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Edwards Lifesciences' (EW) CEO Michael Mussallem on Q4 2014 Results - Earnings Call Transcript

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Edwards Lifesciences Corp. (NYSE:EW)

Q4 2014 Earnings Conference Call

February 2, 2015 05:00 PM ET

Executives

Michael A. Mussallem - Chairman and CEO

Scott B. Ullem - CFO and Corporate Vice President

David Erickson - VP, IR

Analysts

Brooks West - Piper Jaffray

Raj Denhoy - Jefferies LLC

Lawrence Biegelsen - Wells Fargo Securities, LLC

Jason Mills - Canaccord Genuity

David Roman - Goldman Sachs Group Inc.

Frederick Wise - Stifel, Nicolaus & Company

Bruce Nudell - Crédit Suisse AG

Danielle Antalffy - Leerink Partners

Ben Andrew - William Blair & Co.

Kristen Stewart - Deutsche Bank Securities, Inc.

Michael Weinstein - JP Morgan Chase & Co.

Robert Hopkins - BofA Merrill Lynch

James Francescone - Morgan Stanley & Co.

Joanne Wuensch - BMO Capital Markets

Operator

Greetings, and welcome to the Edwards Lifesciences Corporation Fourth Quarter 2014 Earnings Conference Call. [Operator Instructions] As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Mr. David Erickson, Vice President, Investor Relations. Thank you. Mr. Erickson, you may begin.

David Erickson

Welcome, and thank you for joining us today. Just after the close of regular trading, we released our fourth quarter 2014 financial results. During today's call, we'll discuss the results included in the press release and accompanying financial schedules and then use the remaining time for Q&A. Our presenters on today's call are: Mike Mussallem, Chairman and CEO; and Scott Ullem, CFO.

Before we begin, I'd like to remind you that during today's call, we will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include, but aren't limited to, our expectations regarding sales, gross profit margin, earnings per share, SG&A, R&D, interest expense, taxes, free cash flow and foreign currency impacts. These statements also include our current expectations for the timing, status and expected outcomes of our clinical trials, regulatory compliance, submissions and approvals, as well as expectations regarding industry growth, adoption rates for new products and competitive positions.

These statements speak only as of the date on which they are made, and we do not undertake any obligation to update them after today. Although we believe them to be reasonable, these statements involve risks and uncertainties that could cause actual results or experiences to differ materially from the forward-looking statements. Information concerning factors that could cause these differences may be found in our press release, our annual report on Form 10-K for the year ended December 31, 2013, and our other SEC filings, which are available on our Web site at edwards.com.

Also, a quick reminder that when we use the terms underlying and excluding special items, we are referring to non-GAAP financial measures. Otherwise, we are referring to our GAAP results. Additional information about our use of non-GAAP measures is included in today's press release and on our Web site.

Now I'll turn the call over to Mike Mussallem. Mike?

Michael A. Mussallem

Thank you, David. Reflecting on 2014, we ended the year with uncertainty around our product launch timing and new competitor activity. We are pleased to have exited the year with momentum and having significantly exceeded our initial expectations.

We were proud to introduce several innovative products that helped us maintain our strong global leadership position and resulted in annual underlying sales growth of 13%. This growth was led by 29% underlying sales growth in transcatheter heart valves. Importantly, we're particularly gratified to see the meaningful impact that our dedicated employees are having in helping so many patients around the world.

For the quarter, we experienced robust growth across all regions with transcatheter heart valves sales that exceeded our expectations, most notably in Europe, driven by the further adoption of SAPIEN 3. Other new products like our minimally invasive intuitive valve platform and ClearSight also contributed to our growth.

Now turning to quarterly specifics. Total adjusted sales were $640 million, representing an representing growth rate of 16%. In transcatheter heart valves therapy, underlying global sales grew 38%. This was driven by strong sales of our innovative new products in Europe and in the U.S. Globally, average selling prices remain stable.

