St Jude Medical (STJ) Earnings Report: Q1 2016 Conference Call Transcript

The following St Jude Medical conference call took place on April 20, 2016, 08:00 AM ET. This is a transcript of that earnings call:

Company Participants

- Mike Rousseau; St. Jude Medical Incorporated ; President & CEO
- Don Zurbay; St. Jude Medical Incorporated ; CFO
- Eric Fain; St. Jude Medical Incorporated ; Group President

Other Participants

- Matthew Taylor; Barclays Capital; Analyst
- Mike Weinstein; JPMorgan; Analyst
- Bob Hopkins; BofA Merrill Lynch; Analyst
- Bruce Nudell; SunTrust Robinson Humphrey; Analyst
- David Roman; Goldman Sachs; Analyst
- David Lewis; Morgan Stanley; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Welcome to the St. Jude Medical first-quarter 2016 earnings conference call.

Hosting the call today is Mike Rousseau, President and Chief Executive Officer, of St. Jude Medical .

Before we begin, let me remind you that some of the statements made during this conference call may be considered forward-looking statements. The company's 10-K for FY15 identifies certain factors that could cause the company's actual results to differ materially from those projected in any forward-looking statements made this morning.

The company does not undertake to update any forward-looking statements as a result of new information or future events or developments. The 10-K as well as the company's other SEC filings are available through the company or online.

During this call, the company may use non-GAAP financial measures to provide information pertinent to ongoing business performance. Investors should consider non-GAAP measures in addition to and not as a substitute for financial performance measures prepared in accordance with GAAP.

For a reconciliation of our non-GAAP financial measures to our GAAP results, please visit the Investor Relation portion of our website, investors.sjm.com.

(Operator Instructions)

It is now my pleasure to turn the floor over to Mike Rousseau.

Mike Rousseau (President & CEO):

Thank you. Welcome to the St. Jude Medical first quarter 2016 earnings conference call.

Today with me on the call are Eric Fain, Group President; Don Zurbay, Chief Financial Officer; and JC Weigelt, Senior Director of Investor Relations.

Our plan this morning is for Don to provide a review of our financial results for the first quarter of 2016 and to give an update on the sales and earnings guidance for the second quarter and full year 2016. I will then provide additional comments and open the call up for questions.

Go ahead, Don.

Don Zurbay (CFO):

Thank you, Mike.

Earlier this morning, we issued a press release containing our first quarter 2016 financial results as well as the scheduled detailing reported and constant currency results by business area. This press release is available on the St. Jude Medical website.

For participants on today's call, please note that all references to sales growth rates, unless otherwise noted, are on a comparable constant currency basis, which includes Thoratec sales in both comparable years and are adjusted for the impact of currency.

Sales for the quarter totaled $1.448 billion, up 2% from the first quarter of last year. Unfavorable foreign currency translations decreased this quarter's sales by approximately $42 million.

During the first quarter, we recognized $164 million, or $0.57 per share, in net after-tax special charges and amortization expense. For further information regarding these items, please refer to details provided in our press release.

Comments during this call referencing first quarter results and guidance for 2016, including EPS amounts, will be exclusive of these items. Adjusted earnings per share were $0.90 for the first quarter of 2016 compared to adjusted EPS of $0.93 in the first quarter of 2015. We estimate that on a constant currency basis, first quarter adjusted earnings per share increased 9%.

Before we discuss our first quarter 2016 sales results by product category, with guidance for the second quarter and the remainder of 2016, let me provide a few comments about currency exchange rates.

As discussed on prior calls, the two most significant currencies influencing St. Jude Medical's operations are the Euro and the Yen. In preparing our sales and earnings guidance for the first quarter and full-year 2016, we used exchange rates which assumed that each Euro would translate into about $1.05 to $1.10 and for the Yen, each JPY115 to JPY120 would translate into $1.

For the first quarter, the actual average exchange rates for the Euro and the Yen were consistent with these ranges. In preparing our sales and earnings guidance for the second quarter and remainder of 2016, we are now assuming that each Euro will translate into about $1.11 to $1.16 and we now expect each JPY106 to JPY111 to translate into $1.

