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Q2 2024 ORASURE TECHNOLOGIES INC EARNINGS CALL

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CORPORATE PARTICIPANTS

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- Kenneth Mcgrath OraSure Technologies Inc Chief Financial Officer

CONFERENCE CALL PARTICIPANTS

- Operator
- · Casey Woodring JPMorgan Analyst
- Andrew Cooper Raymond James & Associates Analyst

PRESENTATION

Operator

Good day and thank you for standing by. Welcome to the OraSure Technologies Incorporated 2024 second-quarter earnings conference call. (Operator Instructions) Once again, please be advised, today's conference is being recorded.

I would now like to hand the conference call over to your first speaker today, Jason Plagman, you have Investor Relations.

Jason Plagman OraSure Technologies Inc - Vice President, Investor Relations

Good afternoon, and welcome to OraSure Technologies' second-quarter 2024 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, in the annual report on Form 10-K for the year ended December 31, 2023, 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.

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

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Thanks, Jason, and thank you to everyone for joining us today. We are pleased to provide an update on the progress OraSure's making on three pillars of our strategic transformation: strengthening our foundation; elevating our core growth; and accelerating



profitable growth.

A few notable highlights during the second quarter include that we delivered Q2 revenue that was near the top of our guidance ranges for both core revenue and for COVID-19 products where we successfully fulfilled the remaining portion of our largest contract with the federal government.

In product extensions, we earned the World Health Organization's pre-qualification for our OraQuick HCV self-test, representing the first hepatitis C self-test to achieve this designation. OraSure is proud to add the WHO PQ milestone to our legacy of firsts in the diagnostics industry, and we look forward to working with the global health community to expand market access and bring this test to populations in need.

We launched new FDA-cleared packaging and labeling for our OraQuick HIV self-test, which is expected to increase shipping efficiencies and reduced shelf space and plastic usage.

(technical difficulty)

Sorry about that. The new labeling also removes the contraindication for users on PrEP, potentially expanding access for a population that is recommended to test four times per year. We are seeing positive momentum with Syphilis Health Check following our launch of this key sexual health portfolio product.

At the end of Q1, we broadened relationships with several leading oncology companies to expand or collect Dx collection devices into saliva-based liquid biopsy. We expanded our agreement to become a supplier of saliva collection devices for Exact Sciences. Our ORAcollect Dx saliva collection device will be utilized in Exact's hereditary cancer and therapy selection tests. And with our healthy balance sheet, we continue investing in our innovation roadmap and opportunities to leverage our existing strengths in order to position OTI for sustainable profitable growth.

Starting with operating efficiency, we continued to strengthen our foundation and drive operational improvements. As we discussed in May, we launched several new initiatives to further rebalance our cost structure, consolidate our footprints to leverage our centers of excellence, and focus on our core strengths. We made significant progress on each of these programs during the last three months, and Ken will provide additional details in a few minutes.

Overall, these important steps, as well as our enterprise-wide focus on continuous improvement, give us confidence in achieving our target to breakeven in operating cash flow from our core business by the end of 2024. Our work in the past two years has both allowed OTI to deliver a strong return on the COVID-19 opportunity, and it's well positioned us for the future.

Moving to InteliSwab, we had shared that we would fulfill the remaining portion of our largest contract with the US government during Q2, and we did that, closing strong with \$19 million of revenue in the guarter.

Moving forward, it's all about our core business. Q2 core revenue of \$35.4 million was near the top of our guidance range. Performance in both diagnostics and sample management solutions was consistent with the outlook embedded in our guidance.

Within our diagnostics portfolio, we are seeing good momentum with Syphilis Health Check following our launch of Diagnostics Direct product at the end of Q1 and we are receiving strong interest from both existing and new customers.

And more broadly, we are having success with multiproduct sales across our portfolio of HIV, HCV, and syphilis tests as health care providers and public health organizations, such as the National Coalition of STD Directors, recognize the need for a syndemic approach to rapid testing, given the significant overlap in patients at risk for these infections.

Additionally, organizations such as the CDC and SAMHSA have already started to ease restrictions on existing funding streams to increase pandemic testing programs rather than focusing solely on HIV-related purchasing. This evolution is well aligned with our infectious disease product portfolio and our sexual health strategy aimed at expanding our menu of diagnostic tests serving more people.

