 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, 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. We are pleased to provide an update on the progress OTI is making on the three pillars of

our strategic transformation, one, strengthening our foundation, two, elevating our core growth and, three, accelerating profitable growth.

Today I'll discuss some highlights from Q2 and our progress on our key priorities for 2025 and beyond. A few notable developments include:

We reported revenue in Q2 that was in the top half of our guidance range for both total revenue and core revenue.

We continue to advance our innovation roadmap in order to expand our portfolio with new products. To that end, we launched our HEMAcollect PROTEIN offering in July in an effort to meet the evolving needs of proteomic researchers. This product also expands our Sample Management Solutions into a new sample type, blood.

Next, Anne Messing joined OTI this week as Chief Commercial Officer. She will be responsible for sales, marketing, and product management and will help shape the vision and management of our product portfolio with the aim to expand market leadership and drive sustainable accelerated growth.

And as we previewed last quarter, during Q2 we substantially completed the transition from external contract manufacturing of our SMS products outside of the U.S. to our internal capabilities in Pennsylvania.

Looking at Q2. Core revenue of $30.8 million was above the midpoint of our guidance range. Diagnostics grew 3% year-over-year and Sample Management revenue decreased 22% year-over-year, with the decline attributable to a large customer in the Consumer Genetics segment, as we've discussed on prior calls. Excluding the impact of that customer, Sample Management revenue growth would have been positive on a year-over-year basis in Q2 and overall core revenue growth would have been 5% compared to the prior year.

Broadly speaking, our key end markets remain mixed, and we are staying closely aligned with our customers as they navigate an environment with improving but still elevated levels of uncertainty related to funding for public health programs as well as for research.

In our international Diagnostics business, we delivered year-over-year revenue growth in Q2 and the first half of 2025 despite unprecedented disruption due to USAID funding freezes for local distribution and implementation partners in many markets. Due to that disruption, the pace of deployment of HIV tests to end users in those geographies slowed considerably over the last six months, as also recently referenced by other industry suppliers. We now expect a slower pace of international 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.

Longer-term, we remain confident in our competitive positioning in the international HIV testing market due to several important factors.

First, our unique oral fluid-based rapid test is preferred by patients. It's easy to use and interpret at the point of need, and it requires fewer resources and clinical support than tests that are lab-based or require collection of a blood sample. And second, OTI has a history of proven success with 10 years of consistent leadership and strong, enduring relationships with customers and partners.

Of course, we are closely monitoring the situation and actively engaging across the ecosystem in order to deliver on life-saving test-to-treat programs that remain critical to improving global health.

In our U.S. Diagnostics business, revenue has been relatively steady, declining 1% year-over-year in the first half of 2025. Many of our public health customers are dealing with elevated uncertainty given potential cuts to their budgets and significant reductions in staffing at HHS, CDC and other agencies that administer health programs.

In May, we discussed the pending wind down of Together Take Me Home, a federal program with strong bipartisan support in Congress that makes HIV self-tests available through the mail. Since then, program administrators have received a rescission of the closeout letter and Together Take Me Home may continue beyond the end of the federal fiscal year on September 30th.

That said, program funding levels have not yet been communicated, and we continue to actively monitor the situation, which remains fluid. We expect to recognize approximately $0.5 million of revenue from Together Take Me Home in Q3 compared to $2 million in Q2 due to the timing of orders.

We are hopeful that we will be able to continue our work with our partners in the program, which has delivered significant benefits since it launched three years ago including reaching at-risk populations who had not previously understood their HIV status and are now engaged in testing and prevention or treatment that improves their quality of life and helps end the HIV epidemic.

Switching gears to our Sample Management business. Our Commercial segment, which includes advanced diagnostic labs, pharma and biotech, and animal health companies, amongst others, grew in the first half of 2025, excluding the disruption we've experienced with our consumer genetics customer. In the Academic and Research segment, some of our customers have been negatively impacted by reductions in NIH funding as we discussed last quarter.

Looking ahead, we see continued stability in SMS revenue in Q3 and Q4. And specific to our large consumer genetics customer, we view the recent resolution of their ownership as a positive for everyone. Consistent with what we've shared, we do not anticipate any significant revenue from this customer in the second half of the year, and we think orders are more likely to resume in 2026.

As we described last quarter, we continue to believe it's a matter of time -- when, not if -- genomics end segments return to consistently stronger growth, driven by scientific advancements and greater clinical adoption of precision medicine.

At the same time, we remain focused on maintaining strong customer relationships while cultivating new ones. As an example, we're pleased to announce the renewal of our agreement with GeneDx, a valued and long-standing customer.Our ORAcollect kits help enable early diagnosis of rare pediatric diseases through the use of GeneDx's exome and genome analysis.

