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HOLX.OQ - Q2 2021 Hologic Inc Earnings Call

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OVERVIEW:

HOLX reported 2Q21 reported revenues of $1.54b, non-GAAP net income of $674.1m and non-GAAP EPS of $2.59. Expects 3Q21 revenues to be $1.00-1.07b and non-GAAP EPS to be $1.00-1.15.

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PRESENTATION

Operator

Good afternoon, and welcome to Hologic's Second Quarter Fiscal 2021 Earnings Conference Call. My name is Jenny, and I'm your operator for today's call. Today's conference call is being recorded. (Operator Instructions)

I would now like to introduce Mike Watts, Vice President, Investor Relations and Corporate Communications, to begin the call.

Michael J. Watts - *Hologic, Inc. - VP of IR & Corporate Communications*

Thank you, Jenny. Good afternoon, and thanks for joining us for Hologic's second quarter fiscal 2021 earnings call. With me today are Steve MacMillan, the company's Chairman, President and Chief Executive Officer; and Karleen Oberton, our Chief Financial Officer. Steve and Karleen both have some prepared remarks, then we'll have a question-and-answer session.

Our second quarter press release is available now on the Investors Section of our website. We also will post our prepared remarks to our website shortly after we deliver them. Finally, a replay of this call will be archived through May 21.

Before we begin, I'd like to inform you that certain statements we make during this call will be forward-looking. These statements involve known and unknown risks and uncertainties that may cause actual results to differ materially from those expressed or implied. Such factors include those that are referenced in the safe harbor statement included in our earnings release and in our filings with the SEC.

Also during this call, we will be discussing certain non-GAAP financial measures. A reconciliation to GAAP can be found in our earnings release. One of these non-GAAP measures is organic revenue. We define organic revenue as constant currency revenue excluding the divested Blood Screening business as well as the acquired Acessa, Biotheranostics and Diagenode businesses.

Finally, any percentage changes we discuss will be on a year-over-year basis, and revenue growth rates will be expressed in constant currency unless otherwise noted.

Now I'd like to turn the call over to Steve MacMillan, Hologic's CEO.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Thank you, Mike, and good afternoon, everyone. We're pleased to discuss our financial results for the second quarter of fiscal 2021. We posted excellent financial results overall, highlighted by best-in-class growth rates. Total revenue was $1.54 billion and non-GAAP earnings per share were $2.59, both in line with our guidance.

Organic revenue doubled, driven by strong recovery and momentum in our base businesses as well as our continued contributions to the COVID-19 fight. On the bottom line, EPS more than quadrupled.

Our diversified business model again demonstrated its value in the second quarter as strong growth rates in our core businesses enabled us to meet our overall guidance even though COVID assay sales were less than expected. Our base Diagnostics business and our Surgical franchise, both finished slightly better than forecast, even while overcoming a tough January for U.S. health care utilization that was driven by increasing COVID cases. And our Breast Health division clearly outperformed as our diversification strategy has led to a faster-than-expected recovery.

Karleen will cover the revenue and expense details. But before she does, I'd like to discuss 2 primary topics. When the COVID pandemic began more than a year ago, we set out to accomplish 2 things in simple terms: first, we committed to make as big an impact as possible against the pandemic; and second, we wanted to ensure that every action we took helped us emerge from the pandemic as a stronger company. We are clearly accomplishing both goals which makes us more excited than ever about our future.

In terms of our first goal, helping fight the pandemic on a global scale. Let's summarize our contributions by focusing on 4 key numbers. Our first number is 100 million. Soon, we will ship our 100 millionth COVID test to customers, which included 27 million in the second quarter. At the same time, we have maintained our commitment to provide women's health test by dramatically increasing total molecular diagnostics production capacity. We are on track with our expansion plans in San Diego and Manchester, U.K. to have the capacity to make at least 75 million tests a quarter across our portfolio by January of 2022.

Our second number is 40. This is the number of countries in which we've sold COVID tests as we help battle what has been and continues to be a global crisis. COVID testing continues to strengthen our international business, our relationships with customers, our future prospects in diagnostics and even market access for our other franchises. These COVID sales contributed to total international revenue of $474 million in the second quarter, which represented tremendous growth of 142%.

Our third number is 717. This is the number of Panther instruments we have shipped to global customers over the last year, including about 190 in the second quarter. As a reminder, in the 5 years before COVID, we shipped an average of 225 Panthers a year. So we've more than tripled that pace over the last 12 months. In addition, we are encouraged that demand for Panthers remains very high. And for all of fiscal 2021, we expect to exceed last year's record placements. Overall, our global installed base now stands at roughly 2,600 instruments, approximately 40% higher than when the pandemic began, giving us a robust platform for future growth as more customers come to appreciate our system's best-in-class capabilities. And as we have discussed, we are seeing this play out with record levels of new non-COVID business on these Panthers.

All these numbers lead to our fourth number, which is $2.35 billion. This is the total COVID assay revenue we have generated on a global basis since the pandemic began, including $680 million in the second quarter. And this has contributed very significantly to operating cash flow of nearly $1.9 billion over the last year. This has enabled us to acquire 4 companies and sign a deal for a fifth, even while further strengthening our balance sheet. We'll discuss our business development activity more in a minute.