In HIV, during Q2, we received FDA clearance for a new packaging configuration with updated labeling for our OraQuick HIV self-test, which is expected to increase shipping efficiencies, conserve shelf space, and reduce plastic waste.

In addition to sustainability improvements, our product is also now labeled with appropriate warnings for use in individuals on PrEP instead of the original contraindication, a change which has potential to open up a new segment for our offerings as individuals on PrEP are recommended to test for HIV multiple times a year.

We have received very positive feedback from our customers, including public health organizations as well as retailers regarding the potential benefits of the product extension for our leading HIV self-test.



In another example of product extension innovation in our sexual health portfolio, we are proud to share that in July, we earned the first pre-qualification for any hepatitis C self-test from the World Health Organization. We are excited to bring our OraQuick HCV self -test to the global health community while adding its important WHO PQ designation to OTI's legacy of firsts in the diagnostic industry.

We are confident in our hepatitis C self-test potential to expand service for populations in need, including the 50 million people living with HCV and the 1 million individuals who acquire HCV each year, and to help stem that spread. This opportunity is closely aligned with our strengths in delivering high-quality, affordable tests to enable access for more people at scale.

Furthermore, we believe our HIV and HCV product extension launches are great examples of OTI's leadership in not just developing rapid diagnostic tests but also in the innovation that enables ongoing market expansion opportunities over a product's life cycle. I'll share a few more examples of product extension innovation and its potential to fuel market expansion after I finish summarizing Q2.

Shifting to sample management solutions, we are currently seeing stabilization and early signs of a still gradual recovery in the market environments as genetic testing and research segments adapt to the post-COVID environment and an evolving regulatory environment for diagnostic labs.

Additionally, we are seeing increasing interest in our sample collection devices from customers in emerging growth segments like liquid biopsy, animal health, and others. Overall, we remain confident in our strengths leading the market and as the only 510(k)-cleared collection and stabilization devices in several categories.

We are also pleased to announce progress in broadening our relationships with several leading oncology company. We have signed an agreement to become a supplier of saliva collection devices for Exact Sciences, a company dedicated to helping eradicate cancer through prevention, early detection, and personalized treatments. Our ORAcollect Dx saliva collection device will be utilized in Exact Sciences' hereditary cancer and therapy selection tests.

We believe these two tests offer important advancements in precision oncology by providing actionable insights that empower patients and doctors to make informed decisions about treatment options. As the field of precision oncology continues to expand, we are committed to strengthening our partnerships and supporting the advancement of this promising frontier in cancer detection and care.

We are also proud to share that we have expanded our relationship with Variantyx, a commercial laboratory specializing in genetic testing for rare genetic disorders, reproductive health, and precision oncology. We believe their whole genome platform stands out for its high resolution detection and characterization of all clinically relevant variant types, providing a comprehensive report from a single sample. Notably, our Oragene Dx and ORAcollect Dx saliva collection kits play a crucial role in Variantyx's suite of more than 30 tests, advancing genetic science and precision medicine through patient-centric solutions that offer easy, accessible, and efficient saliva sample collection.

It is our goal to power sample collection and management for every molecular diagnostics innovator, to contribute to progress in precision medicine, and to help provide actionable insights to guide critical treatment decisions for physicians, patients, and families.

We continue to highlight that the strengthening of our balance sheet in the last two years is allowing us to invest in innovation for our next phase of accelerated growth. These investments range in innovation from new products and technologies to market-expanding product extensions. The vitality of our product lifecycle is key to our near and long-term growth strategy.

Product extensions include areas of innovation like those I just shared in achieving the first WHO pre-qualification of our HCV self-test for global markets and clearing with the FDA our HIV packaging improvements and labeling update.

Another example is our recently submitted request to the FDA to expand the range on our HIV self-test to include adolescents. Today, our HIV self-test is labeled for use by patients 17 or older. And working with our partners, we identified a critical public health risk for youth, which translates to an important opportunity to expand access to HIV testing for a broader segment of vulnerable populations, in this case, extending to include 6.4 million sexually active 13 to 16 year-olds in the US each year.

In our sample management business, we have additional areas of expansion such as in the applications for saliva-based liquid biopsy. As noted, we have several customers using our current cleared devices for work in oncology and are poised to expand our commercial footprint as these markets gain momentum.

