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PRESENTATION

Operator

Good afternoon, everyone, and welcome to OraSure Technologies 2017 Second Quarter Financial Results Conference Call and Simultaneous Webcast. As a reminder, today's conference is being recorded. (Operator Instructions) OraSure Technologies issued a press release at approximately 4:00 p.m. Eastern Standard Time today regarding its 2017 second quarter financial results and certain other matters. The press release is available on our website at www.orasure.com or by calling (610) 882-1820. If you go to our website, the press release can be found by opening the Investor Relations page and clicking on the link for press releases.

With us today are Doug Michels, President and Chief Executive Officer; and Ron Spair, Chief Operating Officer and Chief Financial Officer. Doug and Ron will begin with the opening statements, which will be followed with a question-and-answer session.

Before I turn the call over to Doug, 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 the company's SEC filings, including its registration statement, its annual report on Form 10-K for the year ended December 31, 2016, its quarterly reports on Form 10-Q and its other SEC filings. Although forward-looking statements help to provide 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. The company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after this call.

With that, I would like to turn the call over to Doug Michels.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay. Thank you, Joni, and good afternoon, everyone, and welcome to our call. It's certainly a pleasure to report that we had an exceptional second quarter. As you can see from our earnings release, we exceeded our public financial guidance and consensus analysts' estimates on both the top and bottom line by a fairly wide margin. I am delighted with our performance. Our message to investors since the end of last year has been that OraSure is in the early stages of several market opportunities and is well positioned to capitalize on them. Our second quarter performance shows that we're doing just that. Many of the countries and customers we serve have only just begun executing on their goals and objectives, and there are many more businesses and countries with which we currently do not transact business. And we think many of these potential customers could benefit from our products. For this reason, we still believe we are in the early stages of our growth potential.

Demand for our molecular collection kits has been extraordinary, primarily because of the growth in the personalized medicine market. Our HCV business continues to perform very well, especially in international markets, in support of broad-based testing and treatment programs. We are very confident and enthusiastic about the growth of the OraQuick HIV self-test after receipt of WHO prequalification, our new agreement with The Gates Foundation and the announced expansion of the self-testing in Africa or STAR project. We are making strategic investments to substantially expand manufacturing capacity in anticipation of continued strong demand for our products. In short, our recent performance demonstrates that we are successfully executing on our strategic growth objectives for both the infectious disease and our molecular businesses.

So turning to the quarter. Our consolidated net revenues grew 28% compared to the year-ago period and topped $40 million for the first time. Product revenue growth was 42%. Our molecular business delivered another record performance as second quarter revenues reached $16 million. This is almost double the revenue generated in Q2 of last year and is, by far, the best quarter ever for this business. Our infectious disease business also performed extremely well with 29% revenue growth from the year-ago period. Significant increases in international and domestic sales of our HCV product were the primary growth drivers here. And on the bottom line, our consolidated net income also improved nicely from the year-ago quarter, and we ended the quarter with over $160 million in cash and cash equivalents.

In short, our second quarter results were outstanding. And as Ron will explain, we expect this trend to continue as we are projecting similar performance for Q3. So with that brief introduction, let me turn the call over to Ron for his detailed financial review. And I will then provide some business updates, after which, we'll take your questions. So Ron?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Okay. Thanks, Doug, and good afternoon, everyone. As you can see in our press release, 2017 continues to be a very successful year. Our second quarter consolidated net revenues increased 28% to $40.2 million compared to $31.4 million reported in the second quarter of 2016. Notably, our consolidated net product revenues were -- rose 42% to $39.1 million compared to the prior year period. Higher sales of our molecular products and our OraQuick HCV products were the primary drivers of this performance. Our molecular revenues rose 90% to $16.1 million in the second quarter of 2017 compared to $8.4 million in the second quarter of 2016. Sales of our Oragene products to commercial customers increased 122%, largely due to higher customer demand.

Academic sales increased 2%, largely due to customer ordering patterns. Our international sales of the HCV tests in the second quarter of 2017 rose 268% to $5.3 million from $1.4 million in the same period of 2016, primarily due to the continued shipment of products to a foreign government, pursuant to a previously announced country-wide elimination program. Domestic OraQuick HCV product sales increased 33% in the second quarter of 2017 to $2.4 million from $1.8 million in the prior year period, primarily due to business growth and customer ordering patterns.

