Seeking Alpha

Edwards Lifesciences (EW) Michael A. Mussallem on Q2 2016 Results - Earnings Call Transcript

Jul. 27, 2016 5:33 AM ET
by: SA Transcripts

Edwards Lifesciences Corp. (NYSE:EW)

Q2 2016 Earnings Call

July 26, 2016 5:00 pm ET

Executives

David K. Erickson - Vice President-Investor Relations

Michael A. Mussallem - Chairman & Chief Executive Officer

Scott B. Ullem - Chief Financial Officer & Corporate Vice President

Analysts

Brooks E. West - Piper Jaffray & Co. (Broker)

Jason R. Mills - Canaccord Genuity, Inc.

Michael Weinstein - JPMorgan Securities LLC

Larry Biegelsen - Wells Fargo Securities LLC

David Ryan Lewis - Morgan Stanley & Co. LLC

Matt Miksic - UBS Securities LLC

Bruce M. Nudell - SunTrust Robinson Humphrey, Inc.

Raj Denhoy - Jefferies LLC

Danielle J. Antalffy - Leerink Partners LLC

John T. Gillings - JMP Securities LLC

Matt J. Keeler - Credit Suisse Securities (NYSE:USA) LLC (Broker)

Glenn John Novarro - RBC Capital Markets LLC

Ben C. Andrew - William Blair & Co. LLC

Joshua Jennings - Cowen & Co. LLC

Operator

Greetings, and welcome to the Edwards Lifesciences Corporation's Second Quarter 2016 Earnings Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Mr. David Erickson, Vice President-Investor Relations. Thank you. You may begin.

David K. Erickson - Vice President-Investor Relations

Welcome, and thank you for joining us today. Just after the close of regular trading, we released our second quarter 2016 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 this call, we will be making forward-looking statements that are based on estimates, assumptions, and projections. These statements include, but aren't limited to, financial guidance and current expectations for clinical, regulatory, reimbursement and commercial matters, as well as therapy trends and foreign currency movements. 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.

Additionally, the statements involve risks and uncertainties that could cause actual results to differ materially. Information concerning factors that could cause these differences and important product safety information may be found in our press release, our 2015 Annual Report on Form 10-K, and our other SEC filings, all of which are available on our website at edwards.com.

Also, a quick reminder that when we use the terms underlying and adjusted, 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 website.

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

Michael A. Mussallem - Chairman & Chief Executive Officer

Thank you, David. We're very pleased to report strong second quarter performance, which reflected significant growth in the number of patients and physicians choosing Transcatheter Heart Valve Therapy. Our results this quarter were better than expected driving strong top and bottom line growth.

Global sales grew 21% on an underlying basis, reflecting significant Transcatheter Heart Valve sales that once again drove the majority of this quarter's growth, with a solid contribution from Critical Care. In transcatheter heart valves, global sales were $419 million, up 45% on an underlying basis over prior year. Growth was led by continued strong therapy adoption across all geographies, with notable strength in the U.S.

Globally, average selling prices remained stable. In the U.S., Transcatheter Heart Valve sales for the quarter were $246 million and grew 66% on an underlying basis versus the prior year. Overall procedure growth exceeded our expectations, and strong sales were widespread in both large and small hospitals. Positive clinical results continue to drive adoption, and clinician feedback on the intermediate risk trial data presented at the ACC conference has been consistently positive.

During the quarter, the final intermediate risk data sets were submitted to the FDA and we're awaiting for approval of the expanded indication. Although it's always difficult to predict regulatory timelines, based on the strength of these data, we anticipate that approval will be received during the third quarter.

As a reminder, intermediate risk patients continue to be treated through our Continuous Access Protocol of the PARTNER II trial, which has been tracking at close to $10 million in sales per quarter. This would end as commercial sales begin.