Before we do that, we wanted to provide our current perspective on the changes in the COVID testing market that you have all seen, with the understanding that the pandemic and its impact on Hologic remain highly unpredictable.

Based on publicly available data for the U.S., molecular COVID testing volumes remain very high, much higher than for any other molecular test. But have declined significantly since January based on a better-than-expected vaccine rollout. In this context, our U.S. sales of COVID tests also declined significantly in March and further in April. We believe that molecular COVID testing demand will likely decline further as vaccines roll out, but remain important into fiscal '22 and beyond. This reflects the ongoing need for accurate clinical diagnosis, the value of testing for infection control purposes and the so-called back to life testing that is helping to reopen economies.

In this environment, the combination of our huge Panther installed base at facilities close to the patient, and our gold-standard assay performance have us uniquely positioned to gain market share. Customers continue to tell us that Panther and Aptima remain their products of choice and that they intend to consolidate on our platforms. But we believe many of them are using up less automated assays before they expire. Customers had accumulated these tests in the winter when they needed multiple manufacturers to accommodate than higher levels of demand. This dynamic is further supported by the public AdvaMed data that many of you see, which show that industry-wide, tests performed are now running ahead of tests shipped, indicating that inventory is being worked down.

In response to these market changes, we pivoted in 2 ways in the second quarter. First, by selling more COVID tests to our base hospital customers who want to bring highly accurate testing closer to their patients, improving turnaround times and clinical relevance. Panther is well positioned for this with first test results being delivered in about 3 hours. Notably, COVID tests are now being run on Panthers in more than 600 clinical labs in the United States. This means that COVID is the second most decentralized test that we sell, following only Aptima Combo 2, which has been on the U.S. market for roughly 20 years.

Second, we pivoted by selling more tests internationally. As everyone has seen in the news, the vaccine rollout is proceeding at different paces around the world. Europe, in particular, has struggled with inoculations, increasing the importance of testing. For example, in the second quarter, almost 40% of our COVID assay revenue came from outside the United States, mainly from Europe.

Now let's shift gears to our second major topic, an update on how the tremendous impact we've made against COVID has strengthened our business for the other side of the pandemic. As many of you will recall, before the pandemic hit, our organic growth rate had been steadily improving to around 5% based on new products international expansion and our early acquisitions.

Now as we begin our annual strategic planning process, we are confident that organic growth for the next several years, excluding COVID assay sales, will be higher than it was before the pandemic hit.

In Diagnostics, we've used COVID cash flows to broaden our portfolio by buying assets that are growing faster than our base business. Since the Gen-Probe acquisition in 2012, we had acquired exactly 0 companies in Diagnostics. But since late February, we have completed 2 deals and announced a third, dramatically accelerating our long-standing goal to become a more complete diversified diagnostics leader.

In February, we closed our $232 million acquisition of Biotheranostics, a leader in molecular tests for breast and metastatic cancers, enabling us to expand into the adjacent growth market of oncology. This business is off to a very strong start, based mainly on the inclusion of the Breast Cancer Index test in NCCN guidelines to predict the benefit of extended treatment with endocrine therapies.

A few days after that, we closed Biotheranostics. We -- I'm sorry, a few days after we closed Biotheranostics, we acquired Diagenode, a Belgian developer and manufacturer of molecular diagnostic assays and epigenetics products for approximately $153 million. Diagenode, which generated more than $30 million of revenue in the last year, will enable us to offer a broader, more differentiated menu of molecular diagnostic tests on our fully automated high-throughput Panther Fusion instrument. We know Diagenode's capabilities in assay development well, since we have partnered with them since 2016 to develop and manufacture PCR-based assays for Fusion.

As you might recall, the ability to leverage external PCR expertise was one of the reasons we developed the Fusion system years ago. Now that Diagenode is part of Hologic, we can accelerate those assay development efforts and make many of their CE Mark PCR tests available on our unique platform, further enhancing European growth.

Finally, earlier this month, we announced our agreement to acquire Mobidiag, a Finnish developer of innovative molecular diagnostics tests and instrumentation for approximately $795 million. In contrast to Diagenode, which helps us leverage our Fusion installed base around the world, Mobidiag brings new capabilities that we have been interested in for more than a decade. Specifically, Mobidiag is an innovator in near-patient acute care diagnostics, a large, rapidly growing area that we don't compete in today. This market encompasses test for respiratory and gastrointestinal conditions, health care-associated infections and antibiotic resistance among others. Having monitored this space closely over the years, we believe Mobidiag's Novodiag platform is a truly differentiated asset with a unique combination of ease of use, rapid turnaround, multiplexing and low cost.

Mobidiag generated more than $40 million of revenue in calendar 2020 with a limited commercial presence and no sales in the United States. So we believe we can accelerate their growth globally, but especially in the United States once we get some of their assays approved here.

Before I turn the call over to Karleen, I wanted to touch briefly on how we have also strengthened our Breast and Surgical businesses during the pandemic.