Domestic professional HIV sales decreased 16% to $5 million in the second quarter of 2017 compared to $5.9 million in the second quarter of 2016 as a result of customer ordering patterns and competition from other products. It should be noted though that while domestic HCV sales was down compared to the prior year period, second quarter 2017 domestic HIV sales increased 30% sequentially over the first quarter of 2017.

Other revenues were $1 million in the current quarter, representing funding we received from BARDA for our rapid Ebola and Zika products. Other revenues in the second quarter of 2016 totaled $3.8 million and included $417,000 of BARDA funding and $3.4 million of exclusivity revenues under the AbbVie HCV co-promotion agreement, which terminated effective December 31, 2016.

Gross margin for the second quarter of 2017 was 63% compared to 67% reported for the second quarter of 2016. Margin for the current quarter decreased primarily due to the absence of the AbbVie exclusivity revenues in 2017 as a result of the termination of the agreement at the end of last year.

Our consolidated operating expenses for the second quarter of 2017 were $18.6 million compared to $16.7 million in the comparable period of 2016. This increase was largely due to higher staffing-related costs and increased spending on lab supplies.

Income tax expense was $1.6 million in the second quarter of 2017 compared to $173,000 in the same period last year and consists entirely of Canadian taxes due. From a bottom line perspective, we reported net income of $5.4 million or $0.09 per share on a fully diluted basis for the second quarter of 2017 compared to net income of $3.8 million or $0.07 per share for the same period of 2016.

Turning briefly to our balance sheet and cash flow. We continue to maintain a solid cash and liquidity position. Our cash and short-term investment balance at June 30, 2017, was $162.1 million compared to $120.9 million at December 31, 2016.

Cash generated by operating activities in the first half of 2017 was $21.7 million compared to $16.7 million in the same period of 2016.

Turning to our guidance for the third quarter of 2017. We are projecting consolidated net revenues of approximately $40.5 million to $41.5 million. We are also projecting consolidated net income of approximately $0.09 to $0.10 per share for the third quarter of 2017.

And with that, I'll turn the call back over to Doug.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay. Thank you, Ron. And I'll now walk you through some of the progress we're making in our various businesses. As noted in the infectious disease area, international product sales and domestic sales of our OraQuick HCV tests continue to be the primary growth drivers. The largest contribution in the second quarter came from international sales growth, primarily in support of large-scale hepatitis C testing programs, including, in particular, the country elimination initiative and related government supply agreement we previously highlighted. Our execution against this contract has gone very well. During the second quarter, we shipped over 1 million hepatitis C tests under this agreement, and we anticipate continued strong demand from this customer.

As previously discussed, this customer has the option to renew the contract and purchase up to 100% of the original quantities of product on the same terms and conditions as provided in the original contract. Discussions around the renewal are progressing well, with conversations occurring on specific volumes and the timing of future shipments.

Assuming the successful conclusion of these discussions, we expect future volumes will exceed those shipped under the original contract. Negotiations regarding this expanded supply arrangement should be completed during the third quarter.

Apart from this government customer, the level of interest in HCV testing and treatment programs remain strong. We previously mentioned that we fulfilled initial orders from 2 other countries that have initiated broad HCV testing programs. We anticipate additional orders from these countries later this year depending, of course, on continued funding which, in turn, will impact the ability of these countries to add the needed infrastructure and define the ultimate scope of their programs.

We previously reported that the WHO has announced its goal of eliminating hepatitis C by the year 2030. The list of countries with plans to reach that goal has grown from 36 to 52. And while this increase does not guarantee available funding or that large-scale HCV testing programs will occur in all cases, it does show that a growing list of high prevalence countries are focused on reducing the burden of hepatitis C infection.

I would note that a key enabler for large-scale HCV testing and treatment programs is the reduced cost to cure hepatitis C with new generic therapeutics available in certain markets. In many countries that are executing or considering broad testing and elimination programs, the cost to cure hepatitis C is now below $1,000 per patient as a result of the availability of these generic drugs. Our research has identified several countries that have obtained these type of reduced pricing for the new therapeutics, and we are working to understand how these developments may open a door to future broadscale testing programs.

Finally, in our -- domestic hepatitis C sales provided a nice contribution to the quarter, increasing 33% compared to the prior year. This was driven by an expansion of existing and the initiation of new testing programs. Sales to the public health hospital and physician office markets all contributed to the growth in our domestic business. And we expect this trend will continue.

