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ATRC - Q2 2018 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Second Quarter 2018 Earnings Conference Call. (Operator Instructions) As a reminder, this call is being recorded for replay purposes.

I would now like to turn the call over to Lynn Lewis from the Gilmartin Group for a few introductory comments.

Lynn Pieper Lewis

Thank you, Crystal. 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 e-mailed to you. Before we begin today, let me remind you that the 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 statement.

Additionally, we refer to non-GAAP financial measures, specifically revenue reported on a constant currency basis, adjusted EBITDA and adjusted loss per share. 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 & Director

Thanks, Lynn. Good afternoon, everyone and thank you for joining us. Total revenue for the second quarter was just under \$52 million, reflecting growth of 14.5% over the second quarter of last year. Our top line performance was driven largely by the strength of our appendage management products, and with that franchise continuing to demonstrate significant and meaningful traction in both our open and MIS procedures. We are updating our 2018 revenue expectations to approximately \$193 million to \$197 million for the year.

Turning now, first, to the area of clinical science. We are very close to completing enrollment in our CONVERGE trial. And as of today, we have 149 out of 153 total patients needed. We anticipate we'll complete enrollment over the next month. This will be a major milestone in our effort to get the PMA label for the multidisciplinary convergent approach.



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Our next milestone will be 1-year patient follow-up, which we expect in the second half of 2019 and then the subsequent PMA submission to the FDA. We are also progressing with our other clinical programs, which underway. But as discussed the past several years and emphasized during our Analyst Day in June, the CONVERGE trial is our top priority clinically.

Moving to the operational performance in the second quarter. We are continuing to build out our product pipeline and platforms and are seeing solid traction. This is particularly evident in the results we reported this quarter in our appendage management franchise. Recent launches of the AtriClip PRO V and FLEX V products are driving expansion into new accounts and importantly, they have maintained strong pricing through the incremental value they bring to clinicians. Since its U.S. launch last year, the AtriClip PRO V device continues to be highly additive to our product portfolio. In fact, many of our convergent accounts are now using the PRO V concomitant to the ablations.

We then launched the AtriClip FLEX V device in March of 2018 and realized an immediate contribution in the Q2 results. The AtriClip FLEX V is our next-generation open chest AtriClip device, which leverages the same technology developed for the AtriClip PRO V. This includes a lower profile implant and easier to use delivery system and a trigger-release deployment mechanism. We are increasingly confident that the AtriClip FLEX V will help us grow adoption of the left atrial appendage management in open procedures.

For perspective on our appendage management franchise and recent product launches, we introduced reduced AtriClip -- the first AtriClip device in 2010 and sold approximately 2,600 devices that year. Since then, we have greatly expanded the appendage management portfolio and now offering 7 AtriClip devices and selling over 150,000 AtriClips to date.

Switching gears briefly to pain management. In the second quarter, we established a small dedicated thoracic team to focus on this opportunity in a few select markets. We continue to address evidence development through our clinical studies and are on track to complete enrollment in our FROST study.

We will also launch a new dedicated [cryo-a-probe] later this year, which is optimized for intercostal cryoanalgesia procedures. The opioid epidemic is real and our products may be one way to help.

Internationally, we had strong result in Q2 with revenues up 13% in the quarter. Importantly, we recently formed a partnership with Baheal Pharmaceutical Group to distribute our surgical ablation devices in China. This new multiyear agreement establishes Baheal as an exclusive distributor for AtriCure in China and replaces our previous distributor.

We have had a presence in China for the past 14 years and during that time, several of China's leading hospitals have adopted the AtriCure devices. We are in the process of pursuing additional product approvals over the next several years to eventually bring our product portfolio of surgical ablation and left atrial appendage management devices into the market.

We are excited to partner with Baheal. They bring a solid reputation, size and scale and when combined with our market-leading devices position us well in China for many years to come. As I've highlighted many times before, we are committed to advancing our training and educational programs. We have several training sessions planned throughout the second half of 2018, both in the U.S. and Europe. We have expanded our programs to go beyond just clinicians and now with nurses, fellows and other health care professionals.

We continue to innovate in our courses and even after many years, we are encouraged by the strong interest. We expect that data from the leading medical institutions and societies, coupled with education and awareness will ultimately improve care for our patients and support growing procedural volumes. The clinician community is increasingly recognizing the benefits of surgical ablation and the downside of nontreatment, and we remain well positioned to take advantage of these marketed talents.