Enrollment in our PARTNER III low-risk trial is underway, and approximately half of our expected trial sites are active. As a reminder, this is a randomized trial and although difficult to estimate, we believe this trial should be enrolled by mid-2017. And, at the request of clinicians, who want to offer this therapy to a broader group of patients, we're revising the trial protocol by removing the 65 years or older age qualification.

Outside the U.S., underlying THV sales grew 23%, driven by the ongoing therapy adoption primarily in Europe, and a contribution from Japan. We are pleased with the adoption seen in Japan following the launch of SAPIEN 3 earlier this year and we expect Japan to be a strong contributor to long-term growth.

In Europe, we estimate total procedures grew around 25% in the second quarter, compared to last year or approximately 20% when adjusted for additional selling days this year. Edwards procedures grew at about the same rates. While the PARTNER II data published in April was widely acknowledged, we do not believe it provided a significant lift in the quarter.

difficult to estimate, we believe more recent competitive entrants continue to account for about 15% of total European procedures.

As we mentioned, we are using our U.S. intermediate risk data to request an expansion of our CE Mark indication. These data were submitted to European regulators during the quarter and we continue to expect approval of an expanded label in late 2016 or early 2017. We expect gradual expansion into intermediate risk patients when the label is broadened and clinical guidelines are revised.

Our updated guidance anticipates that OUS sales may reflect a negative impact in the fourth quarter. The country of France has a policy that limits annual TAVR procedures. Strong therapy adoption there is outpacing this year's rate. We are working with the Ministry of Health in an effort to increase the procedure limit. In the absence of resolution, we expect to discontinue sales in France for the remainder of 2016 when the cap is reached, and this assumption is reflected in our guidance.

Given the strong performance of SAPIEN 3, we have decided to incorporate additional benefits into our new Ultra system before its introduction. This will move the expected European launch to the second half of 2017. This new system featuring an on-balloon delivery system and next-generation sheath technology is expected to enhance ease of use, further reduce possible complications and shorten procedure time.

Questions about transcatheter valve durability, which were first discussed during a EuroPCR presentation, were subsequently more thoroughly addressed at the TVT meeting last month. Physician presentations suggested there is a lack of evidence that TAVR valve durability differs from surgical valves. Edwards has always distinguished itself on the best-in-class performance in heart valves, and we remain confident in our SAPIEN platform and are generating long-term follow-up data in our PARTNER trials.

In summary, based on our strong first half results and anticipated third quarter approval of intermediate risk in the U.S. and momentum of global therapy adoption, we are increasing our 2016 sales guidance by $100 million to between $1.5 billion and $1.7 billion. We now expect our underlying sales growth to exceed 30%.

Turning to Surgical Heart Valve Therapy product group, sales for the second quarter were $199 million, a decrease of 3% over last year on an underlying basis. Sales of surgical mitral valves declined, which was partially offset by solid growth in surgical aortic valves. Globally, sales of our surgical mitral valves were impacted during the quarter due to our identification of a production matter related to the holder that assists surgeons during implantation of the valve, which caused us to temporarily suspend production. We have recently resumed shipping and expect a smaller impact in the third quarter as we replenish inventories.

Worldwide surgical aortic valve units grew approximately 5% and global average selling price saw a slight decline due to regional mix. INTUITY Elite drove sales growth in Europe, and in Japan, growth was driven by aortic valves and the adoption of the recently launched tricuspid valve repair system.

During the quarter, we announced positive clinical data from our COMMENCE, TRANSFORM and FOUNDATION studies at the American Association of Thoracic Surgeons Meeting. These compelling new data on more than 2,000 patients provide important clinical evidence on the benefits of new surgical treatments, including our RESILIA tissue and INTUITY Elite valve system.

We anticipate approval in the near future of our rapid deployment INTUITY Elite valve in the U.S. This system is built upon our proven pericardial valve technology and is designed to facilitate small incision aortic valve replacement surgery and streamline combination procedures. The U.S. launch will be deliberate and focused on adoption and ensuring excellent patient outcomes. The valve system underscores our ongoing commitment to developing innovative surgical technologies to address patient needs. We continue to invest in multiple surgical platforms, as we believe that surgery will remain an important option for patients even as TAVR expands.