Our international HIV business grew during the second quarter as well, although at a more modest rate than in prior periods. This was largely due to the timing of orders for our OraQuick HIV self-test by Population Services International, or PSI, in connection with the STAR program. We believe this is just a timing issue and that stronger growth will resume in future periods. There have been a number of recent positive developments in our HIV self-testing business. We recently announced a new 4-year charitable support agreement with the Bill & Melinda Gates Foundation. Under this agreement, the Gates Foundation will subsidize the price of our HIV self-test in 50 developing countries. The amount of the support payments is tied to the volume of products sold in the covered countries, along with the level of cost we incurred in connection with regulatory approvals and other investments needed to supply the product. The goal of this agreement is to drive the accelerated adoption of our OraQuick HIV self-test, so that more people can learn their status and receive necessary treatment. Since the agreement was signed, we work closely with the Gates foundation to promote this arrangement. Updates on the program have been provided to major funding organizations, such as the Global Fund, to PEPFAR and to the Children's Investment Fund Foundation. This was very timely as these organizations are currently preparing their program budgets. In addition, correspondence outlining the program has been sent to the ministers of health in the 50 covered countries. And our agreement with the foundation was also highlighted last week at the recent International AIDS Conference in Paris, and it generated significant interest.

We also recently announced the receipt of prequalification for the WHO for our HIV self-test. We are now offering the only rapid HIV self-test that has received this designation. WHO prequal allows government organizations implementing self-testing pilots and programs to use international donor funding for the purchase of our test.

As we have indicated on other calls, our work with PSI on the STAR project has gone well. We recently received another large self-test order from PSI that will ship during the third quarter, and we expect more to come. PSI and UNITAID recently announced phase 2 of the STAR program and, importantly, the expansion of the program to additional countries and an increase in test volume from 750,000 units in phase 1 to approximately 4 million additional HIV tests in phase 2. We believe that we will supply the vast majority of these tests. We've been notified by PSI to expect an additional large order of tests to be shipped during the fourth quarter of this year under phase 2. And this next phase will extend the STAR program beyond Zimbabwe, Malawi and Zambia to additional countries, including South Africa, Swaziland and Lesotho. So we remain very optimistic about our HIV self-testing and believe this business will help drive future growth in our infectious disease business.

On the domestic front, our HIV business was down again compared to the prior year quarter. Although as Ron noted, this business grew 30% sequentially from Q1. The negative factors affecting our domestic HIV business remain the same and include the CDC's continued push for the use of fourth-generation automated laboratory testing equipment, public health budget pressures and price competition. In fact, we've been advised that the CDC is instructing public health jurisdictions to prepare for future possible budget reductions as the current administration has indicated plans to cut the HHS budget in the coming fiscal year. The timing of several orders from our larger physician's office distributors also had a negative impact on the quarter. The good news is that the second quarter decline in domestic HIV sales was more than offset by the growth in our hepatitis C business.

As indicated in our last call, clinical studies using our tuberculosis product have been completed by the Foundation for Innovative New Diagnostics, or FIND, in support of WHO endorsement of our OMNIgene SPUTUM product. FIND has issued its final data dossier on our product, and the WHO conducted a technical review of this data, along with data for other sputum transport solutions on May 29. The WHO has not yet issued a final report from its meeting but is expected that they will do so in the near future.

Turning briefly to emerging diseases. I want to briefly update you on clinical activities for our new Zika test. We previously indicated that we expected to submit for Emergency Use Authorization from the FDA either in late Q2 or early Q3. Due to some stability challenges with our test, this supposition will likely now be pushed to Q4. We believe these technical issues will be resolved, and we remain committed to obtaining Emergency Use Authorization approval and to the successful commercialization of this test.

Turning to our molecular business. Our molecular business turned in just another exceptional performance in Q2, with 90% growth over the prior year quarter and 50% growth sequentially from Q1. We expect this strong growth trend, including sequential quarterly growth, will continue in the third quarter. These results were partially driven by shipments of Oragene devices against the $20 million supply agreement we announced last quarter as well as overall strong performance in our commercial business where we saw increases with most of our commercial customers compared to the prior quarter. Along with the continued acquisition of new customers, we expect strong triple-digit growth in our commercial business in Q3 compared to the prior year quarter.