Lastly, I want to make a few comments about the Analyst Day that we held in New York late June. 3 leading physicians: Dr. Gillinov from Cleveland Clinic; Dr. DeLurgio from Emory; and Dr. Gerdisch from St. Francis Health, shared their perspectives on our market opportunity with a specific focus on the treatment paradigm for open procedures, appendage management, the CONVERGE trial and the importance of training and education. What we heard from the clinicians was an overwhelming desire to treat atrial fibrillation and manage the left atrial appendage. Such treatment is possible using innovative tools and solutions, many of which come from AtriCure.



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We also heard about the importance of education to drive a change in mind-set and behavior for our customers, which is a critical part of our approach now and into the future. As we think about our strategy here at AtriCure, we are focused on our 3 pillars: innovation, clinical science and education. We are constantly expanding our reach through innovative new products and product improvements to provide solutions that are effective such as the AtriClip FLEX V and PRO V that we've introduced recently.

We are making consistent progress on our clinical programs and evidence-based data to support our products as we talked about with CONVERGE.

And finally, we are driving adoption through our educational programs and collaborations with the professional societies.

With that, I will now turn the call over to Andy Wade, our Chief Financial Officer, who will return -- and I will return for closing comments.

M. Andrew Wade - AtriCure, Inc. - Senior VP & CFO

Thanks, Mike. For the second quarter of 2018, revenue increased 14.5% on a GAAP basis to \$51.8 million. On a constant currency basis, worldwide revenue increased 13.5%.

Revenue from product sales in the U.S. was \$40.8 million, an increase of 14.9% from the second quarter of 2017.

Revenue from open chest ablation-related products in the U.S. increased by approximately \$1.3 million to \$18.1 million, representing growth of 7.6%, driven chiefly by cryo product sales.

U.S. sales of products used in minimally-invasive procedures was \$9.1 million in the second quarter, up 4.5%. This quarter reflects mixed results across our MIS ablation products, with strong growth in both volume and the number of accounts purchasing EPI-Sense, offset by a decline in legacy MIS product lines, which was driven by our Fusion product.

U.S. sales of appendage management products during the second quarter of 2018 were \$13.1 million as compared to \$9.5 million for the second quarter of 2017, an increase of 38.4%. The increase was driven primarily by volume across AtriClip product lines and boosted by a small pricing impact from strong sales of both the FLEX V and PRO V AtriClips, which carry incrementally higher average selling prices than prior versions of the technology.

We continue to remain confident and robust in sustained growth rates for both open and MIS appendage management products.

International revenue grew to \$11 million, up 13.1% on a GAAP basis and 8.3% on a constant currency basis as compared to the second quarter of 2017.

As Mike mentioned earlier, we are happy to report that we had a solid initial order from our new distributor for China. In addition, we had solid performances from Germany, the U.K., Italy and some of our smaller markets in Europe. Similar to the U.S. results this quarter, appendage management products led growth in our international markets.

Gross margin for the second quarter of 2018 was 73.5% as compared with 72% for the second quarter of 2017. The increase in gross margin was driven primarily by product mix, as products sold in 2017 included a high volume of capital equipment in our international markets. Additionally, AtriClip products launched in late 2017 and early 2018 are realizing a higher gross margin than legacy AtriClip products.

We had positive adjusted EBITDA this quarter of approximately \$780,000 compared to a \$372,000 adjusted EBITDA loss for the second quarter of 2017. Our operating income for the quarter was \$958,000 compared to an operating loss for the second quarter of 2017 of \$6.4 million. Our net loss per share was \$0.01 for the second quarter of 2018 compared to \$0.21 for the second quarter of 2017. Please note that a \$5.9 million noncash credit to operating expenses was recorded this quarter related to a change in the contingent consideration liability. Without this credit, the second quarter 2018 loss per share was approximately \$0.19, and we had an operating loss of \$5 million.



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Excluding the impact of the noncash adjustment to the contingent consideration liability, operating expenses increased 10.6% or approximately \$4.1 million from \$38.9 million for the second quarter of 2017 to \$43 million for the second quarter of 2018.

