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ATRC - Q3 2017 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Third Quarter 2017 Earnings Conference Call. (Operator Instructions) I would now like to turn the call over to [Lynn Lewis] from the Gilmartin Group for a few introductory comments.

Unidentified Company Representative

Thank you. By now you should have received a copy of the earnings press release. If you have not received a copy, please call 513-755-4136 to have one emailed to you. Before we begin today let me remind you that company's remarks include forward-looking statements. Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control, including risks and uncertainties described from time to time in AtriCure's SEC filings. AtriCure's results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statements.

Additionally, we refer to non-GAAP financial measures, specifically revenue reported on a constant currency basis, and adjusted EBITDA. A reconciliation of these non-GAAP financial measures with the most directly comparable GAAP measures is included in our press release, which is available on our website. With that, I'd like to turn the call over to Mike Carrel, President and Chief Executive Officer. Mike?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Thanks, Lynn. Good afternoon, everyone, and thank you for joining us. I'll talk in more detail about our accomplishment and key initiatives during our call, but first, I'll start by summarizing our third quarter revenue performance.

During the third quarter, we posted revenues totaling \$42.2 million, representing year-over-year growth of 10%. We had our best Epi-Sense quarter to date and solid international performance, and our long-term drive to the MIS space continues in earnest. We did experience softer-than-expected results in the Open ablation and Clip businesses, driven particularly by the hurricanes across the Southeastern states. Our quarter was also impacted modestly by a combination of longer vacations and continued physician movement in parts of the United States. As a reminder, the use of our product is a secondary component of the Open procedure. When there is physician movement, it creates an opportunity for us to train new surgeons and expand adoption for the long-term, but it takes time to get even the most skilled cardiac surgeons up to speed on concomitant ablations.

We do expect some continued disruption in the fourth quarter, as communities come back online in Florida and from the fires in northern California.

As a result, we are updating our guidance to incorporate our Q3 results and lower growth expectations for Q4. We now expect full-year 2017 top line growth of approximately 11% to 13% year-over-year.



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As we digest the quarter over quarter variability, we are continuing to evolve our business and grow our minimally invasive presence. Our underlying business momentum in this area is steadily building -- and we are advancing our clinical programs and making meaningful progress with CONVERGE. This all points towards strong medium and long-term market opportunity and continuing our track record of five straight years of double-digit revenue growth.

Now, we'll turn to the specifics of our quarterly performance, beginning with our U.S. Open business. On the heels of a strong growth in the first six months of the year, third quarter performance in our open business was more muted for the reasons that I stated earlier. We continue to work to drive broad, consistent adoption growth by improving adoption of surgical ablation in a concomitant setting through our company-sponsored education programs, as well as partnerships with key societies. We have expanded our Advanced Courses and the MAZE IV training events, and the attendance is at full capacity for the year.

Finally, the updates to the STS and HRS guidelines are spurring energized discussions and enthusiasm in the provider community. Surgeons and cardiologist are recognizing the clinical, safety, and societal benefits of surgical ablation and we believe the updated guidelines are starting to influence care. We expect tailwinds from these and other medical society recommendations to support procedural growth in the coming years, and over the long-term.

Moving to AtriClip, third quarter results were marked by increasing traction across our portfolio. The portfolio was disproportionately impacted by weather disruption in the third quarter, as Florida represents our largest market for the AtriClip products by far.

In our continuing effort to bring innovative and less invasive technologies to market, in Q3 we launched the AtriClip Pro-V device in the U.S. AtriClip Pro-V is another significant step toward a comprehensive strategy for minimally invasive management of the left atrial appendage. It offers an open-ended design, combined with a tip-first closure mechanism to enable easier navigation and placement when operating in a minimally invasive environments. Early experience and feedback from clinicians utilizing the Pro-V device to treat patients has been excellent, and we are happy that it is now available across the entire United States. This platform will also serve as a foundation for future innovation, and increasingly less invasive applications of our AtriClip platform. We expect Pro-V contribution to ramp in early 2018.