In Breast, we have continued to expand on our strategy to diversify the business across the patient continuum of care. We now sell a full portfolio of capital equipment, hardware and software upgrades, interventional tools and service. While the world has been understandably focused on COVID, we have increased our direct presence with Breast Health customers. We have launched new software products based on our investments in artificial intelligence. And we have strengthened our interventional franchise by relaunching Brevera which is doing very well, and buying SOMATEX, a longtime partner and leading developer of breast cancer markers. Together, all these strategies helped Breast Health outperform in the second quarter with total sales exceeding 2019 levels and global growth of 7.3%. While the mammography market is not quite back to pre-COVID levels, we are very pleased with our competitive position and growth outlook for the future.

In Surgical, both our R&D and business development pipelines have been productive. broadening the portfolio of products that we sell through a high-performing, highly-engaged sales force.

New products such as our Fluent Fluid Management System, new hysteroscopes and Acessa's laparoscopic RF product, ProVu are complementing our market-leading MyoSure and NovaSure devices. As a result, Surgical sales surpassed 2019 levels in the second quarter and grew 6.6% on a global basis, even while overcoming a slow January that resulted from reduced procedures in U.S. regions that were hit hard by COVID.

So in conclusion, I want to emphatically state that I have never been more excited or confident in our future. We have responded to the world's need for COVID testing in a remarkable fashion and will continue to be there for testing needs around the world.

Even more importantly, we have literally strengthened every one of our businesses in every geography and added multiple new growth platforms to our company during the last 12 months. I am truly amazed at what our team has done, and we really look forward to the quarters and years ahead.

Now I'll turn the call over to Karleen.

Karleen M. Oberton - *Hologic, Inc. - CFO*

Thank you, Steve, and good afternoon, everyone. In my remarks today, I'm going to provide an overview of our divisional sales results, walk through our income statement, touch on a few other key financial metrics and finish with our guidance for the third quarter of fiscal 2021.

As Steve said, our second quarter results were excellent as revenue and EPS grew significantly compared to the prior year. Reported revenue of $1.54 billion increased 99%. Organically, revenue grew an even 100%, driven by strong growth in our base businesses and a healthy contribution from global COVID testing revenue.

We met our top and bottom line guidance even as the COVID testing market changed rapidly late in the quarter. Based on our strong top line, we significantly improved profitability compared to the prior year. As a result, EPS of $2.59 more than quadrupled in the second quarter, increasing 354%.

Further, operating cash flow has continued to be exceptionally strong, which I'll discuss in a moment.

Before I do that, let me provide some detail on our divisional revenue results. In Diagnostics, our largest division, global revenue of $1.065 billion grew 225% in the second quarter. This was driven by molecular where sales increased 378%.

Although COVID testing declined sequentially from peak levels in the first quarter, demand was still very high. We shipped about 27 million COVID tests to customers, generating revenue of $680 million globally. Excluding COVID, our base molecular business continued to grow as customers capitalize on the breadth of our assay menu and the strength of Panther's best-in-class automation. Rounding out Diagnostics, the Cytology & Perinatal businesses grew 1% in the quarter, in line with trends before the pandemic. In Breast Health, global revenue of $336.3 million grew 7%, which we are very pleased with.

Revenue also increased sequentially compared to Q1 and exceeded the second quarter of 2019 on a reported basis. The division's strong performance was well rounded as breast imaging grew 6%, driven by upgrade packages, and the interventional business increased 14%, driven by Brevera. Furthermore, Breast Health achieved growth in disposables, service and even capital versus the prior year period. Although the capital environment probably isn't fully back to normal, we have been encouraged by the continued improvement in this area as customers have learned to effectively manage through the pandemic and become more comfortable making future investments.

In Surgical, second quarter revenue also exceeded 2019 levels, continuing the division's rapid recovery. Compared to the prior year, sales of $114.2 million grew 7% as elective procedure volumes strengthened throughout the quarter following a challenging January. The improving macro environment, coupled with multiple new products and a motivated sales force gives us confidence in the future trajectory of the Surgical franchise.

Lastly, in Skeletal, revenue of $22.6 million declined 7% compared to the prior year. Overall, in terms of geography, domestic sales of $1.06 billion increased 85% on a reported basis. On an organic basis, U.S. revenue was up 87%. Outside the United States, sales of $474 million increased 142%. Organically, sales outside the U.S. grew 141%, a fantastic result that reflects our growing international strength.

Now let's move on to the rest of the P&L for the second quarter. Gross margins of 75% increased 1,400 basis points driven by the sales of our high-margin COVID tests. Total operating expenses of $277.7 million increased 25% in the second quarter. This included about $1.3 million of credits from BARDA associated with the development of our COVID assays. This is about $5 million less than in Q1.

The increase in our operating expenses was driven by investments in R&D and marketing for future growth as well as incremental expense from the acquisitions that Steve discussed. Also remember, that in the second quarter of 2020, we had begun to pull back on spending, given the initial uncertainty of the pandemic.

Our non-GAAP tax rate in the quarter is 21.2%, slightly lower than forecast, driven by a favorable geographic mix of income, primarily from sales of COVID-19 assays outside the United States. Putting these all together, operating margin increased 2,540 basis points to 56.9%, and net margin increased 2,380 basis points to 43.8%.

