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IRMD - Q4 2019 IRadimed Corp Earnings Call

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CORPORATE PARTICIPANTS

Brent Johnson

Christopher K. Scott *IRadimed Corporation - CFO & Secretary*

Leslie L. McDonnell *IRadimed Corporation - President, CEO & Director*

CONFERENCE CALL PARTICIPANTS

Lisa Springer *Singular Research, LLC - Research Analyst*

Scott Robert Henry *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the IRADIMED Corporation Fourth Quarter 2019 Financial Results Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded today, February 6, 2020, and contains time-sensitive information that is accurate only as of today.

Earlier, IRADIMED released financial results for the fourth quarter 2019. A copy of this press release announcing the company's earnings is available under the heading News on their website at iradimed.com. A copy of the press release was also furnished to the Securities and Exchange Commission on Form 8-K and can be found at sec.gov. This call is being broadcast live over the Internet on the company's website at iradimed.com, and a replay of the call will be available on the website for the next 90 days.

The agenda for today's call will be as follows: Leslie McDonnell, President and Chief Executive Officer of IRADIMED, will present opening comments; then Brent Johnson, IRADIMED's Executive Vice President of Worldwide Sales and Marketing, will discuss customer orders; and finally, Chris Scott, IRADIMED's Chief Financial Officer, will summarize the company's financial results before opening the call up to questions.

Some of the information to be furnished in today's session will constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are those focused on the future performance, results, plans and events and include the company's expected results for 2020.

IRADIMED reminds you that future results may differ materially from these forward-looking statements due to a number of risk factors. For a description of relevant risks and uncertainties that may affect the company's business, please see the Risk Factors section of the company's most recent reports filed with the Securities and Exchange Commission, which again may be obtained for free from the SEC's website at sec.gov.

I would now like to turn the call over to Leslie McDonnell, President and Chief Executive Officer of IRADIMED Corporation. Ms. McDonnell?

Leslie L. McDonnell - *IRadimed Corporation - President, CEO & Director*

Thank you, and good morning, everyone. Earlier today, we announced fourth quarter 2019 revenue of \$10.9 million, an increase of over 30% from the fourth quarter last year. We also reported GAAP net income of \$0.26 per diluted share and non-GAAP net income of \$0.30 per diluted share. We are very pleased with these results and believe they demonstrate the underlying strength of our business.

Now looking back on 2019, I am proud of the achievements made throughout the company. From a regulatory perspective, a few achievements reduced risk for the company and another increased our competitiveness. These include closing out the FDA warning letter, as announced in October; renewing the CE Mark for our patient monitor, allowing us to ship all of the orders to customers who patiently waited for our product and



declined to use other competing devices; and then expanding our claims for the patient monitor by receiving FDA 510(k) clearance for neonatal use of the SpO2 and CO2 features of our patient vital signs monitor, which increases our competitiveness in the marketplace.

In addition to these achievements, our regulatory team successfully completed several audits, which is a testament to our commitment to quality. From a sales perspective, we delivered record revenue with over a 30% increase compared to the fourth quarter last year and over a 26% increase over the full year 2018. We also achieved a new record high for orders during 2019, and the fourth quarter marked our first period in excess of \$10 million in orders. All of this was achieved during a time when we could not actively sell our patient monitor and CE Mark countries for nearly all of 2019. While we are encouraged that our European customers did not cancel their orders for our monitor during this time, we were not able to compete in any tender processes without a CE Mark, and we have considered this dynamic in our first quarter 2020 financial guidance.

Additionally, we recently announced a leadership change in the sales organization, resulting from Brent Johnson's decision to retire. Succeeding Brent is MaryBeth Smith, who is a proven leader with a history of delivering sales growth and establishing new medical technology products as a standard of care. We look forward to MaryBeth's leadership and continuing to build upon the success we have achieved.

Now prior to shifting the discussion to 2020, there is one last item to note. We have received questions regarding how the coronavirus is impacting IRADIMED. At this time, we are not significantly impacted by this event. We remain in communication with our suppliers located in China and wish them good health and a speedy return to work. We will continue to monitor this situation and update you should circumstances change.

I discussed last quarter that I believe IRADIMED has tremendous potential and scalability as we leverage the strength of our current product portfolio and deep knowledge of overcoming the challenges of the MRI environment, it is in that context that I think about our priorities and key initiatives for 2020. First, in our priorities and initiatives list is to drive innovation and revenue growth through higher adoption rates of our MRI IV pump and gaining market share for our MRI patient monitor. We also plan on launching the ferromagnetic detection system or FMD during the second half of 2020.