For our MIS ablation business, the Epi-Sense product line was again strong, with significant growth both year-over-year and sequentially. We are pleased with our traction into new accounts, and we are increasingly confident that our MIS strategy will drive progressive collaboration between cardiac surgeons and EPs. The focus continues to be on both new accounts and deeper presentation into our existing base of customers, driving both increased and steady utilization. As we have discussed before, we are still just scratching the surface here, with our results to date, and expect Epi-Sense to generate momentum through the rest of 2017, which will be sustained into the future.

Internationally, sales were solid in the third quarter, marked by strong performance throughout Europe and Japan, with Japan growth driven by recent registrations for our Cryoablation and AtriClip lines for that market.

Moving to our clinical programs, CONVERGE continues to be our top priority. We now have 25 sites enrolling, and recently enrolled our 95th patient. So far this year, we have significantly increased the number of sites versus last year and have enrolled 43 patients, which is more than double the enrollment achieved in any previous full year. We also received FDA approval to allow a sub-xyphoid approach within the trial, which we feel is another recruiting catalyst and also important, as we feel that many physicians were choosing this approach outside of the trial. We are working diligently to continue expanding the number of sites, and are investing significant resources in patient recruitment activities. With the increased momentum in our new and existing sites, at our current pace we expect to have enrolled more than 100 patients by the end of the year, and complete enrollment by mid-2018.

We also reached the halfway market on our company-sponsored FROST study by enrolling the 50th patient at Beaumont Heart Hospital in Detroit, Michigan. FROST evaluates whether inter-operative intercostal cryoanalgesia using our cryoICE probe, provides superior post-operative and long-term pain relief and return to normal function, as compared to current pain management in patients undergoing unilateral thoracotomy cardiac procedures. The study plans to evaluate lung function, pain, opiate consumption, and duration of hospital stay.



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Anecdotally, surgeons that have adopted cryoanalgesia therapy in their practice are hearing from their pain management partners that this therapy has the potential to change the standard of care in pain management for cardiac and thoracic surgery. With the opioid epidemic at an all-time high in the United States, there is a strong focus on finding alternative ways to manage pain in both acute and chronic pain settings. We know that once a patient is exposed to an opiate, they are at a five times increased risk of developing a long-term addiction to medication. Cryoanalgesia therapy has the potential to significantly reduce the need for opiates. The FROST study brings us one step closer to evaluating this therapy to standard of care.

As many of you know, we had paused the DEEP trial. We recently received approval from the FDA to move forward with the trial, and we are excited about this, as it provides another alternative for minimally invasive procedures.

To wrap up, our third results were mixed, with our overall growth rate softer than we had reported in the first half of the year, yet we are still on track for double digit growth for the year. Our MIS business is thriving, and we continue to be focused on the strength of this growth market. We are also making meaningful progress with our clinical programs, and the new product introduction, all of which set the stage for strong growth in many years to come.

I will now turn the call over to Andy Wade, our Chief Financial Officer, and then wrap up with some closing comments.

M. Andrew Wade - AtriCure, Inc. - CFO and SVP

Thank you, Mike. For the third quarter of 2017, revenue increased 9.9% on a GAAP basis, to \$42.2 million, and 9.3% on a constant currency basis. Revenue for the U.S. was \$33.4 million, an increase of 9.2% from the third quarter of 2016. We estimate that Hurricanes Irma and Harvey had a significant impact on our U.S. revenue, with the bulk of the impact in Florida, on our Open ablation and AtriClip businesses. We estimate that weather-related disruption represented roughly \$1 million of lost sales in the third quarter.

Revenue from open chest ablation-related products in the U.S. increased by approximately \$600,000, to \$15.4 million, representing growth of 4%.

U.S. sales of products used in minimally invasive procedures increased approximately \$1.5 million, to \$9 million, up 20.4%. Epi-Sense growth continues to be strong, and one our fastest-growing products. The products supporting totally thoracoscopic procedures were relatively flat over last year, with the physician-specific weakness described on our second quarter call being largely offset by new business.