As a result, non-GAAP income finished at $674.1 million and non-GAAP earnings per share were $2.59, in line with our guidance and more than 4x the prior year period.

Before we cover our guidance, I'll quickly touch on a few other financial metrics. Driven by demand for our COVID tests and the strong performance of our base business, cash flow from operations was $552 million in the second quarter. These strong cash flows have given us tremendous financial and strategic flexibility. For example, in the second quarter alone, our operating cash flow essentially paid for $568 million of productive capital redeployment. Specifically, we repurchased 1.6 million shares of stock for $120 million, closed the SOMATEX deals for $63 million, acquired Biotheranostics for $232 million and bought Diagenode for $153 million.

As Steve said, we believe these acquisitions will make Hologic a stronger company as the pandemic subsides and sets us up for faster growth.

Overall, we had $816 million of cash at the end of the second quarter, and our leverage ratio was 0.7x. We intend to continue to put our cash to work on a combination of division-led, tuck-in acquisitions and share repurchases that improve our top and bottom line growth rates.

Finally, ROIC was 33.4% on a trailing 12-month basis, a significant increase of 2,090 basis points.

Before we open the call for questions, let me discuss our expectations for the third quarter of fiscal 2021. While we anticipate that fiscal 2021 will be an excellent year for Hologic overall, COVID testing revenue remains highly unpredictable, so we are continuing our recent practice of providing a single quarter of guidance today.

In our third quarter of fiscal 2021, we expect strong financial results again with total revenue in the range of $1 billion to $1.07 billion, representing constant currency growth of 18% to 26% versus the prior year period. As a reminder, in the third quarter of 2019, we generated about $850 million of revenue, which also included the divested Cynosure business, so we expect to grow above those prepandemic levels.

In our base businesses, we expect continued momentum and recovery to generate very strong revenue growth rates compared to the prior year given the negative impact of the pandemic a year ago. In terms of COVID assay sales, the market remains unpredictable as discussed. While trends seem to be stabilizing today, the environment certainly could change again in May or June, depending on a number of factors, so we're going to be very cautious with our third quarter guidance and get back to our usual practice of providing conservative estimates that we have high visibility on.

If demand exceeds our current expectations, we are poised to deliver for our customers. There's a lot we don't know, but what we do know is that our assays and systems are best-in-class, and that we have Panthers in all the right hospitals and labs. So we are confident that we will get more than our fair share of the ongoing demand.

With this background, we expect sales of our COVID test to range from $200 million to $250 million in the third quarter. In addition, COVID-related items in Diagnostics such as collection kits, instruments and ancillaries, are expected to be down $40 million to $45 million sequentially. Our third quarter guidance includes about more than $20 million of revenue from SOMATEX, Biotheranostics and Diagenode. Backing this out, as well as $9 million of expected Blood Screening revenue, we expect organic revenue growth of 15% to 24% in the quarter. This is excellent growth against a difficult comp as we generated 324 million of COVID assay sales in the prior year period.

Beyond revenue, here are a few other points on guidance. Our guidance does not include the impact of the pending Mobidiag acquisition, which is expected to close early in our fourth fiscal quarter. It does, however, include a full quarter of expenses from Biotheranostics and Diagenode, which will contribute to a sequential increase in total operating expenses. Below operating income, I would point out that we expect other expenses net to increase to about $25 million in the third quarter. Our guidance is based on a tax rate of 21.5% and diluted shares outstanding of 261 million for the quarter. All this nets out to expected EPS of $1 to $1.15 in the third quarter. This would translate into very strong growth rates of 33% to 53% that significantly outpaced revenue, even as we increase investments for future growth.

As you update your forecast, let me remind you that macro uncertainty due to the pandemic is still high. We would therefore encourage you to model at the middle of our ranges which incorporate both potential upsides and downsides.

Before we open the call for questions, let me wrap up by saying that Hologic showed tremendous growth in the second quarter and posted results that met our guidance. We continue to make a huge impact on the pandemic and on women's health globally. Further, with organic investments and multiple acquisitions, I am confident that we will emerge from the pandemic a stronger, larger, faster-growing company.

With that, I will ask the operator to open the call for questions. Please limit your questions to 1 plus a related follow-up, then return to the queue.

Operator, we are ready for the first question.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will go first to Jack Meehan of Nephron Research.

Jack Meehan - *Nephron Research LLC - Research Analyst*

Steve, Karleen, I appreciate all the color on the many dynamics at play when it comes to COVID testing. I was wondering, as you look at the guidance for the upcoming quarter, how much of the sequential step down would you say is related to kind of burn down of inventory that's in the channel?

And if you'll humor me, how are you thinking about longer-term demand for COVID testing given all the additional capacity that you're building?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, Jeff, it's a great question. If we dimensionalize, we clearly see the inventory bleeding down, both in the tail -- really throughout last quarter, and we're assuming continuing to bleed down this quarter.

The hard part for us, we kind of internally use the toilet paper analogy, and I think people can understand this really easy. When households first went into COVID, they're ordering toilet paper from everywhere, right, and multiple brands and from multiple vendors.

