OraSure Technologies Inc.2026 First Quarter Earnings Conference Call
May 6, 2026

Corporate Speakers

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

Participants

- Unidentified Participant; Unknown; Unknown
- Mac Etoch; Stephens; Analyst

PRESENTATION

Operator^ Good day. And thank you for standing by. Welcome to the OraSure Technologies, Inc. 2026 First Quarter Earnings Conference Call. (Operator Instructions) Be advised that today's conference call is being recorded. I would now like to hand the conference over to your first speaker today, Jason Plagman, Vice President of Investor Relations. Please go ahead.

Jason Plagman^ Good afternoon. And welcome to OraSure Technologies' first 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 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. OTI undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call. With that, I'm pleased to turn the call over to Carrie.

Carrie Eglinton Manner^ Thanks, Jason. And thank you to everyone for joining us today. Today I'll discuss some highlights from Q1 and provide updates on our key priorities for 2026. Overall, we continue to advance our strategic transformation and execute with discipline as we focus on driving growth in 2026 and beyond.

We have delivered meaningful progress over the last few years and continue strengthening our foundation including leveraging our manufacturing capabilities and capacity to drive gross margin expansion while also streamlining our cost structure. We're also elevating our core growth by expanding and diversifying our product portfolio and customer relationships while several of our key end markets adapt to an evolving funding environment.

Ultimately, we're accelerating profitable growth through investments in R&D, targeting high-value growth markets, as well as acquisitions and partnerships that leverage our existing capabilities and provide an attractive risk-adjusted ROI.

We're also preparing for several near-term catalysts for growth including our two product launches planned for mid-year. One, our rapid molecular self-test for chlamydia and gonorrhoeae, also known as CT/NG. And two, our Colli-Pee at-home urine collection device for sexually transmitted infections, or STIs.

Looking at our Q1 results, total revenue was $27.9 million which was above the midpoint of our guidance range, and we generated solid gross margin expansion.

In our International Diagnostics business, we made significant progress on our initiatives to establish closer relationships with some of our distribution partners in Africa and their in-country value-added assembly and manufacturing, also known as near-shoring. During Q1, we delivered on initial orders to one of our near-shoring partners. We anticipate initial orders from other partners in the second half of the year, and we believe this trend represents a significant opportunity in rebuilding momentum in health program implementation in countries around the globe.

Additionally, our international team is building positive momentum with the integration of BioMedomics into our sales channels and in expanding the reach of SickleSCAN into new markets through our relationships with national health programs.

In our U.S. Diagnostics business, our public health customers are stabilizing as they adapt to the current budget environment. In general, HIV testing programs remain a key priority for state and local public health agencies to control the spread of the virus and to manage downstream costs in the healthcare system. We are also seeing traction in demand resulting from our syndemic approach that leverages our portfolio of rapid tests across multiple conditions including HIV, HCV, and syphilis to deliver value and ease of use for customers.

Switching gears to Sample Management solutions. We are seeing gradual improvement with commercial customers including advanced genetic testing labs, driven by increasing utilization of precision medicine that leverages genetic insights to identify risk factors for cancer and other conditions as well as diagnosis of rare diseases. During Q1, growth in commercial segments was offset by muted demand in academic and government markets related to the continued slow pace of NIH research grant funding. That said, we remain confident that the Sample Management business is positioned to deliver growth in 2026 and beyond as genomic end segments gradually return to stronger growth.

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. From a regulatory standpoint, our two applications for FDA clearances are in the review process. We continue to anticipate midyear clearances and expect that revenue from product launches will ramp in the second half of the year.

As a reminder, our two submissions were for our over-the-counter rapid self-test for CT/NG that is built on the Sherlock molecular diagnostics platform, and our Colli-Pee device for STIs. The Colli-Pee submission which includes its proprietary stabilization chemistry, covers

multiple STI indications, and is being pursued in collaboration with a leading diagnostics platform provider.

These two submissions with their potential clearances, reflect our 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 first quarter was $27.9 million and grew 4% on a sequential basis. Diagnostic products generated $16.9 million of revenue in Q1 with a fairly even split between U.S. and international revenue. Diagnostics revenue grew 12% on a sequential basis. Sample Management Solutions revenue in Q1 was $9.1 million which was basically flat on a sequential basis.

Our GAAP gross margin in the first quarter was 42.3%, compared to 41.1% in Q1 2025. And non-GAAP gross margin in Q1 increased to 43.4%, compared to 41.7% in Q1 2025. Gross margin expansion was driven by operating efficiencies, largely related to our initiatives to in-source production from third-party contract manufacturers into our Pennsylvania facilities. This transition leverages our advanced manufacturing capabilities and capacity developed during the COVID pandemic.

Looking at GAAP operating expenses in Q1, R&D expense was $13.7 million, sales and marketing expense was $6.8 million, and general and administrative expense was $14.6 million. The increase in R&D was primarily driven by investments in activities related to launch preparation and production readiness for our CT/NG test and our Colli-Pee device, including studies gathering data that we believe will position us for successful commercial go-to-market launch. We expect our R&D expense to taper down during Q2 and Q3.

Looking at G&A expense, the sequential increase in Q1 was primarily driven by nonrecurring items including severance expense related to a reduction in force in February, professional services related to our proxy, and the annual reset of accruals for performance-based incentive compensation programs. We expect G&A expense to decline to more normalized levels beginning in Q3 following the conclusion of the nonrecurring items I mentioned.

Noncash stock compensation expense in the first quarter was $2.8 million, and depreciation and amortization expense was $2.3 million. Our GAAP operating loss in Q1 was $23.3 million, and our non-GAAP operating loss was $19 million.