Also in sample management, we continue to make innovation progress on our Colli-Pee self-collected urine device. Building on our existing EU clearances, the potential for Colli-Pee leverages clinical studies, which are required for regulatory clearance and translate those into adoption for future clinical practice.



We've previously talked about on our Colli-Pee studies in Europe, which show that people prefer self-collected urine versus swab, whether self-collected swab or physician-collected-swap. For STI reason -- sorry, for STI testing, there are four main reasons for this: it's private; it's painless; it's simple to use; and it's convenient to perform at home.

And beyond preference for the device enabling self-collected urine, another key aspect of Colli-Pee innovation is stabilizing and preserving the sample. On this front, we recently filed for a new patent for proprietary chemistry to preserve both DNA and RNA and STI applications, which marries urine collection with ambient preservation capability.

We've demonstrated success with this strategy in saliva and Colli-Pee intends to do the same in urine. Regulated healthcare innovation is a multiyear process, and these examples demonstrate why it's worth. Colli-Pee has the potential to expand meaningful market opportunities in large and growing clinical segments such as STI. We plan to submit to the FDA for Colli-Pee's STI application before the end of 2025.

Before I conclude, I also want to discuss the strength of our assets and capabilities and highlight some of the elements that give us confidence in our ability to leverage them to drive sustainable, profitable growth. First, OTI has high quality, differentiated products that are recognized as category leaders.

Our investments in innovation, both new and product extensions have allowed us to maintain our leadership in our core product lines and positioned us to further expand our product portfolio, with additional tests for more people in diagnostics and additional sample types, analytes, and applications in sample management.

The strength of our products and our experienced sales team has allowed us to build long-term, durable relationships with our customers, plus our multiyear investments in our quality and regulatory programs have further enhanced our internal expertise and our external credibility around the globe. These capabilities allow us to successfully navigate increasingly complex and rigorous regulatory review and approval processes and to reliably partner with clients subject to the same stringent requirements.

Our balance sheet is strong and our collaboration with the government during the pandemic has allowed us to significantly expand our automation capabilities and capacity across multiple product lines.

Finally, our focus on instilling an enterprise-wide focus on continuous improvement has provided our organization with the tools to drive meaningful operating leverage as our end markets recover and return to growth.

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

Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Thanks, Carrie. I'm happy to discuss our results for the second quarter of 2024 and provide updates on our financial outlook.

In Q2, we delivered total revenue of \$54.3 million. Core revenue, which excludes COVID-19 products, was \$35.4 million in the second quarter. Within core revenue, our diagnostic products generated \$18.7 million of revenue in Q2 and decreased 5% year over year.

Sample management revenue in the second quarter was \$12.6 million and decreased 3% year over year. Total core revenue growth declined 7% on a year-over-year basis in Q2 and was impacted by a 40% decrease in revenues from the Diversigen molecular sequencing services business that we are exiting, as well as the decline in non-product and services revenue.

COVID-19 products, predominantly InteliSwab, contributed \$18.9 million of revenue in the second quarter. As anticipated, we fulfilled the remaining 17 million of our largest contract with the US government during the quarter.

Our GAAP gross margin in the second quarter was 45.4% and non-GAAP gross margin was 47.4%. Gross margin was at the high end of our expectations and was driven by continued progress in our operational efficiency initiatives and our investments in automation.

Our GAAP operating expenses in the quarter were \$27.4 million, which includes \$3.1 million of non-cash stock compensation expense, \$1.1 million for impairment of assets and \$763,000 for reduction in workforce service. Our GAAP operating loss in Q2 was negative \$2.7 million and non-GAAP operating income was \$3.3 million.

As we discussed last quarter, as part of our transformation journey, we initiated several additional actions to rebalance our cost structure, consolidate our operational footprint, and streamline our portfolio of offerings to focus on our strengths. We have made good progress on these three initiatives over the last three months.



For Diversigen, we have been transitioning customers and expect to complete our exit from the sequencing services business by the end of third quarter. In Belgium, we will close our site by the end of 2024 and finish integrating those activities into our teams in the US and Canada.