Research and development expenses, which include clinical and regulatory activities, were \$8.7 million for the second quarter of 2018 or 17% of sales, a \$250,000 decrease from the second quarter of 2017. SG&A expenses increased approximately \$4.4 million from the second quarter of 2017 to a total of \$34.4 million or 66% of sales. The increase was primarily due to personnel additions in our domestic and international sales organizations as well as increases in legal costs, training activity and other G&A headcount, with slight decreases in tradeshow and professional services.

We ended the quarter with approximately \$37 million in cash, cash equivalents and investments, up approximately \$1 million from the first quarter. Lastly, we are updating our guidance for 2018. We now anticipate revenues in the range of \$193 million to \$197 million on a GAAP basis.

We continue to anticipate gross margin to be approximately 72.5% to 73.5% for the year based on current trends and investments to support growth. The bottom end of this range represents a slight increase from the 2017 reported gross margin. We are still targeting long-term gross margins of 75%.

We expect R&D to be 17% to 19% of sales, a slight improvement compared to 2017. Significant investments in this area include the CONVERGE trial, other clinical science activities and R&D pipeline development.

We expect SG&A to be roughly 65% to 67% of sales in 2018, which includes the noncash adjustment to the contingent consideration liability recorded in the second quarter. Excluding this noncash adjustment, SG&A expenses represent approximately 68% to 70% of 2018 sales. The overall increase in SG&A expenses is driven by investments in our worldwide sales team and training and education expenses along with the heavier -- along with heavier legal expenses.

We expect adjusted EBITDA for 2018 to be positive, a marked improvement from the adjusted EBITDA loss of \$5.3 million reported for 2017. This translates into a loss per share of approximately \$0.85 to \$0.95.

A key watch item that may influence our ability to achieve our adjusted EBITDA goal continues to be legal costs, largely related to the DOJ investigation. While legal spend decreased from the first quarter, we cannot be sure as to the exact timing of the expenses that may be incurred throughout the rest of 2018. We remain confident in our compliance programs and our commitment to ethical business practices.

We expect an adjusted EBITDA loss of approximately 0 to \$1 million in Q3, which translates to a loss per share in the range of \$0.22 to \$0.26. And then we expect positive adjusted EBITDA in Q4.

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

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

Thank you, Andy. In closing, we are pleased with our second quarter performance and our positioning in both the second half of 2018 and for the long term. Our mission is simple. We are intent on decreasing the global Afib epidemic and healing the lives of those affected. We are successfully building a portfolio of products with excellent clinical data that expands our reach and benefits the patients worldwide. Thank you.

And with that, I'll open it up to the operator.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from Danielle Antalffy from Leerink Partners.



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Rebecca Wang - *Leerink Partners LLC, Research Division - Associate*

This is actually Rebecca for Danielle. Can you guys hear me?

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

Yes.

Rebecca Wang - *Leerink Partners LLC, Research Division - Associate*

Okay, can you just -- well, congrats on the pretty strong AtriClip business. Can you just split the volume increases versus the price for that business? And also, what do you see going forward, how do you feel about that business in the guidance?

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

Yes. So the -- the majority of the growth is actually on the volume growth of the business. We are maintaining and getting good margin and good pricing on the V clips. We talked about them, but the majority of the growth that you're seeing is actually coming from just pure volume, number one. In terms of our growth going forward, it's kind of built into the overall guidance. We're not giving guidance by franchise at this point. We're really focused on the overall number, and we feel comfortable with the guidance that we gave out there.

Operator

Our next question comes from Jason Mills from Canaccord Genuity.

David Kenneth Rescott - *Canaccord Genuity Limited, Research Division - Associate*

It's Dave Rescott on for Jason. Can you guys hear me all right?

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

Yes.

David Kenneth Rescott - *Canaccord Genuity Limited, Research Division - Associate*

Congrats on the quarter, especially in appendage management. I think, maybe first if we start there, especially kind of given last year -- or this quarter was the toughest year-over-year comp for appendage management. Can you maybe talk about the factors you're seeing that are contributing to that growth and especially going forward, given that third quarter is going to be, kind of, the easiest comp? And maybe as far as commenting on, kind of, how growth within that segment has been respective as far as new account openings versus utilization within current accounts?