U.S. sales of the AtriClip system during the third quarter of 2017 were \$8.5 million, as compared to \$7.7 million for the third quarter of 2016, an increase of 9.7%.

International revenue grew 12.8% on a GAAP basis and 9.5% on a constant currency basis, as compared to the third quarter of 2016, to \$8.8 million. Growth was robust in nearly all of our key international markets, notably Japan, France, the BeneLux region, the UK, and Germany. Weaker markets included China and Russia.

Gross margin for the third quarter of 2017 was 73.4%, as compared with 71.7% for the third quarter of 2016. The increase in margin from prior year was driven primarily by the mix of product sales and geography.

Operating expenses increased 11.9%, or approximately \$4 million, from \$33.8 million for the third quarter of 2016 to \$37.8 million for the third quarter of 2017. Research and development expenses, which include clinical and regulatory activities, were \$8 million for the third quarter of 2017, or 19% of sales, a slight decrease of approximately \$300,000 from the third quarter of 2016. The decrease was primarily driven by the timing of R&D projects and regulatory filings. SG&A expenses increased approximately \$4.3 million from the third quarter of 2016, to a total of \$29.8 million, or 71% of sales. The increase was primarily due to additions to our domestic and international sales organizations.

Our adjusted EBITDA loss was \$958,000 for the quarter, compared to a \$1 million adjusted EBITDA loss for the third quarter of 2016. Our net loss per share was \$0.22 for the third quarter of 2017, compared to \$0.21 for the third quarter of 2016.

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We ended the quarter with approximately \$34.4 million in cash, cash equivalents, and investments.

Lastly, we are updating our guidance for 2017. We anticipate top line constant currency growth of approximately 11% to 13% year over year. This is based on the weakness we experienced in the third quarter, along with the expectation of ongoing pressure in the fourth quarter. We expect some residual impact from the hurricanes and the California fires, as hospitals and our team get back to full strength.

We continue to anticipate gross margin will be approximately 72% to 73% for the year. The bottom end of this range represent a slight increase from the 2016 reported gross margin. We are still targeting long-term gross margins of 75%, and believe this is achievable within the next few years, due to increased volume and efficiency, along with changes in product mix. We expect R&D to be 20% to 21% of sales, a slight improvement compared to 2016. Significant investments in this area include the CONVERGE trial, other clinical science activity, and R&D pipeline development. We expect SG&A to be roughly 67% to 69% of sales in 2017, which is a slight improvement compared to the 2016 rate.

We continue to expect adjusted EBITDA for 2017 to be a loss of approximately \$4 million to \$6 million, a marked improvement from the adjusted EBITDA loss reported for 2016. This adjusted EBITDA range translates into a loss per share of between \$0.94 and \$1.04. We continue to expect adjusted EBITDA profitability in 2018.

At this point, I would like to turn the call back to Mike for closing comments.

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Thank you, Andy. In closing, we are continuing to advance our business with considerable progress on CONVERGE, robust growth in EPI-Sense, an exciting new MIS platform, with our ProV launch, the addition of some great executive team and board members, and strong bottom line results and progress. We are successfully building a portfolio of products with excellent clinical data that expands our reach, impacts our patients worldwide, and positions AtriCure for both medium and long-term success.

With that, we'll turn the call over to questions.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions) Rick Wise, Stifel.

Unidentified Analyst

It's Drew on for Rick. Just maybe let me start with some of the issues that happened and then look ahead. But Mike, you've talked about- you've explained some of the transitory items, like weather, but there's been some past weakness, if I remember, before, maybe a few quarters ago, from physician movements, so is this maybe an ongoing trend of what you're seeing in the market, and I mean, how does that change, if it does, maybe your outlook for the open ablation business or MIS or the clip business?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Yeah, excellent question, and just to restate them, the predominant piece of the impact for the quarter, and even as we look into the fourth quarter in terms of on a guidance piece, was really a lot of the weather and the impact, not just the weather when it hits, but also the weather in terms of when people are coming back. I mean, a lot of our reps and people moved out of the state of Florida for a few weeks and then had to come back, kind of got their legs underneath them, and they're really just beginning to kind of get themselves back. And that really is the biggest impact of



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uncertainty for us. And Florida happens to be our largest market in the country, and so both for the clip, it's got impact on the MIS, and the open business as well, as I talked about.