On July 24, Helix launched a range of personalized DNA-powered products as part of its online marketplace offering. Since announcing our supply agreement with Helix last November, we have been shipping Oragene devices and providing kit fulfillment and logistics services for Helix through our GenoFIND service. We expect the recent launch of a broad set of products and services provided by their partners will drive increased consumption of our products and services under this agreement.

Finally, our GenoFIND fulfillment logistics service business had a record quarter in Q2, delivering the most kits since we launched the service. We expect this service to continue to grow nicely as we acquire new customers and our existing customers businesses continue to grow. Our microbiome business also delivered record revenues of $840,000 in the second quarter, representing almost a fourfold increase over 2Q of 2016. This brings first half microbiome revenues to $1.6 million, which exceeds our total 2016 microbiome revenue of $1.1 million. This growth has come from both repeat purchasers and new customers acquired during the quarter. We experienced strong double-digit growth in customer acquisition, both sequentially and over the prior year period. And we continue to see strong interest in our microbiome products and services, with the number of new testers almost doubling year-over-year.

During the quarter, we closed one of the largest sales ever in our microbiome business with a long-running academic cohort for the provision of kits, custom packaging and fulfillment services. We will provide additional details on this study when it is publicly announced and we start delivering against this contract, which is expected to be in Q4. We are very pleased with this development.

Turning to operations. As stated earlier, there has been intense focus on the expansion of our manufacturing capacity. The second automated OraQuick production line mentioned on prior calls has received all necessary regulatory approvals and is now being used to make salable product on one ship with a second ship planned for later this year. When fully operational, this line will add additional capacity of up to 10.4 million devices per year. A supplier has been selected, and we have placed an order for yet a third automated OraQuick line. Delivery of this line is expected in mid-2018, and this line should be operational by the end of next year. This line will also add capacity for up to an additional 10.4 million devices per year. Cleanroom construction has begun to add capacity at our contractor in Thailand, which we used to assemble and supply non-U.S. and non-CE mark OraQuick HIV products, primarily in developing countries. We expect installation and validation of an additional semi-automated assembly line to be completed in 2017 with the related regulatory approvals obtained in early 2018. And then an additional line in Thailand is also planned for next year.

We've also ordered 2 additional automated assembly lines for our saliva DNA collection kits and expect the first line to become operational by the end of 2017 and the second in early 2018. These new lines will more than double our capacity. And in addition to increased automated assembly, we've begun the process to add manufacturing capacity here in Bethlehem to meet the expected increased demand for our OraQuick HCV product. A new warehouse, new cleanroom, new manufacturing area and new QC labs will be put in place by the second quarter of 2018 to provide additional capacity for this product.

And lastly, as noted on the prior call, we are working with a consulting firm to help us optimize the global footprint for the manufacture of our products. The initial engagement concluded last quarter and resulted in recommendations for the location of additional manufacturing capacity to meet global demand in 2020 and beyond. The second phase of the engagement will begin this quarter and will include the identification and sourcing of qualified contract manufacturers and raw material suppliers for our OraQuick and Oragene products. The second engagement is expected to be completed by the end of 2017.

And final item I would like to mention is the recent appointment of Mara Aspinall as a member of our Board of Directors. Mara's extensive experience in both the molecular and diagnostics fields makes her an ideal addition to the board. In fact, her background in the molecular field will be especially valuable given the strategic importance of this area to our business. Mara currently serves as Execute Chair of GenePeeks, a computational genomics company and she also spent a number of years serving as President of the genetics division of Genzyme Corporation, which is a leading provider of genetic tests for the reproductive oncology and personalized medicine markets. We are delighted that Mara has joined the board, and we look forward to working with her.

