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OraSure Technologies Inc to Discuss Its Strategic Relationship with Sapphiros Call

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PRESENTATION

Operator

Good day, ladies and gentlemen. Thank you for standing by. Welcome to the OraSure Technologies Strategic Partnership and Investment in Sapphiros Conference Call. (Operator Instructions). Please note that today's conference is being recorded. I will now hand the conference over to your speaker host, Jason Plagman, Vice President of Investor Relations. Please go ahead.

Jason Michael Plagman OraSure Technologies, Inc. - VP of IR

Good morning, and welcome to OraSure Technologies call to discuss the strategic relationship we announced this morning with Sapphiros. 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, new product offerings, future collaborations with Sapphiros, 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, including its registration statements, its annual report on Form 10-K for the year ended December 31, 2022, 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 OraSure Technologies, Inc. - President, CEO & Director

Thanks, Jason, and thanks to everyone for joining us. We are delighted to announce our strategic relationship and investment in Sapphiros, a consumer diagnostics company with unique technology platforms to enable low-cost, high-performance, next-generation diagnostics and sample collection devices.

Before I get into the specifics of our partnership, I want to remind you of our journey to get here. Over the last 18 months, OraSure has made significant progress on the 3 pillars of our strategic transformation. First, in strengthening our foundation; second, elevating our core growth; and third, accelerating profitable growth.

As we've discussed previously, 2 strong points demonstrating our transformational progress in the last year include efficiencies we're delivering to exceed our cost savings targets, and more than doubling our cash balance. It is this stronger foundation, enabling us to advance our internal innovation road map and to invest in external partnerships to expand our portfolio of diagnostic tests and sample management solutions. Our strategic relationship and investment in Sapphiros represents another example of progress on our strategy, one which we believe positions us to elevate our core and accelerate our profitable growth.

Starting with a high-level summary of our partnership and investment in Sapphiros, OTI has committed \$30 million to lead their Series B



funding round, which will give us a minority ownership position and a Board seat. As background, Sapphiros was conceived in 2020 by experienced health care executive, Namal Nawana, and launched with global investment firm KKR in 2021, as a next-generation consumer diagnostics portfolio company. Sapphiros is well positioned to address big market opportunities with future point of care and consumer diagnostics, is developing what we believe will be differentiated technologies and low-cost and instrument-free innovation, has been building remarkable manufacturing capabilities and capacity, and has a proven team led by Namal as Executive Chairman and Mark Gladwell as President and CEO.

As part of the relationship, OraSure secures exclusive distribution rights to a broad portfolio of key products in Sapphiros' pipeline that complements our current portfolio and can allow for expansion in new and existing segments. In sample management solutions, it's Sapphiros' novel platform for self-collection of blood in small volumes. In diagnostics, they are developing visual lateral flow tests in areas such as infectious disease and sexual health. Sapphiros is also innovating next-generation diagnostic platforms for digital lateral flow tests and point-of-care molecular diagnostics. Additionally, we see opportunities for co-funding and co-development of other new products as the relationship progresses.

From a strategic alignment perspective, we believe our relationship with Sapphiros significantly accelerates our innovation pipeline and can unlock opportunities for us in sample management solutions by adding a new sample type, blood. In Diagnostics, we believe our partnership will allow us to offer a broader menu of tests and open opportunities with low-cost, highly scalable platforms and manufacturing. Our distribution efforts will leverage our existing capabilities and strengths, including strong client and channel relationships, along with our track record of execution and consistent delivery for customers. Plus at an enterprise level, OTI and Sapphiros share meaningful purpose, addressing unmet needs in diagnostics to improve access, quality and affordability of health care.

From a financial perspective, accelerating our profitable growth is one of the key pillars of our strategic transformation. This partnership advances that priority, and we expect the distribution of Sapphiros products will add at least 2 percentage points to revenue growth in our core business beginning in 2025. As part of our relationship with Sapphiros, OraSure gains exclusive commercial and distribution rights for key product lines in Sapphiros' development pipelines that strengthen our portfolio, such as blood collection and diagnostics. From a launch timing perspective, we expect to begin distribution of the initial self-collected blood product this year, subject to the receipt of regulatory approvals, with additional products across sample management solutions and diagnostic testing expected to enter the market in 2025 and beyond.