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

Sure. I'll give you some perspective on it. I mean, that part of the business is growing for a variety of reasons. Number one is the new technology that we've rolled out. We've rolled out 2 new clips: both the PRO V last year that is getting great traction in concomitant treatment when you're doing the conversion procedure. And so we -- it's definitely outstripped our expectation relative to that. People really love that clip. It's really simple, easy to use, very minimally invasive. And so we're getting some growth from that. On the FLEX V that we rolled out in March, we saw great traction



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right away. It's actually not cannibalizing at all our core AtriClip business. It's actually just getting into -- because it's so much easier to use, people that may have been just uncomfortable using a clip before, they're actually beginning to put them on and in particular on the CABG market. That is the largest market on the concomitant open side of our business. So you see one of it is just new technology coming out enabling them to do procedures they were either uncomfortable with doing before or they just want a smaller profile device that's implanted. Number two is that the guidelines have, obviously, driven it as well. The open portion of our business is growing nicely. You get a clip with those. The guidelines to treat these patients that these patients live and do better if you treat them at the time of other cardiac surgeries is definitely impacting and having a positive effect on that part of the business as well. And then just the overall awareness that has been created in the market about managing the appendage and the importance of managing the appendage through other products in the market, but also through data that's been coming out. There was a recent JAMA article at the FDS conference earlier in the year that talked about the benefits of putting a clip on. There were no fewer than 5 different specific speeches at that congress talking specifically about managing the appendage and the importance of managing it and the data behind it. So just all of that really is kind of the tailwind that's kind of behind that market, in particular, and we happened to have a great product that everybody knows works very well. In terms of -- I can't recall the second portion of the question. I think I covered most of it with that.

David Kenneth Rescott - *Canaccord Genuity Limited, Research Division - Associate*

Yes, the second portion is just around kind of utilization versus new account openings with that line of business.

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

Yes. We don't get specific on the utilization side, but I mean, we -- it's in a lot of accounts. We saw -- in the U.S. we're in over 1,000 of the cardiac surgery centers overall as a business. And then within there, we sell AtriClips in the majority of those.

David Kenneth Rescott - *Canaccord Genuity Limited, Research Division - Associate*

Okay, then -- and maybe a follow-up to that. Just looking -- I know in the past you've broken up or I know the CABG kind of has been a larger portion of what revenues could be. And I know in the past you've mentioned around less than 10% penetration. Can you break out as far as what those buckets are within CABG, open, MIS as far as penetration across those lines?

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

No, we can't do it on a quarterly basis. The numbers that we refer to are information that we gather from CMS and other databases that usually report on an annualized basis. So nothing's changed because we'd looking back at 2017 data relative to looking at those rates and incidents. What you can see is we're a little bit a barometer of the growth within the market. And I think that we're a leader in that market, but that's really pretty much all we can say about it.

Operator

Our next question comes from Mike Matson from Needham & Company.

David Joshua Saxon - *Needham & Company, LLC, Research Division - Associate*

This is David Saxon on for Mike. Just a follow-up on one of the previous questions. Just given the favorable mix and kind of what you're expecting for U.S. appendage management. Would it be safe to assume that -- just continued gross margin improvement through the year, given the favorable mix?

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M. Andrew Wade - *AtriCure, Inc. - Senior VP & CFO*

No. I mean, the range is kind of what it is. We've reaffirmed the 72% to -- 72.5% to 73.5% and there's always going to be some wiggle based on product mix. This particular quarter it was favorable, but -- and obviously, we continue to try to step forward into our longer-term goal but the guidance we feel very comfortable with.

David Joshua Saxon - *Needham & Company, LLC, Research Division - Associate*

Okay. And then, kind of, just on the comments around training. Do you track utilization of doctors after you train them? And if so, can you comment on that?

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

We do track and watch, kind of, the use and the treatment afterwards. And it's been consistent for all the years that the surgeons that go to our training, they do tend to see an increase in adoption and training the clinicians. Nothing specific, but it's been consistent from that standpoint. We actually see a lot more now than we used as we see a lot of repeat people that actually came to a class before, they want kind of come again, get a refresher course. Maybe do some more advanced ablations. And so we definitely see that as well.

David Joshua Saxon - *Needham & Company, LLC, Research Division - Associate*

Great. And then just lastly, I mean, I can appreciate the legal expenses have decreased since last quarter. Was there any EPS impact? Or was it negligible?