And what clearly happened here, and I don't think it's been as fully grasped in the outside world has been all of the vendors stockpiled as much supply as they could get from multiple vendors because we, of course, had people on allocation. So when you can't get enough what do you? You order and now they're bleeding through that.

I think we look forward to the day where that's probably bled down and we're back to tests matching -- test chip matching test perform. I think as that comes, that would clearly probably be a little bit of upside. We're being a little cautious in how we're continuing to think about that bleed down.

Looking forward to the second part of your question, you've been all over it. Look at everything. I think we still see this as a meaningful business for us in the future. And to put in perspective, the $200 million to $250 million that we've guided to for this quarter, while it looks like a big step down from where we've been, I would remind everybody on this call that is larger than our entire Molecular Diagnostics business ever was pre-COVID. So we're still looking at a big business, and that's why we're continuing to expand our production.

And personally, I think we're going to see a pretty strong -- we're assuming right now in the U.S., call it, June, July, August could be pretty solid. I think as things come down, people get up. But dollars to dots, next fall, you know what? People didn't get the flu this year. They didn't get sick as people start to get out again, there's going to be a lot of people getting sniffles, getting all kinds of stuff. And whether it's COVID or not, the fear of COVID is going to create an enduring demand. And by that point, all the peripheral vendors candidly will be gone. And it's going to be the big folks with the installed bases and the most automated basis that will prevail.

And so I think we feel really good as we listen to all of our customers, they want the automated platforms. They're using up their nonautomated stuff just because they bought it, and they can't wait to really start just running Panthers in our tests. So I don't want to give you an exact number at this point because I think anybody that does is wildly speculating. So -- but I do think this is going to be a big sizable business for us, certainly well into our next fiscal year. But we're planning a little more cautiously near term.

Jack Meehan - *Nephron Research LLC - Research Analyst*

That makes sense. And pricing looked firm in the quarter at around $25. Do you expect to hold at these levels, given your positioning with the automated system in the market? Or do you think it makes sense to get a little bit more aggressive here?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

I think we will be more aggressive here as we go forth, particularly as some of our possible vendors buy for, for example, the school contracts that, you know, just got sort of delayed.

We -- at this point, as supply has ramped up in our ability, we can offer some of the cost savings through to our customers. And frankly, it will still be very good for us and very good for them. But I would think as we look over the next year, you should expect that to definitely move down.

Karleen?

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. I would just say as well, Jack, as international becomes a bigger piece, we'll see the overall average ASP come down for sure.

Operator

And so we'll move to our next question from Dan Leonard of Wells Fargo.

Daniel Louis Leonard - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

So two questions. First off, it looks like your Diagnostics business, excluding COVID, might have grown about 11% organically? First off, is that correct? And then secondly, why wouldn't that be a bit better given the easy comp, the tours, the higher Panther installed base, the things we've been talking about?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. Dan, I think a couple of pieces there. First off, we didn't exactly have an easy comp. Last year, if you recall, in Europe, our Diagnostic -- our Molecular Diagnostics business grew, I think, well over 30% in the quarter. We had actually a monster quarter last year when we reported at this time, so we had a big number. The other piece, candidly, is we're watching the toggle and the shift. So still a huge part of the volume is being used for COVID. I think as we start to shift out here, that will start to grow.

Now it's also dependent on women going back for their health visits. And the one thing we have certainly seen, and I think this bodes well for the future quarters for us is well women's visits are still way down, there are still a lot of basically pent-up demand that should come back here over time, but it doesn't snap back immediately to 100%. A lot of the intercity clinics have been diverted to doing COVID testing as they start to get back up to speed. So in a weird way, I think it gives us more runway going forth, but probably slightly less than exciting in the near term on necessarily that base. We also have the ancillaries and some of the other stuff that are in those numbers.

Daniel Louis Leonard - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

Okay. And then my second question, so the COVID views amongst the peer sets are really diverging this quarter. Some are using the flu analogy for what might be durable. What do you think about that analogy? And how defensible then is your position in COVID, given that you hadn't historically had a whole lot of market share in molecular flu? And how important is Mobidiag to this calculus?

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Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure. Certainly, over the longer run Mobidiag is going to play beautifully into that. For the coming season, as it relates particularly to the United States, Mobidiag will not be a factor for us. But I still think there's going to be a strong need -- there will certainly be the multiplex opportunities out there. But we think there's going to also be a very strong need as we had continued to say through this year to confirm whether something is truly COVID or not as all the broad tests. So we believe, with our customer base, hospitals, especially key labs, everything else, that there is going to be a meaningful need to confirm whether people have COVID and using a true good molecular platform.

Whereas, frankly, traditional flu, you haven't needed the levels of sensitivity and specificity. When it comes to COVID, people are still going to want that.

Operator

And moving on, we'll hear from Tycho Peterson of JPMorgan.