For longer-term value creation and acceleration, we continue to make significant progress on our next-generation IV pump and still plan to submit the 510(k) at midyear. Second, we plan to sensibly invest in the infrastructure needed to support our growth plans while continuing our commitment to quality, clinical education and technical support. Third, we expect to continue leveraging our strong commercial footprint and focus on sales manager productivity gains, especially after considering our recent successes and adding our patient monitor to GPO and IDN contracts that were previously sole-sourced with a competitor. Additionally, we will be opportunistic about exploring external technologies where we can further leverage our commercial team and our technical expertise.

Finally, we look to accelerate growth in targeted international markets by providing additional regional support. I believe we have novel technologies that deliver significant value to clinicians and patients. Our products create MRI access for patients who are critically ill or requiring sedation, while eliminating the risk of projectiles and delivering accurate infusion and vital signs monitoring. We intend to continue driving awareness of the unique challenges in the MRI environment and developing innovative products that facilitate a higher standard of care.

Now I will quickly summarize our financial guidance for the full year and the first quarter 2020. For the full year 2020, we expect to report revenue of \$46.3 million to \$47.1 million, GAAP diluted earnings per share of \$0.72 to \$0.80 and non-GAAP diluted earnings of \$0.84 to \$0.92. We are expecting a higher effective tax rate during the full year 2020 compared to 2019, which negatively impacts the comparison of our forecasted 2020 earnings guidance to 2019 results.

For the first quarter 2020, we expect revenue of \$10.5 million to \$10.7 million, GAAP earnings per share of \$0.16 to \$0.18 and non-GAAP diluted earnings per share of \$0.19 to \$0.21. As previously mentioned, our first quarter revenue guidance includes the expected impact of not being able to participate in any tender processes during the time needed to renew our patient monitor CE Mark.

I will now turn the call over to Brent for a discussion of the sales organization.



Brent Johnson

Thank you, Leslie, and good morning, everyone. As Leslie mentioned in her remarks, the fourth quarter was a record-booking quarter for our sales team, with a strong overall increase in total worldwide orders. This record-booking quarter was well balanced between the U.S. and international teams and between IV pumps and monitors, delivering solid growth in all categories.

Our critical care strategy, that we've discussed many times on prior calls, is continuing to deliver solid increases in IV pump growth, and we are aggressively taking market share from our main competitor with our transportable MRI monitor solution. In fact, the past quarter was also a record-booking quarter in worldwide sales of the MRI monitor, even in light of the fact that we could not book orders for most of the year in the EU marketplace due to the CE Mark issue discussed earlier, which has now been resolved. While we're being impacted by the inability to participate in these tender processes in the EU for most of 2019, we are ramping up our sales efforts with the monitor in EU countries, which we expect will continue to add further growth to this area of our business throughout 2020.

Another factor that helped our monitoring sales for Q4 and for the future with the signing of an agreement for our MRI monitor with the largest group purchasing organization in the nation. This agreement breaks a sole-source agreement with our largest competitor and gives our salespeople an opportunity to compete on equal footing for the monitor business in this GPO's member base that covers roughly half the hospitals in the U.S.

We also continued with our U.S. sales team expansion in the fourth quarter, with 2 additional hires for a total now of 29 U.S. salespeople deployed in the field. We've consistently demonstrated success in translating these additional sales hires into increased sales with our current product offering, and we now have the critical mass that we need to compete and win. We will continue making investments in our commercial team where needed in 2020, both in the U.S. and internationally, but we're also putting increased concentration on additional training and support with our recent hires to increase overall productivity on a per person basis. Our proven record of growth with this strategy and the contract wins with GPOs and IDNs, give us the confidence that we will continue to deliver solid growth now and in future quarters.

As you know, IRADIMED announced last month that I've decided to retire after the end of the first quarter and I've already begun transitioning my duties to MaryBeth Smith. With a combination of an expanded sales team, unique innovative MRI product -- patient care products and planned new products, along with a clear regulatory environment, IRADIMED is well positioned for growth under her leadership.

I want to thank everyone for the opportunity to lead IRADIMED's commercialization efforts over the past 8 years, and I look forward to seeing IRADIMED's continuing success.

Now I'll turn it over to Chris to summarize financial results.