In summary, given our first half results, we're reducing our 2016 underlying sales growth expectation for the full year to between 0% and 2%, and we expect a meaningful contribution to growth from the INTUITY Elite launch in the U.S.

In the Critical Care product group, sales for the quarter were $142 million and grew 7% on an underlying basis. Overall growth for the quarter was strong in our core products and, once again, we recorded double-digit underlying growth in our Enhanced Surgical Recovery program. Our expansion of the U.S. sales team also stimulated stronger adoption of our market-leading products. Based upon the strong first half momentum, we are increasing our Critical Care underlying sales growth expectation to between 5% and 7% in 2016.

In structural heart initiatives, we continue to make progress on our FORMA system for reducing tricuspid regurgitation and our CardiAQ-Edwards transcatheter mitral valve platform.

In our early-generation CardiAQ-Edwards platform, we're in the process of implementing several enhancements, including new delivery systems and utilizing Edwards' advanced tissue. We Plan to incorporate these enhancements as part of our first CE Mark trial, and we

This trial, called the RELIEF trial, includes approximately 15 centers in Europe and Canada and will include Transapical and Transseptal delivery systems. This single arm study will include patients suffering from functional and degenerative mitral regurgitation. You will hear more specific updates about this and other programs at future clinical meetings.

In the legal matter that CardiAQ brought against Neovasc, a federal jury returned a $70 million verdict in our favor. The jury found that Neovasc, a former service provider, breached the non-disclosure agreement, misappropriated trade secrets and breached its duty of honest performance.

During the quarter, we completed two small acquisitions that add future-generation technologies to our transcatheter valve portfolio. We remain committed to developing innovative structural heart therapies and, although it's still early, we continue to believe that these therapies will ultimately benefit patients who are not well-served today.

And with that, let me turn it over to Scott.

Scott B. Ullem - Chief Financial Officer & Corporate Vice President

Thank you, Mike. This quarter, the number of transcatheter procedures exceeded our estimates and drove total sales of $759 million, representing 21% growth over last year, excluding the effects of foreign exchange and the prior year sales return reserve.

Adjusted earnings per share in the quarter grew 33% versus prior year to $0.76, reflecting solid leverage. Our GAAP earnings per share of $0.58 includes $34 million of acquired intellectual property related to early-stage transcatheter technologies, as Mike mentioned earlier. A full reconciliation between our GAAP and adjusted earnings per share is included with today's release.

For the quarter, our gross profit margin was 73.3%, compared to 74.3% in the same period last year. This decrease, which we expected, was driven primarily by the foreign exchange impact from inventories sold internationally and a reduced benefit from our FX hedge contracts. These were partially offset by a more profitable product mix, reflecting strong growth in THV and the impact of the THV return reserve in the prior year.

As we mentioned last quarter, to accommodate our increased sales demand going forward, we are making significant investments in manufacturing capacity inside and outside the United States, including our new facility in Costa Rica. These capacity investments moderately reduced our gross profit margin in the second quarter and are likely to continue to have a negative impact into 2017. These impacts are reflected in our full year gross profit margin guidance, which remains unchanged at 73% to 74%, excluding special items.

Sector quarter selling, general and administrative expenses increased 7% over the prior year to $229 million or 30.1% of sales. This increase was driven primarily by sales and personnel related expenses, partially offset by the suspension of the medical device excise tax. We continue to expect SG&A, excluding special items, to be between 30% and 32% of sales for the full year.

Research and development investments in the quarter increased 16% over the prior year to $113 million or 14.9% of sales. This increase was primarily the result of continued investments in our transcatheter mitral and aortic valve programs. We expect our R&D investments, excluding special items, to be approximately 16% of sales in the second half.