Additionally, we have assumed changes in various other currencies that impact our results. These changes and assumptions regarding currency exchange rates increased our total forecasted sales for the remainder of 2016 by approximately $85 million and we now estimate that foreign currency translations will reduce our total reported sales for 2016 by approximately $35 million to $55 million versus 2015 including approximately $10 million to $15 million in the second quarter.

I will now walk through first quarter results in our new product categories: heart failure, atrial fibrillation, neuromodulation, cardiovascular, and traditional cardiac rhythm management, or CRM. We issued an 8-K

on January 13, detailing the products in these new categories as well as historical St. Jude Medical sales for each category.

For the first quarter, total heart failure sales were $374 million, which grew 2% from last year's first quarter. Sales of HeartMate 3 during the quarter drove strong double-digit year-over-year growth of left ventricular assist devices, or LVADs, and we now assume the LVAD market is growing in the high single digits. We continue to expect full-year 2016 CardioMEMS sales to be approximately $65 million.

Atrial fibrillation, or AF, product sales for the first quarter totaled $291 million, up 9%. Although there was a difficult comparison this quarter given last year's ablation catheter launches, our worldwide AF business continued to demonstrate strong growth. We expect to continue to take share in the AF market this year, with the continued adoption of our ablation catheter portfolio and the worldwide launch of our EnSite Precision Mapping System.

Total sales of neuromodulation products in the first quarter of 2016 were $116 million, up approximately 10% as we continue to take share on a global basis with the most comprehensive neuromodulation portfolio in the market. Total traditional CRM sales for the first quarter of 2016 were $366 million, down 7%. Sales results were largely driven by weakness in the US, which declined primarily due to MRI product gaps in both our low-voltage and ICD product segments.

Total sales of cardiovascular products for the first quarter of 2016 were $301 million, up 3%. We expect sales in cardiovascular to accelerate as we expand our TAVR sales and launch our Trifecta GT tissue valve in the US and European markets.

Turning to sales guidance. We continue to expect our full-year comparable constant currency sales growth rate for 2016 to be in the range of 2% to 4% and expect comparable constant currency sales growth in the second quarter to be in the range of 1% to 3%.

The gross profit margin during the first quarter was 68.7%, down 210 basis points from the first quarter of 2015, primarily due to a decline of 150 basis points related to the negative impact of currency. Additionally, there was a 60 basis point decline related to the continued weakness in our margin, higher-margin US CRM business.

Please note that our gross profit margin in the first quarter included the final $7 million of Medical Device Excise Tax costs amortized from inventory to cost of sales. For the full year 2016, we continue to expect gross profit margin to be in the range of 69% to 69.5%. This expectation includes continued weakness in our US CRM business, a 60 basis point improvement related to the suspension of a Medical Device Excise Tax and a 50 to 60 basis point decline, driven by the negative currency environment.

Our first quarter SG&A expenses were 31.6% of net sales, a 200 basis point improvement from the first quarter of 2015. For the full year 2016, we now expect this ratio to be in the range of 31.3% to 31.8%.

Research and development expenses in the first quarter of 2016 were 13% of net sales. For the full year 2016, we continue to expect R&D expenses to be in the range of 12.5% to 13% of net sales. Other expense was $41 million in the first quarter. For the full year 2016, we now expect other expense of approximately $155 million to $165 million, primarily driven by interest expense on our outstanding debt.

For the first quarter, our effective income tax rate was 15.9%. For full year 2016, we continue to expect the effective tax rate to be in the range of 15.5% to 16.5%.

Moving on to the balance sheet. At the end of the first quarter, we had approximately $325 million in cash and cash equivalents and $6.1 billion in total debt. During the first quarter, we repaid approximately $400 million of outstanding debt. There were no borrowings outstanding under our $1.5 billion revolving

credit facility available with the group of banks.

Next, I want to offer some comments regarding our EPS outlook for the second quarter and the full-year 2016. In preparing our EPS guidance, we have assumed that in the second quarter of 2016, the weighted average outstanding shares used in our fully diluted EPS calculation will be about 287 million to 288 million shares, and the weighted average shares outstanding for the full year 2016 will be about 288 million to 290 million shares.

For the full year 2016, we now expect adjusted EPS to be in the range of $4.01 to $4.11. The adjustment this quarter to our annual EPS guidance of $0.06 primarily represents the impact of our favorable currency expectations for the remainder of the year. The Company expects adjusted EPS for the second quarter of 2016 to be in the range of $1.05 to $1.07.