We're also pleased to highlight one of our newer relationships with Targeted Genomics, the developer of GlutenID, the first and only U.S. FDA-cleared direct-to-consumer test for celiac disease genetics. Celiac disease, the most common intestinal autoimmune disease worldwide is triggered by dietary gluten in people who carry certain celiac risk genes. Individuals who test negative for these genes have less than a 1% chance for developing celiac disease.

GlutenID assesses all 15 possible genetic combinations of the risk genes using DNA isolated from saliva and collected with our ORAcollect Dx device. This test allows for at-home collection of saliva samples, simplifying the test process so patients can get actionable answers and ultimately relief. OTI is proud to collaborate with Targeted Genomics to make celiac disease screening more accessible and convenient for at-risk individuals and their families.

In addition to expanding our customer relationships, we also continue to advance our innovation roadmap. As planned in July, we launched our HEMAcollect PROTEIN product. This blood collection device and chemistry has the potential to transform proteomic research and discovery through extended protein stabilization at room temperature and a simplified workflow, and it is anticipated that use of the device for sample collection will deliver operational and financial efficiencies to researchers.

The HEMAcollect PROTEIN collection kit is compatible with a broad range of proteomic technologies including mass spec, immunoassays and high-throughput affinity-based platforms. We believe our HEMAcollect PROTEIN offering represents a significant advancement in sample collection for proteomics and that it can support research and laboratory developed tests in rapidly growing applications such as oncology, neurology, cardiology, metabolic disorders and beyond.

Moving to our Colli-Pee device, which is designed for first void urine collection. We're making strong progress toward our planned goal of a 2025 FDA submission. We're in active discussions with leading diagnostics platform providers seeking to expand into self-collected non-invasive testing across large and growing markets including sexually transmitted infections, HPV and other disease states. These segments represent multibillion-dollar global TAM, and we see significant growth opportunities for Colli-Pee, driven by patient preference for less invasive sample collection and increased demand for convenient, accessible and private diagnostic options.

For HPV specifically, Colli-Pee also addresses long-standing challenges with urine-based testing by enabling assay sensitivity and specificity comparable to invasive swabs, opening the door to broader, more inclusive screening programs.

Meanwhile, oncology and liquid biopsy applications are also gaining momentum with urine emerging as a powerful new matrix for early cancer detection. Coupled with our proprietary DNA, RNA stabilization chemistry, Colli-Pee is uniquely positioned to power the next generation of high-impact patient-centric diagnostics.

Next in product innovation, our clinical study for Sherlock's first over-the-counter molecular self-test for chlamydia and gonorrhea or CT/NG is progressing well. We remain on track to submit data to the FDA by the end of 2025. As a reminder, CT/NG testing is the largest market within STIs, and it requires molecular technology. Sherlock CT/NG test is truly disposable at-home test designed to deliver lab-like clinical performance with a rapid turnaround time at what we believe will be an attractive price point.

Of the tens of millions of CT/NG tests performed in the U.S. each year, the vast majority are currently processed in a centralized lab. We are confident that the introduction of an affordable over-the-counter test has the potential to drive incremental market adoption through improved access to convenient, private testing options in a segment where privacy is a key priority.

As I've described today, our team is making meaningful progress in advancing our innovation roadmap in order to expand our portfolio through new product launches, and we are also expanding and diversifying our client relationships in new segments.

We expect our momentum to accelerate under the leadership of our new Chief Commercial Officer, Anne Messing. Anne brings more than 25 years of commercial leadership experience in life sciences, diagnostics and clinical laboratory services. Prior to joining OTI, she was Vice President and General Manager of the U.S. region for Becton Dickinson, BD Biosciences. And Anne's prior experience at Danaher, Quest Diagnostics, Siemens, and in hospital labs is both valuable and relevant for OTI and for our customers.

Anne has a proven track record of driving growth, building high-performing sales teams and transforming strategic vision into demonstrable results and sustainable success. We are excited to welcome Anne to our business and leadership team.

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 second quarter was $31.2 million. Core revenue, which excludes COVID-19 products and the molecular services and risk assessment testing businesses that we exited was $30.8 million.

As Carrie mentioned, core revenue growth in Q2 would have been positive on a year-over-year basis if you exclude the decline in revenue from the large consumer genetics customer. Diagnostic products generated $19.2 million of revenue in Q2 and grew 3% year-over-year.

Sample Management Solutions revenue in the second quarter was $9.9 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 Q2.

COVID-19 and risk assessment testing products contributed $474,000 of revenue combined in the second quarter, which was consistent with our guidance, and we completed our exit from the risk assessment testing business during Q2.