In our sample management portfolio, we are in-sourcing production of certain sample management products from external contractors into our own manufacturing center of excellence in Bethlehem, Pennsylvania over the next 15 months. As we discussed last quarter, internalizing these activities is expected to improve our operating efficiency and further leverage our existing infrastructure.

In total, we continue to expect the actions that we announced in May will result in more than \$15 million of annual expense reduction following completion, which is an important step in our plan to achieve our target to breakeven in operating cash flow from our core business by the end of 2024. These initiatives are in addition to our ongoing, enterprise-wide focus on operational efficiency and continuous improvement.

Moving to our balance sheet, we ended the second quarter with zero debt and total cash, cash equivalents, and short-term investments of \$267 million. During the quarter, we generated \$7.8 million of operating cash flow and we invested \$1.6 million for CapEx.

Turning to revenue guidance, we are guiding to third-quarter total revenue of \$37 million to \$41 million, which includes core revenue of \$36 million to \$39 million and InteliSwab revenue of \$1 million to \$2 million. Our Q3 guidance does not include any revenue from the Diversigen molecular services business that we are exiting. Within our Q3 revenue outlook, we expect international diagnostics will drive most of the sequential increase in revenue from Q2 to Q3.

Looking at the fourth quarter, we expect core revenue will moderate compared to our Q3 outlook, which is consistent with the seasonal ordering patterns that we have observed in 2022 and 2023.

Moving to gross margin, we expect our gross margin in Q3 to be in the low 40% range, followed by a return to mid-40% range in Q4. Our Q3 gross margin outlook is impacted by two short term factors. First, the expected increase in international diagnostic revenue in Q3 that I mentioned earlier, which carries gross margins that are lower than our blended corporate average. And second, wind down costs associated with our exit from the Diversigen molecular sequencing services business that we expect to fully exit by the end of Q3.

From a long-term perspective, we continue to believe we can drive additional gross margin expansion and operating leverage by delivering efficiencies across our enterprise, including consolidating operations into our centers of excellence and further leveraging our automation capabilities.

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

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Thanks, Ken. As we detailed today, we continued to make solid progress on our strategic transformation. This quarter, we generated positive operating cash flow and we continue to streamline our operations and unlock efficiency gains.

In our core business, we are seeing positive momentum with the launch of Syphilis, along with product extensions and enhancements that expand access to our products and address the needs of patients and our customers. And we continue to strengthen our existing customer relationships while adding new customers.

Overall, we are confident that OTI is well positioned to leverage the strength of our differentiated assets and organizational capabilities to drive sustainable, profitable, long-term growth as key segments further recover in 2025 and beyond.

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

QUESTIONS AND ANSWERS

Operator



(Operator Instructions) Jacob Johnson, Stephens, Inc.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Hey, Jacob.

Unidentified Analyst

Good afternoon. It's Mac on for Jacob today.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director Oh, hey, Mac.

Unidentified Analyst

Yeah. Hi. How are you doing? I appreciate the color around the margin progression in 3Q. I think you cited low 40% given the efforts there. But I was curious how that should progress in 4Q and maybe into 2025 as we start to roll off some of these -- in these different costs there feeding into this the P&L at the moment.

Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Yeah. Thanks, Mac. I appreciate the question. Yeah. So just to reiterate our drivers for Q2 to Q3 for margins, the first is that we expect to have a higher percentage of international revenue. And as you know, that carries with it a little bit below our average of our gross margin, has a negative draw on mid-margins.

Also, we're still going to remain having Diversigen expenses in Q3. So that's far as we progress to Q4, we expect to get a benefit from the overall mix, the mix between international and domestic. We'll be eliminating those Divsersigen expenses. So that will help us in Q4.

In addition, we're continuing our operational efficiencies. We've -- I think we said last quarter about our version 2 packaging improvements, our footprint consolidations, how we're continuing to progress in those areas, which drive overall efficiencies.

Unidentified Analyst

Appreciate the color there. And just in light of the improvements in the overall backdrop and funding of some of your end markets, I think you called out sample management as a one that's gradually recovering. But can you highlight any particular areas of strength and weakness that you are currently seeing?

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Yeah, Mac. In sample management, we are seeing that strong volume of new customer entities. And what we've talked about in prior quarters is that offset of some of our largest customers while we add high volume of new customers, new applications, new customers, new segments is part of the reason that we've highlighted liquid biopsy applications, animal health applications, and we continue to share that strength in those green shoots of the volume of those customers.