Christopher K. Scott - *IRadimed Corporation - CFO & Secretary*

Thank you, and good morning. Today, I'll be discussing our financial results on a GAAP basis as well as on a non-GAAP basis. Our non-GAAP operating results exclude stock-based compensation expense and the related tax effects. And frequent tax items are considered based on their nature and excluded from the provision for income taxes as these items are not indicative of our normal provision for income taxes.

Free cash flow is cash flow from operations less cash used for purchases of property and equipment. We believe the presentation of these non-GAAP measures along with our GAAP financial statements, can be helpful in providing a more thorough analysis of our ongoing financial performance. You can find a reconciliation of these non-GAAP measures to the nearest GAAP measure on the last page of today's press release.

As we reported this morning and stated a few moments ago, fourth quarter 2019 revenue increased 30.6% over the fourth quarter last year. This increase was driven by continued growth across all line items. Revenue from devices for the fourth quarter 2019 was \$8.0 million compared to \$5.9 million for the fourth quarter 2018, a 35% increase. Included in revenue from devices for the current quarter is \$3.5 million in sales of our MRI monitor compared to \$2.1 million for the 2018 quarter, a 64.5% increase. Revenue from disposables, services and other was \$2.4 million for the 2019 quarter compared to \$2 million for the 2018 quarter, a 21.7% increase. And lastly, revenue from the amortization of our extended maintenance contracts was \$455,000, a 9.4% increase over the fourth quarter last year.

Domestic revenue was \$8 million for the current quarter compared to \$6.7 million for the 2018 quarter, an 18.9% increase. And revenue from international sales, which was favorably impacted by the shipment of approximately \$800,000 of monitors that were previously held awaiting renewal of the CE Mark, was \$2.9 million for the fourth quarter of 2019 compared to \$1.6 million for the 2018 quarter. The average selling price of IV pumps recognized in revenue during the current quarter was approximately \$33,100 compared to approximately \$35,000 for the prior year quarter.

The decrease in ASP is a result of higher international unit sales during the 2019 quarter compared to the 2018 quarter. ASP for our MRI monitor was approximately \$32,600 for the fourth quarter 2019 and \$34,900 for the 2018 quarter. The decrease in ASP is due to higher international sales when compared to the 2018 quarter. Gross margin was 74.8% for the current quarter and 76.2% for the prior year quarter. The decrease in gross margin percent as a result of higher international sales during the fourth quarter of 2019 compared to the fourth quarter 2018.

Operating expenses were \$5.9 million or 54.3% of revenue compared to \$4.6 million for the fourth quarter 2018 or 54.7% of revenue. On a dollar basis, operating expenses increased due to higher expenses for payroll and benefits, employee recruiting and relocation costs, stock compensation expense, regulatory approval costs and sales commissions. Our effective tax rate for the 2019 quarter was negative 37.7% compared to 9% for the 2018 quarter. The lower effective tax rate is primarily due to higher tax benefits associated with the exercise and sale of employee options and vesting of restricted stock units.

On a GAAP basis, net income was \$0.26 per diluted share for the fourth quarter 2019 compared to \$0.14 for the fourth quarter 2018. On a non-GAAP basis, net income was \$0.30 per diluted share for the current quarter compared to \$0.16 for the fourth quarter last year. Both GAAP and non-GAAP earnings were favorably impacted by approximately \$0.10 per share from the lower effective tax rate.

From a cash flow perspective, for the year ended December 31, 2019, cash provided by operations was \$10.2 million compared to \$7.4 million for the 2018 year. During 2019, cash provided by operations was positively impacted by higher net income, deferred revenue, other accrued taxes and accrued payroll and benefits, partially offset by negative impacts from an increase in accounts receivable, prepaid expenses and other current assets. For the 3 months ended December 31, 2019 and 2018, our free cash flow, a non-GAAP measure, was \$3.8 million and \$3.5 million, respectively.

I will now turn the call over for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Scott Henry with Roth Capital.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

A couple of questions. I guess, for starters, when we think about 2020 and I guess 2021 as well in the next-generation pump and as kind of news as that comes about as you filed the 510(k), do you think that will have any impact on the selling cycle? At some point, will account just kind of hold off? Or how should we think about that?

Brent Johnson

Scott, this is Brent Johnson. Yes, that's a good question. The -- it's interesting. We don't have a competitor in that marketplace. So it doesn't affect us as much as if we did have a competitor. Certainly, there's a high demand for our products and buyers continue to buy them on an ongoing basis. As we get closer to that, there may be some necessity for some time sort of a bridge type of a program, but we don't foresee anything like that in the near-term future here as far as any impact to our selling efforts in 2020.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay, great. And when we think about monitor sales, which are obviously very strong in Q4 and helped by international, how should we think about seasonality in 2020? I mean I guess, we'd expect a downtick in Q1 and again, ramping into the year, perhaps not quite as much, but is that how we should think about kind of the trajectory of monitor sales throughout 2020?