Tycho W. Peterson - *JPMorgan Chase & Co, Research Division - Senior Analyst*

I actually want to follow up on the Mobidiag question and a couple as well on Diagenode. I'm just wondering, Steve, if you could talk a little bit more about the strategy here with Diagenode? You talked about the CE Mark assays infusion, so how do we think about bringing those to the U.S.? and time lines to build out the menu? And then similarly, with Mobidiag, you're giving 2 instruments, the Amplidiag, which similar to Panther, so how do you think about kind of future menu development on those platforms? Obviously, those are multiplexing, but those platforms versus content on Panther?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. I think, clearly, the way we think about Diagenode is all about content on Panther. And particularly, a lot of the -- if you look at the European landscape, particularly too, there's a much broader base of menu needed over there. And we've been at a little bit of a competitive disadvantage is why we started to work with Diagenode in the first place. So it's really filling out that menu with largely still a focus on our European business.

And I think a totally underappreciated aspect of what's happened to this company in the last 12 months, I would argue, is the strength of our European and frankly, broader international business. We are a completely different player in Europe today when looked at by leading customers, leading governments, everything than where we were 12 months ago. We were barely known, and now we are front and center on so many discussions. So Diagenode is going to play there beautifully.

And then for Mobidiag, we really see it, over time, especially getting into the acute care settings as a big, big opportunity. First, obviously, in Europe, where they've already got a little bit of a presence, but ultimately getting everything ported over and cleared here in the United States. That's probably going to be more of a 2024, 2025 massive growth drivers then. We're being a little conservative in terms of when we get all of that proof tier. But it's going to give us another chance to place a box, that's a different kind of box with different capabilities closer to the patient setting. So I think a really great technology. We know that was a highly competitive process, and are really pleased we've prevailed in that.

Tycho W. Peterson - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Okay. And then for the follow-up, back to kind of the COVID dynamics. As we think about the Panthers you placed over the past year, what percentage of those went into the reference labs? Because I think Quest has said they're expecting 50% sequential decline in COVID volumes this quarter.

And then on the hospital side, how long do you think that inventory work down lasts?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, we're not going to get into the exact split between the reference labs and the hospital labs. I would say they were all meaningful when you look at 717 that we have placed. I think the magic, for us, even with the reference labs as their volumes come down, recall, on TIGRIS, we only have 4 assays approved. On Panther, we have in the teens. So it's immediately opening up the dialogue with those customers to expand our menu, particularly as we come out with the BV/CV other things. So I think that's going to be part of the magic for us as well as being there certainly, if they do end up getting some help on if they get some of the school contracts or other things, but even as we go into next year. So I think we just feel better poised across the board with our Panther placements, which just gives us much more optionality.

Operator

We'll move to our next question from Patrick Donnelly of Citi.

Patrick Bernard Donnelly - *Citigroup Inc., Research Division - Senior Analyst*

Steve, maybe just a follow-up on that last comment. It's great to obviously see the Panther placements, I think, 190 in the quarter. The installed base is obviously much more significant now. Just kind of wondering, I guess, when you think out about the utilization and demand going forward, labs have clearly built out a lot of capacity given kind of this unprecedented demand for COVID. Just wondering, in your view, kind of the key pieces that fill that gap as COVID pulls back clearly comping now. But even if that remains some level of volumes, what are the key pieces to kind of fill that? And where do you see utilization going on this larger fleet even a couple of years out?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. I think it's hard to probably fully describe our excitement, Patrick, as to where this goes. And let's take it in simple terms. First off, lab folks have been going on adrenaline for the last year trying to get -- there's been so much automated stuff they were dealing with. They all want to consolidate on an automated platform. We're even hearing out of Europe is from a number of customers just recently they just can't wait to get our Panthers fully up and running because they know they can run them after hours. They don't need to be handheld. They don't need people there.

And so I think, as you really look at it, everybody is going to go to the best-performing most automated machines with the best menu. And I hate to say it, but we say it all the time, the cream rises to the top. It's hard to beat our Panther system and with our menu. And I still -- the number of governors that called us last year early on asking why they wanted more samples was because "They kept touring their labs in their states and the people kept saying, look, we need Panthers. We want Panthers, That's the one we want." So I think as this all shakes out here in the coming months, that we will do what we've always done really well and continue to grow our menu and Panther and that volume, which, as you had seen, average revenues per Panther, we've had a tremendous track record over 7, 8, 9 years now. That number is just going to continue to go north.

Patrick Bernard Donnelly - *Citigroup Inc., Research Division - Senior Analyst*

That's helpful. And then maybe just focusing on COVID again. Can you just talk about the trends in the quarter? And clearly, as you noticed, we can all see the data that showed significant softening in March and April. Any metrics you can give around kind of Hologic-specific volume decline?

And then going forward, just how you're specifically thinking about your share as the pie continues to shrink here in the U.S.? And I know you guys have some pretty large contracts historically tied to COVID. How much can those help provide a level of stable volumes? And should we expect any more of those? Or is that dialogue quieted down a bit?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

That was a great like 5-part follow-up, Patrick. We're going to give you the new award. Let me -- I'll try to get it all. And if I don't get it, hopefully, Karleen and Mike were paying close attention. The -- in terms of the quarter, January continued to be remarkably strong. So at the time we were sitting here giving our guidance, think about it, only 90 days ago, vaccines were just barely beginning. We were just transitioning from 1 President to another, vaccines were in the very early days and the post-holiday testing was spiking.