M. Andrew Wade - *AtriCure, Inc. - Senior VP & CFO*

For the second quarter, it was somewhat negligible. We talked about around \$1 million in the first quarter. So it's come down pretty dramatically, as we talked about most of the work was in Q1. And then early Q2 to prep for document production, but right now, it's very quiet at this point while the DOJ takes all of that into review.

Operator

And our next question comes from Matthew O'Brien from Piper Jaffray.

Matthew Oliver O'Brien - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Just a quick housekeeping question. International stocking, you mentioned a bigger order from your Chinese distributor, can you quantify how much that was?

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

Actually, it was not an international stocking order. So it was a typical order of demand coming out of China. It was the first time that they were into the market. We signed the agreement with them. But it was for real demand with sub-distributors that they've basically got in the market today, so we anticipate that, if you recall back in Q1, we had 0 orders from China and we're kind of back on to a normal track at this point in time. We don't get specific by country numbers. So this is more typical to what we would have otherwise expected in previous quarters under our previous distributor, but no big stocking order.



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Matthew Oliver O'Brien - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

Okay. So then as I look at guidance then for the rest of the year, I mean, you've done just under \$100 million in the first half of the year. You're telling everybody it's going to be \$95 million, \$96 million for the back half of the year. Typically, you do about 51% of your sales in the back half versus the first half of the year. So why the guidance for the back half of the year? Is there something specific that we should be looking for, just given all the momentum in the appendage management business?

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

No, nothing specific. I think that we're just -- we want to make sure as, obviously, the growth in the clip has far exceeded our expectations through this portion of the year. We've had mixed results on the MIS portion of our business and particularly on the legacy side. And we've seen disruptions in the past and surprises. And so those things just, kind of, warrant, I think, an outlook that basically says, hey, we're halfway through the year, and that we don't want to get too far ahead of ourselves.

Matthew Oliver O'Brien - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

Okay, that's fair. And then last for me, Mike...

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

Nothing specific.

Matthew Oliver O'Brien - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

Okay, that's fair. I know you don't want to get us -- you don't want us to get too in front of ourselves on the pain management side of things, but can you talk about the team that you've built there? And how to frame up that market as you explore it or even think about it more broadly into '19?

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

Sure. I mean it's a -- so we've got 4 people that joined. We set up a, kind of, a director that's kind of running that unit right now. Top -- calling on and working with thoracic surgeons, who tend to use this product for pain management. That group is rolled out in 4 cities that we're kind of piloting right now. We will likely expand that group quite substantially next year. The early results right now is we're getting great feedback. I wouldn't say it's driving revenue yet, but it is on the course to definitely driving some revenue and getting into some new accounts from that standpoint. We do view that as a good lever for growth, as we look at '19 and '20 for sure. And as we expand that team from 4 and more than likely at least double it next year.

Operator

Our next question comes from Suraj Kalia from Northland Capital.

Unidentified Analyst

This is [Mike] on for Suraj. First maybe on AtriClips. Can you give us an idea how many were implemented in the quarter and are we still on track to implement 40,000 or 50,000 during the full year?

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

Yes, we didn't give a specific number for the quarter, but we are on track to hit the numbers that you talked about, yes.

Unidentified Analyst

Got it. And then just on MIS ablation, seems to be slowing down a bit both in U.S. and internationally. Any specific dynamics there that we should be looking at?

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

Can you repeat that?

Unidentified Analyst

Yes. Just on the ablation internationally and U.S. with a little bit of slowdown on minimally invasive. Is there any dynamics there that we should be looking at?

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

No dynamics specifically actually on the international front. And we feel really good about the results that came in, overall. I mean, country by country, we actually did well. We talked about China before. We didn't get growth out of China, but we had a consistent number. So we have that, Japan actually had a very good growth. And as we look at the -- on the European side of things, we're beginning to see traction for CONVERGE in Germany and Italy. We've had traction there in the U.K. But other than that, it's just like MIS, in general, you just have some heavy users sometimes that you might feel a little bit of pressure. The same is true in the United States on some of the legacy business that we have.

Operator

And I am showing no further questions from our phone line. I'd now like to turn the conference back over to Mike Carrel for any closing remarks.

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

Great. Well, again, everyone, thank you so much for joining us this evening. Look forward to talking to you over the course of the quarter. Have a great evening. Bye now.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program. You may all disconnect. Everyone, have a wonderful day.



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