Brent Johnson

Well, yes. I mean there is a certain seasonality that you're talking about there in your experience with the medical device market. The fourth quarter of the calendar year is typically the strongest quarter for medical devices. Q1 does typically show a little bit of a drop-off there as far as ordering. But with that product, we are seeing strong increases in our sales. So with -- especially with the MRI patient monitor product, we don't see a drop-off with that product as far as sales -- excuse me, orders in Q1. But again, there is some seasonality in that business.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. And then final question. Just when we think about 2020, how should we think about the gross margins? Obviously, Q4 was hurt by the international volume. Would maybe Q3 be more reflective? Or just any sort of sense and directionally, how we think about gross margins relative to maybe Q3 as opposed to Q4?

Christopher K. Scott - *IRadimed Corporation - CFO & Secretary*

Yes. Scott, Chris Scott here. We see -- I mean you're exactly right. Fourth quarter gross margins were depressed in large part because of the international business that we did. And so as we see that normalize and remove the impact of that \$800,000 shipment into the EU and we see international normalize relative to total revenue, we do see margins coming back into where we have historically played, which is in that mid-70s, mid- to upper-70s range. And that's how we've modeled it for the rest of the year. We see increases quarter-over-quarter as -- like I said, as the geographic sales mix normalized but also output -- unit output increases over time.

Operator

(Operator Instructions) Our next question comes From Lisa Springer with Singular Research.

Lisa Springer - *Singular Research, LLC - Research Analyst*

Congratulations on a strong quarter and a good year.

Brent Johnson

Thanks, Lisa. Thank you.

Lisa Springer - *Singular Research, LLC - Research Analyst*

I wanted to -- could you give us a little more specifics on the progress of the new infusion pump? I know you were going to -- you discussed starting initial testing early this year. I wonder if this has happened yet or what the status of that is.



Brent Johnson

Lisa, I think we remain committed to submitting the 510(k) at midyear, as Leslie mentioned, and we're progressing in that direction. We don't see anything that's going to cause us right now to make a shift off of that time frame. So I think that's kind of all the comments that we have on that right now.

Lisa Springer - Singular Research, LLC - Research Analyst

Okay. And do you feel that you have the sales team in place to accomplish your 2020 goals? Or could we perhaps see more sales hires during the year?

Leslie L. McDonnell - IRadimed Corporation - President, CEO & Director

Lisa, this is Leslie McDonnell. I can take that question. I think we largely have the team in place that we need to hit our goals for this year. We'll make additional commercial investments where required. It won't be quite at the same pace as you've seen in the past. We're going to turn a little bit more of our focus on balancing that with some productivity as well.

Lisa Springer - Singular Research, LLC - Research Analyst

Okay. And my final question. There's quite a bit of cash on the balance sheet. I'm just wondering what would be the -- would you be interested in making an acquisition that might help you leverage your sales organization, another product? Or what is the opportunity in that area?

Leslie L. McDonnell - IRadimed Corporation - President, CEO & Director

Yes, we definitely. Because we've been so profitable in the past, there is some cash on the balance sheet. And as I mentioned in the prepared remarks, we are open. We plan to be opportunistic about other technologies that may become available that makes sense for us to make part of our portfolio. And generally, how I'm thinking about that is looking at it through the lens of where we would have leverage from a call-point perspective, from a commercial footprint, distributor network, but also through what I call sort of the domains of technical expertise. What we're good at doing here, right? Software-controlled electromechanical systems, precise fluid delivery, vital signs monitoring and processing. Those are the types of things and criteria that we'll take a look at is some of those things might become available to us over time.

Operator

I'm not showing any further questions at this time. I would now like to turn the call back over to Leslie McDonnell for any closing remarks.

Leslie L. McDonnell - IRadimed Corporation - President, CEO & Director

I would like to thank everyone for listening and participating in the call this morning. I believe there are exciting opportunities ahead of us. And as a team, we are working on developing and implementing plans that are focused on value creation through innovation, sensible investments and efficiencies. We look forward to speaking with you and updating you on our progress after the first quarter.

Operator

Thank you. This concludes the call. You may now disconnect.



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