So in summary, our second quarter performance exemplifies the tremendous momentum in our business and our ability to execute on our key strategic priorities. We remain excited about our future prospects. This optimism is based on our discussions with both existing and potential new customers as well as the recent addition of a new funding vehicle and the potential for additional funding channels in international markets. As

evidenced by our third quarter guidance, we are confident that our international HCV and HIV products and our molecular business will continue to drive strong growth. We're making the necessary investments in our manufacturing capacity to capitalize on these opportunities. And we believe the recent trends in our business will continue through the remainder of 2017, and I look forward to reporting on our progress and continued growth in future calls. And before we open the floor to your questions, I'd just like to take the opportunity to recognize and sincerely thank my OraSure colleagues for all their contributions and making this a tremendously successful quarter. Many thanks to the team. And with that, we're ready for your questions. So operator, could you please proceed?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Brandon Couillard of Jefferies.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Doug, following the Gates Foundation announcement and WHO prequalification, I'm curious how the conversations have changed since that time. And if we look longer-term, what do you think is a reasonable expectation for the percentage of the $100 million-or-so rapid HIV tests you think you could ultimately, I guess, convert to self-testing?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Yes, thanks for the questions, Brandon. So I'll answer both those questions. The first one is how the landscape changed. We just got back from the International AIDS Conference in Paris last week. I haven't seen the level of enthusiasm and excitement around the OraSure booth like we saw last week since more than a decade ago when the OraQuick test was first approved. We were swamped with interested countries and interested programs in our HIV self-test. Certainly, the prequalification was a big driver for that because that enables now these country governments to use their public funding, whether that's from the Global Fund or PEPFAR, to now buy the product and to incorporate that into their country plan. Second, the announcement by UNITAID and PSI of the second phase of the STAR program, which we anticipated was going to include the provision for 2 million tests was actually announced for 4 million tests. So that was like epic, a huge positive for us. And obviously, that expanded the STAR program from the 3 countries, Malawi, Zambia and Zimbabwe, to 6 countries adding South Africa, Lesotho and Swaziland. So that 4-million test is still just going to 6 countries. And there's 40, 4-0, countries as of July this year that have policies. They're in support of HIV self-testing. That's up from 16 countries that had policies supporting self-testing just 1 year ago. So that should give you some indication of the enthusiasm for self-testing just over the last year. And now there's 48 additional countries that are planning to introduce HIV self-testing policies, 1/3 of which intend to have those completed by the end of 2018. So the enthusiasm at this conference where all the international players in HIV were in attendance was palpable, and we're certainly leading the way in HIV self-testing. I think there were nearly 100 either papers, oral presentations or programs presented at the conference. And the vast majority of all of that work had been completed using the OraQuick HIV self-tests. So we're beautifully positioned to capitalize on what we believe is going to be a significant opportunity. To the second part of your question, with regard to what percentage of the total testing is likely to convert to -- from professional to HIV self-testing, I think, that's a TBD. There's many estimates out there, and they are continuing to develop. I think we'll have a better read on that after these countries begin to incorporate HIV self-testing into their national plans. And as that continues to develop, we'll provide whatever color we can on that. But our assessment says it's going to be in the tens of millions of tests down the road. And the big question is how quickly that market develops. All will be certainly supported by our work with the Gates Foundation, the work that we're doing with PSI STAR and future programs, which we expect will be made available, both through the Global Fund as well as PEPFAR. So it's a big opportunity for certain.

Samuel Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

That's very helpful. And one for Ron, any chance you could perhaps parse out the contribution in 2 areas, number one, from the $18 million contract in infectious disease; and then number two, the $20 million contract within DNA Genotek for the second quarter?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

Yes. I certainly can look at the contribution from the country-wide elimination program, and that's probably in the neighborhood of a little over $4 million for HCV in the quarter, Brandon. As far as the contribution from the $20 million contract, I'm reticent to give that kind of granularity on that particular contract award. That is deference to our customer.

Operator

Our next question comes from Drew Jones of Stephens.

Andrew Luten Jones - *Stephens Inc., Research Division - Research Analyst*

I'm trying to think about the molecular collection growth another way. Last quarter, I think you guys called out 17 of your top 20 customers were up year-over-year. Do you have a similar stat for this quarter? Or was it really heavily dependent on a handful of those commercial customers?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

No, I would -- we followed a very similar pattern to the first quarter. The majority of our top customers showed quarter-on-quarter growth. And seeing this kind of performance, 2 strong quarters in a row really suggest the strong momentum that we have in our molecular business. As Ron mentioned, we delivered revenues against that $20 million contract. But some of our newest customers with bold plans delivered in the quarter as well, the Helixes, the WeGenes, the Wuxis, along with others. So we have great momentum in this business, and that doesn't -- and that's on the commercial front. We also mentioned our microbiome business grew nicely, delivering over $800,000 in revenues in the quarter, up from slightly over $200,000 in the second quarter of 2016. So good momentum across the board, and we expect it to continue.