Moving to our balance sheet. We ended the quarter with zero debt and total cash and cash equivalents of $177 million. During the first quarter, we deployed $5 million to repurchase 1.8 million shares of our common stock. Over the last four quarters, we have returned $20 million of capital to shareholders through the repurchase of 7.1 million shares.

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 first quarter was negative $14 million which was consistent with our expectations. As we discussed in February, we expect to return to breakeven from an operating cash flow standpoint as we enter 2027. This view is supported by our outlook for

revenue growth including contributions from our anticipated product launches, as well as our continued focus on delivering cost savings and operating efficiencies.

Moving to guidance. We expect revenue in the second quarter of $27 million to $30 million which includes a negligible amount of revenue for COVID-19 testing. We expect our gross margin in Q2 to be similar to Q1. We anticipate our operating expense will be in the high $20 million range in Q2 which includes non-run rate expenses and excludes stock compensation. Then we expect operating expenses to decline further to the mid-$20 million in Q3 as non-run rate expenses wind down.

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

Carrie Eglinton Manner^ Thanks, Ken. As we move through 2026, OraSure is positioned to accelerate our growth as we approach a series of regulatory and commercial milestones, and we continue to transform our business as we deliver on our strategy to decentralize diagnostics.

We are excited about all of our opportunities, near-term and long-term, to expand our portfolio with our innovative product pipeline and our ability to leverage our manufacturing capabilities and capacity as we work to create value for our customers and all shareholders.

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

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from the line of Patrick Donnelly from Citi. Your line is now open.

Unidentified Participant^ This is Brendan on for Patrick thank you so much for taking our questions and congrats on the quarter. I want to start on the near-shoring initiatives. It's great to see orders kind of start to come through there. I was wondering if you'd be able to size those and down the line as more are added, what those could potentially turn into from a revenue standpoint? And then also along those lines, can you talk about what the pipeline kind of looks like to add more sites to that program?

Kenneth McGrath^ Sure. Thanks, Brendan. So as far as near-shoring, we're really excited about the opportunity. And just for background, this is something that we've been working with these countries for several years to put in place. We did -- we said it was significant.

We haven't given an exact number as far as dollars, but you can imagine in the millions is significant for us. And not all will be -- all relationships will be in that range, but we are seeing good progress as we continue to advance conversations and initiate near-shoring opportunities with other countries as well.

Unidentified Participant^ Thank you. And then to touch on the margins, we view that -- it's great to see the first quarter kind of come in ahead of expectations. Should we kind of view this as a new baseline for gross margins? And is there more internal like in-sourcing initiatives that you guys are planning on implementing to kind of further that margin expansion? Thank you.

Kenneth McGrath^ Yes. And yes, so what we said is Q2 will be similar to Q1. What we're seeing as far as tailwinds for improving our margins is our operating efficiency which you may

recall we've talked about in the past where we consolidated our manufacturing into some core operation facilities.

As we take advantage of that operating efficiency overall on our improved absorption, and in addition, as we increase our volumes, we will continue to see improvements in our gross margin. That could be offset, obviously time to time by mix and other dynamics that play out within our margins. But we're encouraged by the strong tailwinds that we have.

Unidentified Participant^ Got it. Thank you so much.

Operator^ Thanks Brendan. One moment for our next question. The next question comes from the line of Mac Etoch from Stephens. Mac, the line is now open.

Mac Etoch^ Hey good afternoon and thank you for view on the outlook for the CT/NG test. As you approach the launch of these products, I assume the commercial teams are already advancing discussions around the agreements and partnerships. So what progress have you made on that front so far? And how should we think about the early commercialization traction there?

Carrie Eglinton Manner^ Hi, Mac. You're right in that, when you have the product launch expectation, everybody starts gearing up. There is an important distinction to be made, of course, as you well know in FDA, with FDA-cleared products, unlike research use only, you really can't premarket. We do, of course, well understand market interest and opportunity in infectious disease, in STIs, in sample collection, and urine collection because we have such strong portfolios there today. So we've done good market research. We stay very connected to these customers.

We're thinking about the kinds of conversations you can have ahead of time which is really about how the whole test-to-treat system would work upon clearance. And so I'd say, it's those dialogues that are all within bounds that really give a sense for the enthusiasm and interest to make STI testing, private, convenient, affordable, accessible, and that make urine self-collection something that can be done outside of a doctor's office. So yes, I kind of frame it that way. But with the FDA process, we're also very smart and compliant around not premarketing.

Mac Etoch^ Fair enough. Thanks I appreciate the colors there. And then maybe following up on the margin question. I appreciate the color that you gave, Ken. But just thinking about the launch of some of these products that you have in the pipeline, should we expect any maybe near-term volatility or decremental margins just as we think about near-term margin progression?

Kenneth McGrath^ Yes. I'll tell you what we said in the past, and then -- and will be answering your question as I go through that. So what we've said for CT/NG is in the fullness of time it will be accretive to our overall margins. But to your point, there's a ramp-up of that. When your volumes start out lower, you don't have as large -- as good margins. So we will experience some of that as we ramp up. For our Colli-Pee device, similar, we expect margins in the fullness of time to be equal or accretive to our overall current margins, but there is that ramp-up time that takes place, to your point, as we ramp up the volumes and kind of get that full absorption over time.

Mac Etoch^ Appreciate the color there. Thanks for taking the questions.

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

Carrie Eglinton Manner^ Thanks, Tyler, and just thank you to everyone for joining us. We hope you have a great day. And with that, we'll close the call. Thanks.

Operator^ Thank you for your participation in today's conference. This does conclude the program. You may now disconnect.