As it concerns physician movement, it was as much and really more than anything else, the bigger impact was actually some physician vacations. We were very strong through the end of July, and then it was just a larger proportion of physicians that took vacation than had previously done that, two to three week vacations that we saw in the August and early September timeframe, right around the time when the hurricane was hitting, so that really put some pressure on the business for sure in the summer months. And we saw that pretty dramatically after the- after the earnings call last time, when we saw the month of August was softer primarily because of that.

Physician movement is definitely something that is now going to happen, and we see that, because as physicians become employees of the hospitals, which over 80% of the cardiac surgeons today are at hospitals, what we're seeing is that they do move almost like free agents, and we're tracking it very closely but when that does happen, we've got to figure out was that surgeon doing the procedure, when they moved to the new site, how do we get them up to speed as quickly as possible, and they don't want to ruffle feathers when they get to a new site, so yes, it's something that we're looking at. It did impact us in the past, and we're going to continue to kind of monitor that and we're looking at ways, how do we make sure we're training those younger surgeons to make sure there's more surgeons at those sites training, and that's something that we're actively working on, and so yes, I think it's something that we'll continue to see in the open business, as we go forward. And remember, even with the open business, when we started the year, we said we were going to be in the mid single digits on that. We still anticipate it-- on the annualized basis, we'll still be in those kind of numbers. It was just softer as I mentioned here in the third and fourth quarter, again, primarily because of weather and the Florida hit.

Unidentified Analyst

OK, I understand that, and I just to move to DEEP for a moment. So congratulations on getting it approve again, but can you just maybe remind us of where you stood with DEEP enrollment, prior to the pause, and maybe how should we think about enrollment? Would it be a similar cadence to- with CONVERGE, now that it's in your hands the past couple of quarters? And just what's your focus more, is it CONVERGE or is it getting DEEP enrollment going?

Michael H. Carrel - AtriCure, Inc. - CEO, President and Director

Our number one priority is right now, CONVERGE. We are really getting near the finish line on the enrollment there. That is what the clinical team is incredibly focused on, so that is- that's the focus, and we're at 95 patients, it's 153 patients total. Again, we'll be done by the middle of next year, we've made great progress over the last several quarters as we've gone down that path, and so we're starting to feel really good about that. In terms of the DEEP, we're kind of letting it come on line in terms of- it's been a year and a half with the FDA, obviously, but that didn't take a lot of man hours or resources to do that. We're coming on slowly, we're bringing on three sites right away, because the FDA wants us to videotape them. So we're going to be bringing that along slowly. We were at 41 patients at the time; it's a 220 patient trial in total, and I'm not ready to kind of give any kind of cadence yet, because we're really bringing it online slowly, we're focused on CONVERGE, and then as we kind of get to the finish line on enrollment in CONVERGE, we'll move a little more aggressively with some of the sites on the DEEP trial as well.

Operator

John Gillings, JMP Securities.

John Trevor Gillings - JMP Securities LLC, Research Division - VP and Research Analyst

OK, so first, I want to follow-up a little bit on the challenges with the weather, so maybe you can talk just a little bit about how you got comfortable with the level that those would impact the fourth quarter, and then also whether you're comfortable resolving in the fourth quarter, or if they could actually spill over into the first quarter of next year?