Andrew Luten Jones - *Stephens Inc., Research Division - Research Analyst*

And then last one from me. If I go back to last summer, it seemed like you guys were -- had a high degree of confidence in finalization of the large HCV elimination program before you had the contract in hand. Your commentary today sounds like we're approaching kind of similar levels of confidence when we look out what this could contribute to 2018, is that fair to say?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

I think, to be honest, we're probably more confident at this point in time than we were a year ago, only because now we have that experience with this customer. We know that the product is being deployed and deployed successfully. We know that they're identifying positive individuals and getting them on treatment, and we know that they've got an aggressive goal to eliminate hepatitis C by 2025. So -- and we know also that they need to ramp up their testing if they are to reach the number of individuals that are affected in the country to achieve that goal. So we've had, as we mentioned in our prepared remarks, very positive and productive discussions. It's not done until it's done. So we're talking specifics about volumes, delivery dates and the like. And like we said, we expect, we believe that will be successfully completed. We would expect that, that would happen in Q3 here. And as soon as that happens, we'll report on it. We also indicated that we do expect that it will likely be for a higher volume commitment than the initial term. Exciting.

Operator

Our next question comes from Nicholas Jansen of Raymond James & Associates.

Nicholas Michael Jansen - *Raymond James & Associates, Inc., Research Division - Analyst*

Two questions from me. First, I think on Amazon's Prime Day last month, 23andMe's DNA collection device or platform was one of their top-selling -- it's one of the top-selling things on Prime Day. So certainly a very strong performance as we think about demand for genomic testing. So I just want to get a better sense of how we think about not only that customer but your large customers that are just ramping up. What level of visibility do you have beyond, let's say, 3 months or so in terms of their purchasing patterns? So I get 2Q is very strong, 3Q is going to be even stronger. But beyond 3Q, what's the level of visibility do we see on some of these larger customers that are just now launching quite aggressive programs to reach out to consumers?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

We work very closely with them and enter into agreements with them that are usually at least a year and oftentimes multi-year types of contracts for certain volumes of products at certain prices. And then generally, they provide us rolling 12-month forecast with usually the most current 90 days being a firm commitment. We're seeing across the board a high level of interest in these kind of DTC personalized medicine kinds of offerings. We did see the enthusiasm on Amazon Prime Day for 23andMe's offering. We talked to 23andMe about that, they are very excited about that. I think to get more color on that, you probably should talk to them about just what that represented. But there's a heck of a lot of enthusiasm around this. We expect it's going to continue. And then, of course, with new businesses, like the Helixes of the world, they're creating something new. And so in these early stages, we're both doing the best we can to forecast and project. And it's -- we're going to continue to work very closely with our customers to anticipate demand. Obviously, we're investing in the capacity to serve what we expect is going to be significant increase in demand over the future periods.

Nicholas Michael Jansen - *Raymond James & Associates, Inc., Research Division - Analyst*

That's very helpful. And then my second question would just be on the update of STAR phase 2, pilot 2. I think you said 4Q is when we'll see some purchases toward that 4 million-or-so volume. Any sense of how we should be thinking about the cadence of that over the next 12 to 18 months beyond 4Q? Certainly, it can be a pretty solid contributor to next year's growth.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Yes, we expect it'll be a solid contributor to future growth. I think we'll have better visibility as to the cadence in future periods. Remember, UNITAID and PSI just announced that this new grant was funded and just announced the increase in the volume of this new grant from what was expected, 2 million units to 4 billion. So the timing on that is going to have to be worked out with the countries, but it certainly represents a nice opportunity for us. And we do expect that there will be programs funded, respectively, by the Global Fund and PEPFAR, this according to global WHO. And those will likely be announced in the months to come.

Operator

Our next question comes from David Westenberg of CL King.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

So just a quick one on the DNA Genotek business. Was there any usual, unusual large or one-time orders that you don't normally see in the quarter or you expect in this quarter?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

No, there were none, Dave.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Great. All right. And then in terms of the $20 million deal that you signed in the DNA Genotek business, if this deal -- I know it's for a little more than a year, if things go, say, beyond projections, does this have a chance to be shortened? Or is it just kind of a new deal? I mean, how does that structure look?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Well, so there's a contract period that we anticipate that $20 million of product will be purchased over. Certainly, if business ramps faster than anticipated, we'll exhaust that $20 million, and we'll get into a position where we'll begin to discuss the renewal and expansion of that.