Our GAAP gross margin in the second quarter was 42.1% and non-GAAP gross margin was 43.2%, which was better than our expectations. GAAP operating expenses in the quarter were $31.2 million, which includes $3.2 million of non-cash stock compensation expense, $751,000 of severance expense, $733,000 of expense related to an increase in the estimated fair value of acquisition-related contingent consideration.

Our GAAP operating loss in Q2 was $18 million, and our non-GAAP operating loss was $13.2 million. Looking at our balance sheet. We ended Q2 with 0 debt and total cash and cash equivalents of $235 million.

Operating cash flow in the second quarter was negative $10 million, which was consistent with our expectations given our investments in the Sherlock platform, the CT/NG clinical trial as its first assay, and other innovation projects.

Switching to capital deployment, we deployed $5 million during the second quarter to repurchase 1.8 million shares of our common stock. Consistent with our capital deployment strategy, we also continue to evaluate inorganic growth opportunities that would expand our product portfolio, especially with commercialized innovation and accelerate near-term revenue.

Turning to guidance. We are guiding to third quarter revenue of $27 million to $30 million, which includes less than $100,000 of COVID testing revenues.- On a sequential basis, our Q3 revenue outlook is influenced by the international order trends in our diagnostic business that Carrie described as well as the timing of orders from the Together Take Me Home program in the U.S.

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 Q3 2024. And as Carrie mentioned, we don’t expect significant revenue from them this year.

We expect our gross margin percentage in Q3 to be consistent with the second quarter. As we previewed last quarter, we have substantially completed the transition from

external contract manufacturing of our Sample Management Solutions products to our internal capabilities in Pennsylvania. This project was completed months ahead of the expected timeline when we initiated the project in early 2024. We expect that our operating efficiencies from the transition to in-house manufacturing will gradually ramp up in the second half of 2025 and gain additional momentum in 2026, which we can optimize further with increasing volume.

Moving to operating expenses. In Q3, 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. As we've discussed today, we delivered Q2 results that were on the higher end of our guidance range across many key metrics despite a challenging external environment where uncertainty remains through 2025.

That said, we are confident that OTI is positioned to return to growth in 2026 as our end segments and customers adapt to the new normal environment and as we continue to focus on providing differentiated solutions that our customers value, like HEMAcollect PROTEIN, as well as exciting new product launches that are on the near-term horizon.

Our work over the last three years to strengthen our foundation including fortifying our balance sheet and instilling an enterprise-wide focus on innovating and operating with disciplined execution and accountability, allows us to make investments in new products that we believe can deliver strong returns beginning in 2026, such as our Colli-Pee urine collection as well as Sherlock low-cost molecular diagnostics.

We are focused on deploying our capital for long-term value creation. And we are confident that OTI has the expertise, capabilities, customer relationships and product roadmap to methodically build a stronger enterprise.

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

QUESTIONS AND ANSWERS

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

Unidentified Participant^ This is [Brendan] on for Patrick. I wanted to start on the 3Q guide. I definitely appreciate the color you guys gave there.

But I was wondering if you can go into the specifics between like the HIV and HCV platforms. And then on the margin line, if you can go into a little bit more color on like how much more additional leverage you guys can get for 2025, moving the manufacturing in-house.

Kenneth McGrath^ Yes. Thank you, Brendan. I'll start with the margins from -- and as we guided to, we guided to Q3 being relatively consistent with Q2. And what we are expecting now and with project of transferring or transitioning our manufacturing in-house from contract manufacturing, we have substantially completed that transition.

And so now we are expecting as -- it also depends on volume, volume dependent. We are expecting the benefits of that transition to start in the second half and then ramp up in 2026.

Carrie Eglinton Manner^ And then the second part of it is around Q3 revenue. So Brendan, while we don't provide sort of segment guidance, what we would say is we would call out what we called out in our prepared remarks, which was the Together Take Me Home change of expectation where we would typically expect a run rate more in the $2 million a quarter range where what we have in the plan is $0.5 million.

We do have and -- the potential for that program to continue. The current appropriations bill that will be voted on in the house has bipartisan support that includes that HIV moving forward. But I don't think that changes the expectations around Q3.

Q3 really is at the volumes we've talked about, we think that's kind of the line of sight we have, and there is uncertainty beyond that. But we think with real potential for that program to continue, funding hasn't been shared, but it's definitely a real potential.

Kenneth McGrath^ And then related, I think you were asking about HIV and HCV. For HCV, we expect that to be relatively stable on a quarter-over-quarter basis.