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Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Excellent question. The way we got comfortable in terms of where it was in the fourth quarter is we've done a deep dive, obviously, within our Florida territory area, and a lot of it is, we are a secondary procedure, so we get hit a little bit harder than other companies might get hit because of it not being the primary procedure, per se, and so as things come online, that definitely has impact on us. So some people can respond and come back very quickly, ours is taking a little bit longer, and as our team gets there, it's coming online. We're starting to see some activity, in the Florida area. It's starting to come back nicely, and we were conservative as we kind of looked at the fourth quarter, we said- that's why we gave a wide range on the guidance, is that we want to make sure that we covered any kind of hit that might happen along those lines, and we do feel that by the end of the fourth quarter, as we enter 2018, we should be in a good spot and we should be through most of it. We've talked and worked with every rep and pretty much every one of the accounts over there.

John Trevor Gillings - *JMP Securities LLC, Research Division - VP and Research Analyst*

OK, that's helpful, and then maybe just turning to the PRO V for a minute. You mentioned that you got kind of some early good feedback from physicians. You know, any sort of specific examples of what they're saying they like the most, or what matters the most to them?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

It's the profile is the number one thing, and it's a really simple and small profile, is number one. Number two is just the ease to put it on, the open-ended nature of it, slides on simply, they know they get to the base, the get around it, they love the fact that it works with the exact same pressure points like the existing clip that there's today that, as you well know, we've got about 115,000 implanted today, and so there's a lot of comfort in it from that standpoint, in terms of how it works. But it's a smaller profile, the ease of use of putting it on, manipulating in much smaller spaces, which obviously shows how we can use a more minimally invasive procedure is what they like most about it. And people are getting creative with it, from that standpoint.

John Trevor Gillings - *JMP Securities LLC, Research Division - VP and Research Analyst*

OK, and then just one last quick one from me, and I apologize if I missed it in your prepare remarks, but I think last quarter you had 20 sites up and going for CONVERGE and the goal was to get to 27 by the end of the year. Is that still the plan?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

No, we're focused on- we could get to 27. We've got the two sites that are going through this IRB process, to go from 25 to 27, but our focus now is even though sites that come on line, those last two, probably won't be contributing many patients, because the other ones are doing such a good job right now in the enrollment side, that we're really just focused on just making sure that those are up and running and going, that have been doing and have been part of the program so far are actually doing a good job, and so we're really focused on those sites at this point. And the sub-x thing is also a focus, so we likely will be at 27, but I don't want to commit that we'll be exactly at 27. In fact, it's not going to have any kind of meaningful impact on the overall enrollment.

Operator

Mike Matson, Needham and Company.



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Unidentified Analyst

This is Dave Allen in for Mike. Thanks for taking our questions. So with the PRO V, I was wondering if you can comment on what kind of price premium you're getting for it, and then also if you have a target launch for an open product with the V clip?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Excellent question, actually, and a good set up in many ways. In terms of the pricing, we are definitely getting a price increase for it. We aren't going to talk about the ASP quite yet, because we haven't sold enough of them yet to kind of see if it's sticky on that front. We're holding the line, though, in terms of the pricing pretty well, and we've been able to get most of it, so you can see definitely an increase on the price on that front, but to give a specific amount, I'm not comfortable quite yet to kind of do that. Number two though is an excellent question as well, which is the open-ended clip for the open procedure, we do anticipate that we'll have that product in 2018. I did not mention that in my comments, but I talked about the PRO X, which is the sub-xiphoid approach to it, but we will have an open-ended approach as well in 2018.

Unidentified Analyst

OK, and I mean, I guess, do you have a target for that, or just sometime throughout that year?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Sometime throughout the year. Right now, it's going to be more about when is the right time to roll it out, like to our sales team, and get them trained properly, as opposed to the timing. I think we'll probably- like with the PRO V, the PRO V we actually got through the FDA about a year ago, when we finally launched it, because what we did, we did- we just wanted to make sure it was ready to go and the sites were ready to kind of take it on, and we had the PRO2 in the market. The [ACH], which is our existing clip that's in the market today, people love that product, it works really well. It represents from a volume basis 2/3 if not more of our overall volume of clips, and so we just want to be careful as we roll it, so it will more about the rollout timeframe than it will be about necessarily getting FDA clearance or anything like that.