Outside the U.S., THV sales grew 41% on an underlying basis during the quarter, once again driven by the strong procedural growth in Europe and the ongoing launch in Japan. Growth was seen broadly across most countries in Europe which speaks to the large number of untreated patients benefiting from strong TAVR adoption.

SAPIEN 3 with its enhanced features represented more than 85% of our European THV sales this quarter, and continues to generate favorable clinician feedback. We estimate competitors moderately gained ground in the quarter. While we expect procedure growth rates to slow going forward, we estimate that Europe TAVR procedures grew in excess of 20% in 2014.

In Japan, we ended the year slightly below our full-year guidance of $40 million to $50 million. Even though clinicians remain enthusiastic about our SAPIEN XT valve, our launch has been slower than expected due to the Japan's extensive site certification process. We continue to believe that Japan represents a very attractive market opportunity for TAVR and we expect adoption will continue to steadily increase.

million. During the fourth quarter we recorded minimal clinical sales due to the completion of enrollment in the intermediate risk arm of the SAPIEN 3 trial in September. Our performance in the U.S continues to be driven by the strong adoption of SAPIEN XT, which was available in all of our accounts by year-end.

During 2014, we added approximately 50 new centers which is in line with our estimate. As a reminder, our SAPIEN 3 U.S pivotal trials for both high risk and intermediate risk patients completed enrollment in 2014. And during the year, we received approval for our SAPIEN 3 continued access program for 1,000 intermediate risk patients. Enrollment in this program began in January.

As we discussed at our investor conference, we recently submitted our PMA for SAPIEN 3 in the U.S. Our plan assumes a one-year FDA review process. Based on our estimates, we expect the first approval of SAPIEN 3 in early 2016. At the same time, we're actively engaged with FDA to discuss ways to bring our latest technology to patients in the U.S more quickly.

At the upcoming American College of Cardiology conference in March, there will be numerous transcatheter valve sessions including late breaking presentations of five-year data from the partner trial and early clinical outcomes with SAPIEN 3. We are planning on hosting an investor update on Sunday evening March 15 to discuss the latest presentations. Additional details will be forthcoming.

Our self expanding CENTERA valve platform featuring an enhanced motorized delivery system continues to make progress. We have a pivotal trial set to start in the second quarter in Europe with the expected commercial launch of this new platform in 2016.

In summary, we're pleased with the strength of our global THV sales performance. We believe current procedure growth rates will moderate and competitive activity will increase. As such, we continue to expect 15% to 25% underlying sales growth in 2015.

Turning to the Surgical Heart Valve Therapy product group. Total sales for this quarter were $206 million, up 3% on an underlying basis. Heart Valve unit gains across most geographies drove the majority of the growth, while a favorable product mix also contributed to a slightly higher overall valve ASP. As expected, sales of Cardiac Surgery System products or CSS detracted from this product group's growth rate.

As a reminder, last quarter we discussed the strategic decision to integrate the operations of our Surgical Heart Valve and CSS product lines. Key activities were completed by year-end as planned. Simultaneously we announced our plan to exit certain non-strategic CSS products representing annual sales of $10 million to $20 million as part of our Utah remediation efforts. This is included in our 2015 guidance.

Globally underlying surgical valves grew 4% led by unit growth of our premium valves. Growth was strongest in Europe, led by the continued adoption of INTUITY Elite, our minimally invasive valve platform. In the U.S., we experienced double-digit growth in mitral units while pericardial valve adoption propelled significant growth in China.

During the quarter, we completed enrollment of our U.S TRANSFORM Trial for INTUITY Elite and continue to expect a 2015 PMA submission. This would keep us on track for a planned U.S approval in 2016. Enrollment in the study of our RESILIA tissue technology remains on schedule and we still expect to complete European and U.S regulatory submissions this year.

At the Society of Thoracic Surgery meeting last week, data from the largest single center experience on our INTUITY system were presented which showed favorable early clinical and hemodynamic outcomes.