For HIV, for international, we do expect a slower pace of the orders in Q3 as -- and we talked about a little bit of the dynamics in the past calls around some of the disruption from USAID funding, where the disruption was really in the infrastructure portion.

And where we saw was that countries were building up inventory, and now they're working through that as they work through and build up that infrastructure again, they're working through the existing inventories. So we do expect a slower pace in Q3 in the second half of the year to kind of bleed through that event.

Carrie Eglinton Manner^ So it's part of international, it's part U.S., and that's really a big driver of that quarter-over-quarter change.

Unidentified Participant^ Got it. And then also, I just wanted to touch on the blood proteomics, definitely understand that it's early in kind of the launch, but what's kind of the initial traction been like or feedback from customers been? And then if you could kind of remind us on what -- are there any specific areas you guys are kind of targeting and what the potential opportunity looks like there?

Carrie Eglinton Manner^ Yes. Thanks, Brendan. We've had enthusiastic customer engagement around the launch of HEMAcollect PROTEIN.

As a stabilization device, we think it's uniquely positioned to help researchers in the operational efficiency and workflow with stabilizing proteins for up to seven days at room temperature and really high-quality analysis potential on multiple types of technologies including next-gen proteomics technologies.

So this is an emerging space. There are a lot of platform providers making headway in this space as well. And I think the opportunity here with an RUO launch and research is really to be a part of that exploration.

We've called out clinical opportunities that range from oncology, neurology, cardiology, cardiometabolic disorders. And I think there's -- the applications are broad because proteomics is so broadly applicable in clinical disease growth and opportunities.

So -- and we think momentum, we've talked about gaining momentum with that product launch into '26, but I think off to a really good start.

Operator^ Our next question comes from Andrew Cooper with Raymond James.

Noah Lewis^ This is Noah on for Andrew. First question for me. Kind of going back to the gross margin, thing that Brendan was asking about.

In the quarter, you brought things back from Canada or moved things from the external contract manufacturing back into Bethlehem. Was there any impact to -- I think you called out packaging improvements, maybe some technological improvements.

I don't think you mentioned any volume, but just trying to get some of the moving pieces there because you came in a little above our number this quarter. Was it purely the manufacturing? Or was there a little bit more at play there?

Kenneth McGrath^ It was a combination of some of the manufacturing. So the improvements that we talked about in prior quarters around packaging, around internalization of reagents and areas there, a lot of that is volume dependent. And as we ramp up volume, we take advantage of those benefits.

But as far as -- and those are more long-term opportunities as -- again, as the volume ramps up. In this particular quarter, again, like you said, mostly driven by the improvements from manufacturing. We did have a little bit lower scrap in this quarter in Q2 than prior quarters. But you got it -- you nailed it on the head there.

Noah Lewis^ Okay. Awesome. And then Diagnostics came in a little bit better as well versus our numbers. And I know you called out some of the international growth despite the headwinds. I'm just kind of curious, like what are you seeing in the clinical setting? I think you called out in 1Q.

So how is that trajectory gone? And then also, I would just want to know if there's been any like pull forward from tariffs on that end that might be causing a little bit of the strength.

Kenneth McGrath^ Yes. From Diagnostics, part of it was, Carrie mentioned, Together Take Me Home and some of the timing of the patterns there. And what we are expecting in Q3 is a little bit of a slowdown there for Together Take Me Home.

So Q2 saw some of the benefit of pulling ahead there. From international, and we've talked about this in the past there, it's a little bit the timing of some of these big orders. And we did see timing -- positive timing in Q2.

We are expecting a little bit of a slowdown in Q3 and the second half. And as we described earlier with Brendan, part of that is just where the countries -- with the disruption, the countries have built up some inventory within -- particularly in Africa, and they are now bleeding out that inventory. So we're seeing a little bit of a slowdown in the second half and then expect somewhat return going forward.

Carrie Eglinton Manner^ And the only thing I'd add, Ken hit it right on, but the only thing I'd add is that we are intentionally expanding across customer types in domestic diagnostics as well to hit more of the clinical health care settings, emergency rooms, clinics and beyond to try and offset some of the challenges in public health, quite frankly, programs, both in the U.S. and international as well as bringing the Syphilis offering in, which is our -- in partnership with Diagnostics Direct with Syphilis Health Check and selling that side-by-side with HIV and HCV.

So there's some momentum, but I'd say those are really the offsets to what have remained kind of this mixed domestic public health and international public health.

Operator^ That concludes today's question and answer session. I'd like to turn the call back to Carrie Eglinton Manner for closing remarks.

Carrie Eglinton Manner^ Thanks, Liz. We just want to thank everyone for participating in today's call and for your continued interest in OTI. And with that, we'll close out. Thank you.

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