What we're really looking for is for their growth to, yeah, that trajectory to change. And with that, we believe we're very well positioned to grow with them. We don't think we're losing share. We actually think we remain really strong adding net customers, and that it's about that market turn, a matter of when and not if it, is what we believe. And yeah, lots of segments, many customers and really just well-positioned to grow as they grow.



Unidentified Analyst

Appreciate the color. Thank you for taking my questions.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Thanks, Mac.

Operator

Patrick Donnelly, Citi.

Unidentified Participant

Hi. You have Brendan on for Patrick. To start off, it was good to see a nice sequential step up within diagnostics segment. Can you walk through some of the moving pieces within that and different trends that you may have seen? Were there any tests that are really driving our growth in revenue there?

Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Yeah. We saw some several areas of improvement quarter over quarter. We saw HCV increase with some of our contracts with the Department of Health in several states. In addition, as we mentioned last year, we -- or last quarter, we launched our syphilis test, which we are starting to see growth there. So those are two of the areas. And then internationally, we saw growth in HIV.

Unidentified Participant

Got it. Thank you for the color on that. And actually on the HCV, it was pretty clear about the WHO pre- qualification there, can you talk about like the opportunity that presents for the company, both in the near term and long term?

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Yeah. We love to be a leader in WHO PQ. And for those who know the global market, that's really about future procurement for by UN agencies and it is the key designation that really can open up -- help open up donor funding.

I would describe that as quite a lengthy process, can definitely take many months. We never conjecture on the timing, but just to give a range, that can be 12 months, 24 months onward. But WHO PQ is a really important qualification to be on the list that open up donor funding. So terrific news on the potential market access expansion.

We're not sizing it right now other than to point out, it's 50 million individuals living with HCV around the globe. It's 1 million individuals who acquire it each year. There is more funding for treatments being available. That's actually one of the drivers internationally. And Ken mentioned our HCV strength in Q2.

And with that increase in funding comes a desire for more diagnostic testing.

So timing, TBD, but I think, obviously, great news to become the first HCV self-test with the designation and it opens up some global market expansion possibilities.

Unidentified Participant

Great. Thanks again for the color and congrats again on the quarter.



Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director Great. Thanks, Brendan.

Operator

Casey Woodring, JPMorgan.

Casey Woodring JPMorgan - Analyst

Great. Thanks for fitting me in. So I just had a question.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director Hi, Casey.

Casey Woodring JPMorgan - Analyst

Hi. Can you just elaborate on the international revenue step-up in the back half that you called out? Where is that coming from? What sort of visibility do you have? And just any more color on what your expectations are there internationally?

Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Yeah, we have -- internationally, we were continuing to have another strong year just like we did last year. Part of it is timing that happens within internationally, where the orders are fairly large relative to other books of business. And so some of it happens with timing.

And what we are expecting to see in Q3 is a step-up relative to Q2 orders and Q4 orders. But really, it's about the offerings that we have. Our HIV testing, our oral fluid testing is really -- is preferred versus other blood testing.

In addition, we have good relationships with a lot of our public health distributors. And so those are driving the preference for our products internationally. But the Q3 step-up is really driven by timing of orders. But, overall, we're seeing another strong full year in 2024 versus in addition just like we did in 2023.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

And that's exactly right and we said it in the scripted comments, but it is similar to 2023 and 2022, in terms of that seasonality. So strong year in total; Q3, particularly strong.

Casey Woodring JPMorgan - Analyst

Okay. Got it. That's helpful. And then, maybe just one follow-up, apologize if I missed in the script, joined late. But what are you guys expecting in terms of revenue contribution from Syphilis in 3Q? And then I guess just generally how are you seeing that test ramp over time? Thank you.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director



Yeah. Thanks, Casey. Well, we aren't calling out the segment yet for Syphilis. What we're highlighting is a really strong launch. We launched that product in Q1. We have strong syndemic testing trends, which is the HIV, HCV, syphilis testing and the overlap in the vulnerable populations for that.

So our public health partners and in the private markets as well, have really been asking for that syphilis test to able to bring that first FDA-cleared -- CLIA waived test to market has just been a great opportunity. So we'll continue to share more, but it's an important part of our diagnostics portfolio and really goes hand-in-hand with those HIV and HCV test.