From a profitability standpoint, sales of Sapphiros' products are expected to be accretive to OraSure's operating profit beginning in 2026 due to our ability to leverage our existing infrastructure, capabilities and customer relationships. We anticipate a modest amount of incremental SG&A expense in 2024 and 2025 to successfully launch new Sapphiros products into market. Additionally, we believe that our investment in Sapphiros is an efficient method to deploy capital, preserving flexibility for additional organic and inorganic innovation.

In addition to financial benefits, I'd also highlight purpose. We are very excited about our strategic relationship with Sapphiros and the strong fit with our vision and mission. We at OTI are focused on transforming health while connecting people to insights wherever they are. And similarly, Sapphiros aims to empower global communities to act on health insights with confidence. Our purposeful alignment, along with our interactions to date, give us confidence in the strong cultural fit between our organizations.

OraSure and Sapphiros are well aligned with important long-term trends in health care as well. These included the move to point-of-care and home testing, which the COVID-19 pandemic helped accelerate; growth of precision medicine where diagnostics are integral to more personalized insights; and increasing consumerism in health care, empowering individuals to take charge of their health. Alignment around key trends bolsters our confidence in the opportunities for sustainable long-term growth in the segments we serve and in new ones.

In sample management solutions, we've previously discussed our desire to expand our offerings to include additional sample types along with new analytes, applications and clearances. Our partnership with Sapphiros advances on the objective with an expectation to deliver a novel self-collection device for blood that addresses what our customers have been asking for. We are excited for the opportunity to add a user-friendly solution in self-collected blood and expand upon our existing portfolio of saliva, skin, fecal and urine sample management.



Moving over to Diagnostics, Our portfolio today is strong in lateral flow diagnostics. And over the last year, we've discussed our focus on adding more tests to our product portfolio. Our relationship with Sapphiros can significantly accelerate our pipeline of low-cost, easy-to-use diagnostics for self-testing and at the point-of-care. plus its significant potential to access innovative technology platforms that enable future molecular-like performance in lateral flow form factors along with high-performing, low-cost point-of-care molecular systems.

Diving into more details on Sapphiros' technology platform, we believe their innovation across the value chain can deliver low-cost, high-performance solutions at scale. Sapphiros has developed unique capabilities that facilitates automated, high-volume manufacturing that is scalable potentially into the billions of tests per year by leveraging advanced techniques such as printed electronics to produce low-cost diagnostics in an attractive and sustainable form factor.

Sapphiros' areas of focus include sample collection devices and rapid detection systems for visual and digital lateral flow tests. Additionally, Sapphiros is involved in development of next-generation technologies in the areas of biosensor diagnostics and a point-of-care molecular diagnostics platform that could deliver lab comparable diagnostic results at lower cost.

Moving to Slide 10 in case you're following on our deck, Sapphiros' innovation builds upon our OTI strengths. In choosing our strategic partner, we recognize that Sapphiros' platforms and product road map fit well with our OTI strengths and our areas of interest for portfolio expansion over both the near term and longer term. As I've described in sample management, our partnership with Sapphiros will allow us to expand the portfolio of products we are able to offer to our customers to include self-selected blood. In lateral flow diagnostics, Sapphiros' automated, highly scalable production capacity has the potential for us to bring low-cost diagnostics with strong performance and future digital capabilities to our existing customers and to new segments of the global market.

We are also excited about Sapphiros' next-generation technologies in the works, as well as opportunities for collaboration and co-development unlocked by our partnership.

Overall, we are confident in the long-term success of our strategic relationship because Sapphiros' innovation and product pipeline aligns well with our OTI strengths, commercially and otherwise. This partnership expands our development portfolio of low-cost, high-performing diagnostic tests and sample management solutions that we can bring to our customers across multiple end markets and segments, such as infectious diseases, sexual health and respiratory conditions. And Sapphiros' innovative, highly scalable manufacturing capabilities unlock opportunities for us to enter attractive new markets and geographies that were previously challenging to reach, and provides the potential to better serve our existing customers as well.

In summary, we are so pleased to share news with you of our partnership with Sapphiros today and believe it supports several key elements for OraSure's long-term success. First, it expands and diversifies our product portfolio and pipeline in both sample management and diagnostic testing, and it opens opportunities in new segments through scalable low-cost manufacturing. Second, it provides access to future next-generation technology platform that have the potential to deliver molecular-like sensitivity at lower cost and in accessible form factors. We also see opportunities for co-funding and co-development of additional products as the relationship progresses.