In summary, we are pleased with the continued strength of our premium products in our surgical valve product line. Consistent with our active product portfolio management strategy, we will experience reduced sales growth as we discontinued certain non-strategic CSS products as such we're reiterating our underlying sales growth for the total product group of 1% to 3% in 2015.

Turning to the Critical Care product group. Total sales for the quarter grew 4% on an underlying basis to $144 million. Growth was solid in the U.S and sales outside the U.S were aided by a favorable comparison as in this -- as inventory levels stabilized in China. Enhanced Surgical Recovery product sales, including FloTrac and ClearSight grew in the double-digits.

In 2015, we plan to expand the reach of our non-invasive ClearSight system with our upcoming launch in Japan. The optimization of patient's fluid management through enhanced surgical recovery plays to our strength as leader in hemodynamic monitoring. As clinical support for ESR continues to gain momentum, it should enable us to capitalize on the global under penetrated opportunity.

Separately at the start of the year, we were happy to officially welcome Katie Szyman who is now successfully transitioned into a new role as Head of our Critical Care team.

To summarize, our Critical Care product line, we're pleased with the continuing adoption of our ESR products and are reiterating our

Before turning it over to Scott, I'll close with a brief statement about our transcatheter mitral valve program. We are continuing to make progress in the study of our FORTIS transcatheter mitral valve. As previously discussed, we recently received approval to begin a multi-center early feasibility study in the U.S and expect to begin enrollment during the first quarter.

We are continuing to aggressively invest in the development of additional mitral technologies as we believe multiple solutions may ultimately be needed to address this large patient need.

And now, I'll turn the call over to Scott.

Scott B. Ullem

Thanks, Mike, and hello everyone. For the full-year, we reported adjusted earnings per share of $3.50. Net sales increased 13% on an underlying basis. Gross profit margin was 73.7% and adjusted free cash flow was $445 million.

In the fourth quarter, we reported adjusted sales of $614 million. Our strong sales performance in transcatheter valves drove an overall 16% underlying growth this quarter. Adjusted earnings per share was $1.06 representing 12% growth over the prior year.

The THV sales return reserve added $4 million to reported sales in the fourth quarter. We completed the next-generation product exchanges in the U.S and Europe during the fourth quarter bringing the THV sales return reserve to zero at year-end in closing out this reconciling item.

I'll now cover the details behind our results and then share guidance for 2015. For the fourth quarter, our gross profit margin was 74% as expected compared to 73.2% in the same period of 2013. This increase was driven primarily by a more profitable product mix and a positive impact from foreign exchange. These items were partially offset by higher costs associated with our CSS operations in Utah, as well as higher incentive compensation expense.

The stronger U.S dollar will have a significant impact to our results in 2015 even more so than we projected at our investor conference in December. Based on current exchange rates, we now expect sales in 2015 to be reduced by $160 million compared to prior year rates. We enter into foreign exchange hedging contracts that generate income at the gross profit line when the U.S dollar strengthens relative to other currencies.

If today's foreign exchange rates persist, we expect our gross profit margin for the full-year 2015 excluding special items, to bump up to the range of 76% to 77%. This includes an estimated mix improvement of approximately 100 basis points over last year's adjusted gross profit margin of approximately 74% and currency impact of 100 to 200 basis points.

Fourth quarter selling, general and administrative expenses were $223 million or 36% of sales compared to $187 million in the prior year. The largest drivers of the increase were related to the global expansion of transcatheter heart valves and a larger accrual for performance-based incentive compensation.

We continue to expect SG&A excluding special items to be between 35% and 36% of sales for the full-year 2015. Research and development investments in the quarter grew 7% to $84 million or 13.6% of sales. This increase was primarily the result of continued investments in our aortic and mitral valve programs partially offset by lower spending on clinical trials. For the full-year 2015, we continue to expect R&D as a percentage of sales to be between 15% and 16%.