Unidentified Analyst

OK. Understood. And then lastly, can you give an update on the size of your salesforce and do you have plans to continue expanding?

Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

Yeah, today, we've got about- what we call RSMs, which are our direct reps, there are about 54. We've got almost an equivalent amount, about 50 or so, clinical reps, that help with cases, and then we've also got what we call Minimally Invasive Manager, who helps with CONVERGE and DEEP, and we've got 13 of those today.

Operator

Suraj Kalia, Northland Securities.

Suraj Kalia - *Northland Capital Markets, Research Division - MD & Senior Research Analyst*

So first [inaudible] my comment-



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Michael H. Carrel - AtriCure, Inc. - CEO, President and Director

I think we're missing- you're breaking up on the call. Can you- you might want to try the--

Operator

(Operator Instructions) Danielle Antalffy, Leerink Partners.

Danielle Joy Antalffy - Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices

Mike or Andy, just curious on the weather-related impact in the quarter. It sounds like you're saying there is going to be some bleed into Q4. Are these the type of procedure that you think get made up at some point, and so we should be thinking about possibly some positive impact in Q1 of next year, in fact you think Q4 sees a negative impact?

Michael H. Carrel - AtriCure, Inc. - CEO, President and Director

I don't see that. I mean, usually, with the MIS procedures in particular, what happens is, these are patients that may have been down a pathway- they might happen sometime in 2018 or 2019, but these are likely patients that you've lost on the MIS side, in particular. On the open side, they'll probably come back for cardiac surgery, but the lost ones are those that maybe they got treated but they were really focused on just kind of getting these patients in and out of the hospital pretty quickly, they weren't trying to get the A fib, they weren't focused on it, for whatever reason. You definitely start to see that as they come back. Now they're starting to do the A fib again, within most of those cases, and some of those patients see it as a loss as well, so I don't see us as getting sort of big uptick relative to that next year. I think we'll see the impact on the soft side this quarter, and then we'll just seeing getting back to normalization in the January-February timeframe.

Danielle Joy Antalffy - Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices

Got it, OK, that's helpful. And then just a question on- are you seeing any impact yet through changing guidelines? I know you've talked in the past about more interest in physician training, advanced training courses, so you know, have you started to see some benefit from that, do you continue to think that's going to be a significant, potentially significant, tailwind in 2018? Thanks so much.

Michael H. Carrel - AtriCure, Inc. - CEO, President and Director

I think we're seeing some benefits. It's tough for me to say that on a quarter where our open business wasn't super strong, and I know a lot of it was the weather, but it's just kind of difficult, obviously to stare at the Polycom and say that, "Oh gosh, we're getting a lot of benefit," but there is a lot of positive comments going on, we're having more people come through training, people that had never done these procedures before are now starting to do them, so we're definitely seeing that dialogue. People are realizing that they must treat, and they must get trained. Our courses, we added 20% capacity to the courses this year, we would have added more if we could have had faculty, and we've got- and they're all sold out, and they're all sold into the beginning of next year, so we're seeing a lot of traction and activity and net new people getting trained. And so I do think that that's going to, long-term, benefit treatment overall and enable us to kind of have strong growth as we look out into the future.

Danielle Joy Antalffy - Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices

That's super helpful color. Thanks so much, Mike.

Operator

And I am showing no further questions. I would now like to turn the call back over to Mike Carrel for closing remarks.



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Michael H. Carrel - *AtriCure, Inc. - CEO, President and Director*

I just want to make sure, if Suraj had a chance to call back in; maybe give him a couple of seconds. If not, then I'll close out. All right, so if Suraj can't get on right now, I'll thank you very much for joining the call today, and look forward to talking to you as the quarter comes out. Have a great day.

Operator

Ladies and gentlemen, this does conclude today's conference. Thank you for your participation. Have a wonderful day.

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