Third, there is a strong commercial fit. Sapphiros' products in development complement our core business and can leverage our existing strengths, including in distribution and customer relationships, in addition to allowing us to extend our reach into new segments. Fourth, our investment and partnerships provide multiple paths to potential financial benefits including revenue and profit contribution for our exclusive distribution agreements for a portfolio of key products. and our minority ownership stake allows us to participate in Sapphiros' growth while maintaining flexibility for additional internal and external investments. And finally, we believe in the cultural fit of our strategic partnership, companies aligned in common purpose, focused on improving global health and comprising highly motivated teams with track records of success.

In conclusion, we are very excited about our strategic partnership and investment in Sapphiros and confident in its potential to advance our vision, deliver on our mission and to fundamentally and sustainably create future value together.



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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question is coming from the line of [Alexandra Howard] from Evercore ISI.

Alexandra Howard Evercore ISI

I just had 2 quick ones. The first one is on the pricing of the Sapphiros test and just how that comes in versus your existing portfolio at OTI? And then any opportunities or expectations for taking further a greater financial stake in Sapphiros in the future and kind of what that conversation looks like with their [team]?

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Thanks, Alexandra. Good to kick it off. And what we're sharing on the potential pricing for Sapphiros' test in development is, our expectation will be that they are well lower cost based on these high-volume scalable manufacturing capabilities and other innovation that they are creating. So that's the expectation, significantly lower cost.

The second around financial expectation that was -- yes, future financial expectations. What we're sharing is that we expect in 2025 revenues from Sapphiros distribution to contribute an incremental 2 percentage points to our revenue growth. That's really the extent of what we're sharing at this point. We do anticipate based on regulatory approval first product launch in the self-collected blood. And of course, we'll share more along the way through that process. But those are kind of the 2 anchor points that I'd point to.

Operator

And our next question coming from the line of Jacob Johnson with Stephens.

Jacob K. Johnson Stephens Inc., Research Division - MD & Analyst

A couple of questions. Maybe just first, just they've got a lateral flow infectious disease portfolio. I think you have the same -- you talked about complementary, but can you just kind of talk about how much overlap there is between your portfolios and maybe what they bring -- what this partnership brings on the infectious disease testing side to OTI with this partnership?

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Yes. Of course, they had a COVID lateral flow test, which was obvious -- InteliSwab is one of our hallmarks. But beyond that, there is little overlap. They -- part of the reason we chose them as strategic partner is the potential really for this underpinning platform of low cost, high volume, that has the potential to expand in areas that were directly aligned with our strategic planning. So while they aren't sharing the specific tests yet, we will do that along the way and I would just reassure that there's little overlap in the tests for development. It is that road map that aligned with where we wanted to go that really made them a well-positioned partner for us.

Jacob K. Johnson Stephens Inc., Research Division - MD & Analyst

Got it. That's helpful. And then just maybe one for Ken. Carrie, you mentioned, I think, some investments in SG&A in '24 and 2025. Ken, is there any way to quantify those investments for those who do have an Excel model? And then maybe along similar lines, kind of operationally, what's required to scale this partnership up?

Kenneth J. McGrath OraSure Technologies, Inc. - CFO

Yes, from the investment, think of in the few, lower millions for SG&A. And what we're really planning on doing is leveraging our existing capabilities. And that's why this ends up, as Carrie mentioned, in probably 2026, we'll be operating profit accretive.

Operator

And our next question coming from the line of Casey Woodring with JPMorgan.



Casey Rene Woodring JPMorgan Chase & Co, Research Division - Research Analyst

Congrats on the deal. So can you just maybe give us a bit more color on the dynamics of the deal? So you said you have exclusive rights to select portfolio of key products. Just which products exactly? Just asking because there were a number of interesting ones. You mentioned benchtop molecular and so forth. And then how long does that exclusivity last for? Just any sort of color around the dynamics of the deal?

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Yes. Great multiple points, and I'll hit each of them. So in terms of the product portfolio, Sapphiros is a group of portfolio companies that span a number of innovative platforms, and we have access to a broad group of those. It starts with the self-collected small-volume blood on the sample management side and it extends into technologies and technology platforms from visual and digital lateral flow, on to the molecular diagnostics platform and the technologies that they have in development around that, and in their partner and related entities.

So while -- we will share more and more about that as they submit for regulatory approval and those regulatory approvals come through. Then in terms of exclusivity, it's multiple years in length. We're not specifying exactly, but I will assure that it is multiple years in length by product. So that exclusivity period starts upon commercial product launch, lasts multiple years with -- this is really a strategic partnership intended for that innovation road map and the strength of our commercial team to help that scale very quickly upon launch. So broad portfolio, multiple years in length of exclusivity. And I think the potential that we highlight, too, that I would just reemphasize is the potential to co-fund and co-develop future products together as well.