David Michael Westenberg - *CL King & Associates, Inc., Research Division - Senior VP & Senior Equity Analyst*

Perfect. And then in terms of domestic, both HCV and HIV, do you have any estimates in terms of percent of the population that they know -- that have those respective disease. And has it changed rapidly now that there's, obviously, a cure for HCV and, pretty much, antiviral therapies are almost a cure for HIV?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Yes, so I'll speak to both of the conditions. So there's estimated somewhere around 1.2 million to 1.4 million individuals affected with HIV here in the United States, estimated somewhere in the neighborhood of 12% to 14% of those are unaware of their infection. That's down from more than a decade ago when approximately 30% of individuals infected were unaware. So there's been good progress in diagnosing infected individuals here in the United States. There's still ways to go, but good progress has been made. On the hepatitis C front, it's estimated there's around 4 million Americans infected with hepatitis C. And it's believed that more than 50% of those are unaware of their infection. So this represents, obviously, still a very large market opportunity. And it's supported, of course, by the CDC's testing recommendations at all baby boomers they tested for hepatitis C as well as individuals at risk. So we think in both cases, there's a big opportunity. Certainly, with hepatitis C, the fact that people can be cured is a real benefit. And the fact that most of the chronic hepatitis C infection is within the baby boomer population, they've been infected for a long period of time that are now presenting with later-stage liver disease, fibrosis, cirrhosis and liver cancer, so there's an incentive by all providers and the government to identify these individuals, get them on treatment and cured so as to reduce the morbidity and mortality clause associated with later-stage liver disease. So those are the factors that are really playing into our hands here in the domestic market. Certainly, on the global front, the opportunities we talked about, both with HIV self-testing and hepatitis C, the availability of generic drugs really makes the case even more compelling for these governments to implement broad-based screening programs that they can cure a large number of people that are infected worldwide. There's over 170 million people believed to be infected with hepatitis C on a global basis. So this is a huge, huge market, with most of those individuals unaware of their infection.

Operator

(Operator Instructions) Our next question comes from Mark Massaro of Canaccord Genuity.

Unidentified Analyst

It's Max on for Mark. How many countries are you in dialogue with for the HIV self-test and how many for hep C? And have you seen any new countries come in the table in the recent weeks or months? And how should we think about these? Are they large or small countries?

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

So I can tell you on the -- I don't have the compilation from last week's meeting in Paris, but I can tell you, on the HIV self-testing front, it's way more than 20 countries that were in discussions with. And as I mentioned, as part of my comments, 40 countries have policy supporting HIV self-testing as we speak. And so we know who those are. And obviously, we're reaching out to them. We've also, as I mentioned, reached out to the 50 countries that would be eligible for pricing subsidy under the Gates agreement, and we've had a good response from our communications with those countries. And to your point, indeed, there are some new players that we've engaged with, primarily as a result of our WHO prequalification because some of these countries have policy that, in essence, prohibits their use of any product until such is prequalified by WHO. On the hepatitis C front, we're actively engaged with these several countries that we talked about and believe will purchase product before the end of this year and some volume. And then there's at least half a dozen other countries that were in discussions with as they begin to consider and plan for expanded hepatitis C testing. So that's a very exciting, very big opportunity that we spoke about as well.

Unidentified Analyst

Great. And one more, can you generally characterize the M&A environment? Is there anything heating up relative to your prior quarter intelligence? And is there any appetite to maybe repurchase stock over the next year or so?

Ronald H. Spair - *OraSure Technologies, Inc. - CFO, COO and Director*

So Max, we've been looking at a great number of opportunities out there in the M&A space and business development area whether it would be for outright acquisition, licensing, partnering transactions. And competition for quality assets is high. And sometimes valuation expectations are occasionally unrealistic, but we continue to go down that path and are committed to it.

Operator

This brings to an end the Q&A section of today's call. I will now turn the call over to Doug Michels for closing remarks.

Douglas A. Michels - *OraSure Technologies, Inc. - CEO, President and Director*

Okay. Thanks, everybody, for joining us this afternoon -- this evening. We look forward to delivering another great quarter in Q3 and discussing our performance in a few months. Have a great rest of the summer.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. You may disconnect, and have a wonderful day.