So then we clearly saw it start to -- it kind of turned a little bit in Feb. I think March and April have really been a lot of inventory catch up. And I would argue that, that will shake itself out here probably pretty quickly, and then we'll be to a good place.

The longer-term contracts on the last part, it is why we feel really good about a lot of the approaches we've taken with our governments, particularly around the world, where we often sign folks up for 6-, 9-, 12-month contracts, where we guaranteed them supply. And as of right now, we've not -- you want to knock on wood, but every customer that we've sold into has continued to come back and wants to continue to work with us. And I think that's where we feel really good.

We know a number of the countries that even early on when we said we couldn't provide them what they wanted and they went elsewhere they also came back to us. So I think we see this being more persistent and it is where, certainly, our international footprint, particularly Europe and then the Australia's and New Zealand's of the world. Obviously, we're not a big player in India, so don't expect anything there. But for the major Western markets, we're in a really good place.

Operator

And we will move to our next question from Chris Lin of Cowen.

Chris Lin - *Cowen and Company, LLC, Research Division - VP of Health Care - Life Science and Diagnostic Tools*

I have 2 questions. So first, I want to follow up on the COVID-19 dynamic. So Steve, Hologic has meaningfully accelerated organic and inorganic investments due to the cash flow associated with COVID-19. So with this in mind, could you just comment on how lower-than-expected COVID-19 volume and potential cash flow impact how you think about making these investments going forward? Do you need to pull back? Or are you still going to invest significantly with the longer-term horizon in mind?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

We don't need to pull back on anything because none of the forward-looking thinking is any different than what we probably really expected. So I think what's been magical is we've used the cash, and it just kind of worked out really well in terms of the investments that we've made. We never expected this. It's why we didn't give guidance for the full year. We've taken this entire -- the way we've approached COVID completely has been, look, there's an opportunity here, we're going to try to maximize it for as long as it's there. And eventually, we'll get back to our other business. So I think we feel really good.

I'd also say the balance sheet is even stronger despite being able to buy shares back, done 5 acquisitions, we are still -- will still generate a meaningful amount of cash here even in the coming quarters. And candidly, we'll probably hit a point where there's only so many more assets we'd be able to metabolize in the recent term, especially in the Diagnostics and European footprints. So I wouldn't expect us to be continuing to try to gobble up as many companies in the coming quarters as we just have. It's been an opportunistic thing, but also no reason to pull back. We're not pulling back on any forward-looking plans.

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. And I would say we are not different from prepandemic. We had talked about we are focused on deploying our free cash flow to share repurchase and tuck-in acquisitions, so we'll continue to do that even as the COVID testing comes down.

Chris Lin - *Cowen and Company, LLC, Research Division - VP of Health Care - Life Science and Diagnostic Tools*

Okay. Great. And then for my follow-up question, I think your 10-Q mentioned that chlamydia and gonorrhea volumes were lower on a year-over-year basis. Could you just elaborate how sexual health testing volumes are tracking to prepandemic levels? And when you see that fully recovering? And I guess, specific to Q3, whether you have built into guidance for non-COVID-19 tests?

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. So I think what we're seeing is that business is still recovering, that women still aren't getting back to their well visits at the prepandemic levels, coupled with a temporary guideline from the CDC about not doing a screening for asymptomatic women. So I think that's some of the pressure we see here in the current quarter.

I think we're assuming that will continue into the next quarter, probably some improvement on well women visits, but we fully expect that, that business will recover as again we kind of get back to prepandemic life.

Operator

And we'll go next to Dan Brennan of UBS.

Daniel Gregory Brennan - *UBS Investment Bank, Research Division - Senior Equity Research Analyst of Healthcare Life Sciences*

Great. Steve, you talked about in the opening remarks how the company was growing 5% pre-COVID. And now, certainly, given the acquisitions and the installed base, you expect to be a higher level. I haven't heard the question asked, maybe I missed it, but can you elaborate a little bit on that? Give us a sense of what you're thinking about for go-forward growth rate for Hologic? And any other kind of building blocks to get to that number?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. Dan, we're not going to articulate on this call exactly what that looks like. But clearly, as you know, for years, we were kind of in that 3- to 4-ish range. We were moving it up into that 5 range. And I think as we look at what we've been able to do both organically, but really strengthened -- the acquisitions we've been able to do put us a lot better off than if COVID hadn't hit, right? We probably wouldn't have bought Mobidiag, Biotheranostics, all of these things, all of which should be accretive to that growth rate. So do we see us moving a little north of that 5%? Yes. Are we ready to commit to an exact range? We have our June Board meeting where we will be looking at our strat plan with our Board.

But I can just tell you the early roll-ups, I think we look at every business being able to be at least mid-single, if not moving into the higher single digit and particularly with our international business.

Now on a completely different footing than it ever was, we think we'll be able to really drive all of our franchises stronger outside the U.S. So I think it puts us clearly north of 5, which I think is a very meaningful step-up for this company. It's not something we've had from a sustained growth, and I think that should not be lost. And I'm glad you asked about it.