Casey Rene Woodring JPMorgan Chase & Co, Research Division - Research Analyst

Got it. That's helpful. And then maybe can you talk about the commercial strategy at the onset on their blood sample collection? What's the go-to-market there? Curious of how much your legacy or if your customers are using blood now? That's something that has been a customer sticking point for a while. And then on the SG&A side as you kind of scale up that expense, are you adding to your headcount or the products that Sapphiros sells, more or less adjacent and that's where you can kind of plug them into your current channel? Maybe just any sort of further color on kind of where these dollars are going?

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Yes. Good question. So the customer launch, we'll share more about that as regulatory -- upon regulatory approval. But I'll just sort of frame philosophically. Blood collection is an area of current activity for our customers. It's an area they absolutely expressed interest in and small volume self-collected blood that's easy to use is where they're interested. A lot of our customers on the molecular side, very much play in saliva where we have our leading offering today, and they also do blood. So we've talked about this for the last 18 months as one of our areas of interest and expansion and upon regulatory approval, we'll be excited to share more both commercially and in terms of what we think is unique and differentiated.

To your point around leveraging our strength, we do expect this to plug directly in on our molecular sample management solutions side teams today, we have very strong offerings in a number of other collection types, you all know that. But this plugs directly in and we will be -- we are already working those launch plans. And there's a factor of market adoption here that's part of the reason we launched this year and have expectations for 2025 growth is that we expect to do the work and to do -- have a strong launch with Sapphiros through our current channels to our current customers and then build from there. And that's where the SG&A dollars come in. We're not specifically describing heads or marketing support or otherwise, but we will share more of that along the way.

Operator

And our next question coming from the line of Andrew Cooper with Raymond James.

Andrew Harris Cooper Raymond James & Associates, Inc., Research Division - Research Analyst

Lots already been asked, but maybe just one more on sort of launch timing and expectations. I guess, first, in terms of -- you mentioned the first product, but then how quickly after that should we expect additional products to perhaps be reaching commercial stage? What's assumed in reaching 2026 operating profit accretion? Just a little bit of a sense for sort of the pacing beyond one product this year and what's needed to hit some of the goals you've talked about in terms of '25 and '26?



Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Yes. Thanks, Andrew. What we've shared is that we do expect those additional product launches to follow and ramp up in 2025 and beyond. It starts with self-collected blood, again, based on regulatory approvals for 2024, we'll share more as that launches. But while we're not specifically talking yet, and we're not providing guidance for 2025, we are sort of anchoring on that expectation for the 2 percentage points of incremental revenue growth beginning next year. We will share more about those specific tests. And I'd say, what we'll share is that they align with our focus in lateral flow diagnostics and infectious disease, respiratory and sexual health. So beyond that, we're not providing guidance or specifics, but that's kind of the platform expectation for both this year and next.

Andrew Harris Cooper Raymond James & Associates, Inc., Research Division - Research Analyst

Okay. Helpful. And then maybe just one on the economics here. In terms of serving as a distributor, is there any inventory risk you'll be taking on? Should we expect that you book the full revenue sort of buy-sell relationship? Is it more agency kind of accounting? Just how should we think about what this looks like on the P&L as it continues to ramp?

Kenneth J. McGrath OraSure Technologies, Inc. - CFO

Yes. So think of that as a typical distribution agreement, but where we are focused on is a strategic partnership. When you think about the margins along this, it's kind of -- from a gross margin perspective, it will be a little bit lower than our overall margins, but in line or above typical distribution agreements. Where we really make up for this is in the leveraging of the SG&A. And that's where we will see operating profit accretion in 2026 and beyond.

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

And we do not have inventory risk.

Kenneth J. McGrath OraSure Technologies, Inc. - CFO

That's correct.

Operator

And I see there are no further questions in the queue at this time. I will now turn the call back over to Carrie Eglinton Manner for closing remarks.

Carrie Eglinton Manner OraSure Technologies, Inc. - President, CEO & Director

Thank you, Livia, and thank you to everyone for joining us this morning on short notice. We are pleased to share the news on our strategic partnerships and investments and appreciate your ongoing interest in the company. Thank you so much, and have a good day. Bye-bye.

Operator

Ladies and gentlemen, that does conclude our conference for today. Thank you for your participation. You may now disconnect.

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