During the second quarter, we recorded $9 million in intellectual property litigation expenses, which have been excluded from adjusted earnings per share. The expenses include litigation against Neovasc in the United States and with Boston Scientific, where we now have multiple litigation matters in the United States and Europe.

Our reported tax rate for the quarter was 25.1%, up from 20.7% in the prior year period. This increase was driven largely by the impact of our early-stage intellectual property acquisitions and our increased sales in the United States, our highest tax rate region. We continue to expect our full year tax rate, excluding special items such as this quarter's intellectual property acquisitions, to be between 22% and 23%.

Foreign exchange rates increased second quarter sales by $5 million compared to the prior year. Compared to our April guidance, foreign exchange rates boosted sales and favorably impacted earnings per share by $0.01 in the second quarter. At current rates, which have been volatile, we now estimate an approximate $10 million favorable impact to full year 2016 sales compared to the prior year. Brexit has obviously contributed to rate volatility, but the impact to our bottom line this year will likely be insignificant as most of the foreign exchange rate changes are expected to be offset by our hedging program. As a point of reference, UK sales represented less than 3%, of our global sales last year.

Free cash flow generated during the quarter was $153 million. We define this as cash flow from operating activities of $190 million, less capital spending of $37 million.

Turning to the balance sheet, at the end of the quarter, we had cash, cash equivalents and short-term investments of approximately $1 billion. Total debt was approximately $600 million. Average shares outstanding during the quarter were $217 million. We continue to expect average diluted shares outstanding for full year 2016 of $216 million to $220 million.

Turning to our 2016 guidance, given our strong THV momentum and expectation of continuing growth, we are raising guidance for full year 2016 THV sales to be $100 million higher than we forecasted last quarter. We now expect THV sales of $1.5 billion to $1.7 billion and total Edwards sales to be at the high end of our $2.7 billion to $3 billion range.

We continue to expect sales for Surgical Heart Valves within the range of $780 million to $820 million. And given the strong first half performance of Critical Care, we now expect sales within the range of $540 million to $580 million.

With today's increase in sales guidance, we now expect our adjusted earnings per share to be between $2.78 and $2.88 and we continue to expect free cash flow, excluding special items, to be between $500 million and $600 million. For the third quarter of 2016, at current foreign exchange rates, we project sales to be between $720 million and $760 million, and adjusted earnings per share to be between $0.62 and $0.68.

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

Michael A. Mussallem - Chairman & Chief Executive Officer

Thanks, Scott. We are very pleased with our strong performance achieved through the first half of the year. As patients and clinicians increasingly prefer TAVR and based on the substantial body of compelling evidence, we remain as optimistic as ever about the long-term growth opportunity represented by transcatheter therapies.

Overall, we remain committed to aggressively investing in structural heart disease and critical care technologies. We are confident that this will result in more patients being treated with our innovative therapies and continued strong organic growth.

And with that I'll turn it back over to David.

David K. Erickson - Vice President-Investor Relations

Thank you, Mike. Before we open it up for questions, I would like to encourage you to mark your calendars for Thursday, December 8 when we will be hosting our 2016 Investor Conference in New York. This event will include updates on our latest technologies as well as our outlook for 2017. More information will be available in the next couple of months.

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

Question-and-Answer Session

Operator

Thank you. Our first question comes from the line of Brooks West with Piper Jaffray. Please proceed with your question.

Brooks E. West - Piper Jaffray & Co. (Broker)

Hi. Thanks for taking the questions. Can you hear me?

Michael A. Mussallem - Chairman & Chief Executive Officer

We can hear you fine Brooks. Can you hear us?

Brooks E. West - Piper Jaffray & Co. (Broker)

Great. Mike, actually, you were fading in and out quite a bit in the first part of your prepared remarks. I was actually going to ask if it would be possible maybe for you guys to email out your script or post it to the website, because I felt like I did miss a lot of what you said. I'm sure we'll be useful...

Michael A. Mussallem - Chairman & Chief Executive Officer

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.