Daniel Gregory Brennan - *UBS Investment Bank, Research Division - Senior Equity Research Analyst of Healthcare Life Sciences*

Great. Steve. And then as a follow-up, I know it's been asked a number of times. I'm just wondering, given the COVID strength that you've had and obviously, the rate of decay that we see will be important for your top line results. But just how do you think about the right mix, if you will, of testing as we move out beyond this year into next and we get to a steady state on COVID between PCR and maybe rapid testing. I think you discussed earlier the accuracy is really important here, much more so than flu. So we're just trying to try to think about what the right numbers to plug into models and kind of that aspect will help in terms of the mix that you see unfolding as we -- as COVID flows.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. Thanks, Dan. I think consider us biased because we are in the molecular space. But I think as more and more people have had bad experiences candidly with rapid tests. And I think all of us know a number of people who have had false results. I think the dynamic is going to play out where there's going to be less testing -- less people racing out to need the immediate test and to try to get something super quick.

And as you move into a vaccinated world and more of an ongoing monitoring where a few hours isn't going to make a difference, I think it's going to revolve much more towards most diagnostic testing, which is you want to use the most sensitive and most specific tests. We just think that's going to ultimately prevail and that a lot of the euphoria and urgency and design -- even some of these people calling for -- everybody would be taking a test every day, dah, dah, dah, you know what, it's just we don't see it that way.

Ultimately, the market will decide and you can come back and slap us upside our heads if we're wrong. But I think we see it playing out as a more traditional market over time where it goes to our advantage.

Operator

And we'll go next to Anthony Petrone of Jefferies.

Anthony Charles Petrone - *Jefferies LLC, Research Division - Healthcare Analyst*

A few follow-ups on just all around Diagnostics and one on capital. Steve, maybe in the 200 to 250, if you could give us a break on U.S. and Europe? I know, in the past few quarters, Europe, as it relates to COVID testing, was underweighted for Hologic, but was growing. So I'm just wondering how Europe plays out when there's still heightened pandemic there? And then on Mobidiag and Diagenode, I'm wondering what the combined installed base of platforms is there? And is there a pathway to consolidating those tests on Panther over time?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. The -- in terms of the first part, the COVID, I think we'll see Europe being a bigger percentage of our revenue probably this quarter than even the 40%, I think, we -- part of our business, we feel really good about the longer-term contracts we booked with Europe. And obviously, with the rollout of the vaccinations not going nearly as rapidly there. I feel pretty good about the persistence of the COVID testing in Europe. And then Mike is waving his hand here.

Michael J. Watts - *Hologic, Inc. - VP of IR & Corporate Communications*

So Anthony, on the second piece about installed base, you remember Diagenode, think of Diagenode as an assay factory. So the priority there is to really get their PCR expertise in those tests onto our Fusion installed base, right, which is roughly 15-or-so, 1 5 percent, of the 2,600 that we have out in the field.

Mobidiag is a little bit of a different situation. The focus there is really on their Novodiag instrument, which is the more rapid turnaround instrument, and they're really just getting started with a relatively small installed base, even in Europe. And in the United States, I don't think they have any revenue, so there's clearly some big opportunity there on that Novodiag instrument.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. It will be more focused on driving that instrument than necessarily taking their stuff over to Panther.

Operator

And we'll go to that last question from Vijay Kumar of Evercore ISI.

Unidentified Analyst

This is Cindy on for Vijay. We notice the gross margin this quarter was down about 200 basis points sequentially. Could you walk us through those drivers behind that decline?

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. That's simply just because of the lower COVID revenue. So COVID revenue was about $745 million in Q1 and $680 million in Q2, so that decline in that very accretive gross margin revenue was the reason for the decline. But note, it's still at -- 75% is pretty exceptional.

Operator

One more question. And we'll go to Ivy Ma of Bank of America.

Xiaoxiao Ma - *BofA Securities, Research Division - Associate*

So just wanted to follow up on the broad screening opportunity. Steve, as you mentioned earlier, the school programs sort of got delayed. So just wanted to see if there's any details you could share around upcoming catalysts? And when we could expect those would be helpful.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. I think the broad approach we're taking is just trying to be there for our customers. If some get the school contracts, that would be great, we'll be there for them. If they don't, we'll be supporting other stuff. So I think that's probably the only potential bigger catalyst, I think, Ivy on the horizon, but other than -- and obviously, that will really kick in for the fall. But I think there'll be ways that, obviously, we'll be working with various customers to be able to help support any of those initiatives.

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. And we have the pooling claim as well, which will be helpful for those screening programs.

Xiaoxiao Ma - *BofA Securities, Research Division - Associate*

Great. And a quick follow-up for Karleen. Could you maybe comment more on the margin profiles of the recent acquisitions? And any opportunities for margin upside from those? And how long those might take?

Karleen M. Oberton - *Hologic, Inc. - CFO*

Yes. I think we had talked about Biotheranostics as probably a little accretive to the overall gross margin profile of the company, but more in line with diagnostics. And I would think that Diagenode, at this point, may be a little less than the overall average and Mobidiag would be a little less than the average at this point. But those are things that as we build those installed base and grow those revenues they should get in line.

Operator

And thank you. That is all the time that we have for questions today. This now concludes Hologic's Second Quarter Fiscal 2021 Earnings Conference Call. Have a good evening.