Thanks, Casey.

Operator

(Operator Instructions) Andrew Cooper, Raymond James. Your line is now open.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director Hi, Andrew.

Andrew Cooper Raymond James & Associates - Analyst

Hi, Thanks for the questions. Maybe just first, thinking about new products. I think back to I think it was the Sapphiros deal you talked about adding 2 points of growth in '25. Can you just give an update on that as we think about both those products and what the progress is and then what things like Syphilis, et cetera, maybe are doing relative to your prior expectations and how you think about that beyond 2024?

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Yes. It's great to talk about our partnership in Sapphiros as well as new products. You've got a couple of things layered, and I'll start with the start of your question, which was Sapphiros. Partnership is off to a very good start.

Our teams are collaborating, and we have co-development opportunities across multiple product portfolios, both in diagnostics and sample management. As we shared when we talked about the strategic partnership, we are not expecting a meaningful revenue contribution, just as a reminder, in 2024. As you referenced, we did call out growth in 2025. We still expect that modest contribution to growth from Sapphiros next year.

We will describe more about the technology road map. What we have shared so far is, the first product we expect is in sample management and aligned with our strategy to add more sample types. The first product is for small volume, self-collected blood and that's the Satio product line, we -- I should say Satio small volume, self-collected blood.

In '25, we are expecting to also be adding diagnostic testing progress and we'll talk more about that as we get closer. So on track. We are still expecting the contribution in '25, did not expect a '24 impact. And I think just excitement around the partnership, and we've gotten off to a good launch with them. Was there another part of your question, Andrew?

Andrew Cooper Raymond James & Associates - Analyst

No, that was the bulk of it. Maybe just to shift gears and then with a follow-up. Back to gross margin timing, I mean, you've got revenue stepping up, but gross margin is kind of stepping down and doing the opposite. I know the O-US piece weighs, but can you size how much of that headwind is Diversigen?

Just because we end up with the second half, that looks like it'll be a little bit lower than at least what you just did in the second quarter. And I would think that international timing is really something that washes out over the course of a broader year. So just would love a little bit more color on what normal is, at least now that InteliSwab is at a new normal.



Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Yeah. It's a great question. Thank you. Yeah, just to reiterate what we said just for context. So, international is driving most of it. Typically, our international is about 20% to 25% of our core revenue, our total core revenue. In Q3, we expect it to be at a higher range than that getting up into the mid-30s range of total core revenue. So it is a significant contributor in that sense.

As far as Diversigen, we do have some remaining expenses, which will contribute probably 100 or so basis points in that range of headwinds to the gross margins. But overall, going forward, once we remove that and continue operating efficiencies, we're expecting Q4 in the mid-40s and then our plan is to get into the 50s long-term. That is our plan, as we progress with our operational efficiencies that we've driven as well as the mix balances out and we see growth in other parts of the business.

Andrew Cooper Raymond James & Associates - Analyst

Okay. Great. I will stop there. Thank you.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Thanks, Andrew.

Operator

Vijay Kumar, Evercore ISI.

Unidentified Participant

This is Kevin on for Vijay. Just a clarifying question on the 3Q margin outlook. You talked about international diagnostics and Diversigen, but was there any contribution from COVID revenues dropping off there? This is one of the first quarters in a while where there's no InteliSwab, so wanted some color there?

Kenneth Mcgrath OraSure Technologies Inc - Chief Financial Officer

Yeah, great question. Yeah, for the impact of InteliSwab, we've known this drop-off several quarters in advance given the timing of the purchase orders. So we've been planning accordingly, and by driving out operational efficiencies, improving automation. So, yeah, it has some impact, but not as much as you'd expect, because we've been planning for the last several quarters now.

Unidentified Participant

Thank you.

Operator

Alright. I am seeing no further questions at this time. I would like to turn the call back over to Carrie for closing remarks.

Carrie Eglinton Manner OraSure Technologies Inc - President, Chief Executive Officer, Director

Thank you, Haley, and thank you for everyone joining. We appreciate your interest in OTI, and we look forward to talking again with you next quarter. With that, we'll close the call.

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Wonderful. Thank you for participating in today's conference. This concludes our program. You may now disconnect.

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