During the quarter, we recorded three adjustments to our GAAP results as follows: first, the impact of the THV sales return reserve benefited our GAAP net income by $2.5 million or $0.02 per share. Consistent with prior quarters, we excluded this impact from our non-GAAP results. Second, we excluded $10.2 million for a previously announced acquisition of Transcatheter Mitral Valve intellectual property which we expensed as in process research and development. And third, consistent with our reporting convention, we excluded $600,000 of intellectual property litigation expense. Complete reconciliations were included in our press release.

Net interest expense for the quarter was $2 million, down from $4 million in the prior year. This reduction was driven by lower interest rates and increased interest income from higher investment balances. For the full-year 2015, we continue to expect net interest expense to be approximately $10 million.

Our reported tax rate for the fourth quarter was 17.8% or 16.9% on a non-GAAP basis as we expected. The quarter's rate benefited from the renewal of the federal research and development tax credit for 2014. Assuming a renewal again in 2015, we continue to expect our full-year tax rate to be between 21% and 23%.

Based on an expectation of a fourth quarter renewal, the tax rate for the first three quarters should be higher than the fourth. FX rates

Compared to our recent guidance, FX rates positively impacted earnings per share by $0.01. As I mentioned earlier, at current rates we now estimate a $160 million negative impact to full-year 2015 sales, which is $70 million higher than the impact we estimated at our December investor conference. The resulting impact to earning should be mitigated by our foreign exchange hedges.

Cash flow from operating activities for the fourth quarter was $93.2 million. After capital spending of $34.5 million and excluding the tax impacts of previously reported special items, free cash flow was $107.5 million.

Turning to our balance sheet, at the end of the quarter we had cash, cash equivalents and short-term investments of $1.4 billion. Approximately 55% of which is outside the U.S. Total debt was $598 million.

Now turning to our 2015 guidance. Given the impact of foreign exchange, we expect full-year reported sales to be at the lower end of the $2.3 billion to $2.5 billion guidance range we provided at our December investor conference. We also expect each of our product groups to be at the lower end of our previously stated ranges. Those ranges are $1 billion to $1.1 billion for Transcatheter Heart Valve therapy, $780 million to $820 million for Surgical Heart Valve therapy, and $520 million to $570 million in Critical Care.

For the full-year 2015, we continue to expect free cash flow excluding special items to be between $375 million and $425 million. Given the momentum of Transcatheter Heart Valve sales and the mitigating effect of our foreign exchange hedging program, we're raising our diluted earnings per share guidance to $4 to $4.30 excluding special items.

For the first quarter of 2015, at current foreign exchange rates, we project total sales to be between $570 million and $610 million and diluted earnings per share excluding special items to be between $1.02 and $1.10.

And with that, I'll hand it back to Mike.

Michael A. Mussallem

Thanks, Scott. In conclusion, Edwards is poised for solid growth in 2015. Our foundation of leadership and our commitment to transform patient care with innovative therapies remain the source of our strength. Our exciting product pipeline positions us well for continued long-term success and greater shareholder value.

With that, I'll turn it back over to David.

David Erickson

Thank you, Mike. In order to allow broad participation in the Q&A, we ask that you please limit the number of questions. If you have additional questions, please re-enter the queue and we will answer as many as we can during the remainder of the hour. Operator, we're ready for questions, please.

Question-and-Answer Session

Thank you. We will now be conducting a question-and-answer session. [Operator Instructions] Our first question is from Brooks West of Piper Jaffray. Please go ahead.

Brooks West

Thanks for taking the question.

Michael A. Mussallem

Sure.

Brooks West

Mike, can I press you a little bit on the mitral valve comments? You talked about having multiple platforms. Can you give us a little bit more detail on your thought process there? Is it multiple valve platforms, could there be some repair products in there? Just a little bit more about how you're thinking of approaching that opportunity

Michael A. Mussallem

Sure, Brooks. Broadly even though we think replacement mitral valve will be a very important offering for mitral patients, we don't think

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