I will now turn it back to Mike.

Mike Rousseau (President & CEO):

Thank you, Don. Thanks again to everyone for joining us today.

First quarter results reinforce our confidence that we are focused on the right priorities and are making progress against the objectives we discussed at our Annual Investor Meeting in February.

As a reminder, we told investors that we would successfully execute against four key priorities to set the stage for accelerating growth in 2017. Those priorities are: successfully launch key products to drive sales growth; establish US reimbursement for CardioMEMS nationwide; successfully integrate our Thoratec acquisition; and execute the plan for recovery in US CRM.

Before addressing each of these items in my comments today, I would like to briefly highlight that year to date, we have achieved a number of important milestones that support our objectives, including 10 regulatory approvals. Some of those approvals include our Axium DRG System, MultiPoint Pacing and Quartet Leads here in the US.

In Japan, we received approval for our OPTIS Mobile System, MRI-compatible Ellipse ICD, and MRI conditional labeling on our Quadra Assura CRT-D device. In Europe, we received approval for MRI labeling for Nanostim. The launches supporting these important product approvals are underway and we are pleased with our progress so far.

For the first quarter, sales grew 2%, which is at the high end of our guidance range. I am pleased with our ability to continue to drive adjusted EPS growth at approximately 9% constant currency, above the high end of our guidance range, while at the same time, funding innovation to drive future growth.

Our international business grew approximately 4% in the quarter, driven by growth in left atrial appendage, or LAA closure; LVADs; TAVR; Optical Cohorence Tomography, or OCT; the OPTIS Mobile System with co-registration; and the expansion of our Quadripolar Lead portfolio.

We view the performance of our innovative products when launched internationally as a leading performance indicator for when these products are approved and launched in the US. In addition, our portfolio of commercially available products around the world continues to grow.

I will now discuss our progress in our areas of focus. As many of you know, we have been working to expand our heart failure portfolio through recent acquisitions and internal innovation. Our teams are actively working with governments, payers, hospitals, and physicians worldwide to expand market access to these proven technology solutions across the heart failure continuum.

While our success with MPP and HeartMate 3 are driving growth, we continue to actively address challenges with reimbursement for our CardioMEMS Heart Failure System. And in late January, we applied for a national coverage determination from CMS. We expect formal acceptance of our submission in Q2 and anticipate this to be a 9 to 12 month process before we have a final decision.

Clinical evidence supporting strong effectiveness of the CardioMEMS Heart Failure System continues to grow, with more than 30 key publications and abstracts published to date. We are pleased that the Journal of the American College of Cardiology recently accepted for publication data that was presented at the 2015 HRS Meeting. This retrospective analysis of the CHAMPION trial data shows monitoring pulmonary artery pressure is able to prompt therapeutic changes that improve heart failure management, and in turn reduce hospitalizations.

As importantly, we continue to see real world commercial experience data that is as strong as or stronger than our initial CHAMPION data. For example, real world data recently presented at the American College of Cardiology Annual Meeting showed improved quality of life metrics and improvements in exercise capacity for patients monitored with our CardioMEMS device.

We believe real world data, combined with the growing body of clinical evidence in support of CardioMEMS, continues to demonstrate the tremendous value this important technology offers for improving patient care and reducing overall cost.

To increase our focus on expanding the market for CardioMEMS and LVADs, we have leveraged the legacy Thoratec sales structure to form a combined dedicated US heart failure organization. Our first quarter sales give us confidence that we are on track to achieve our previously issued sales guidance of $65 million in 2016.

We closed on our acquisition of Thoratec about six months ago and our integration process is essentially complete. This important milestone is a full quarter ahead of our initial expectations.

As Don mentioned, LVAD sales in the quarter were strong. Much of this success can be linked to our integration efforts that have included a strong focus on clinical and sales execution and the improved clinical experience that our customers have observed with HeartMate 3. Customers have also shared that they have enjoyed a seamless transition without disruption over the course of this integration process.

Since its launch in October 2015, we have implanted HeartMate 3 in centers across 15 different countries internationally and are now in planning in all four of the largest heart failure centers in Germany, which make up approximately 20% of the European LVAD market. Access to these accounts can be attributed to the strong relationships that St. Jude Medical has cultivated over the years. There will be a number of presentations later this month at the International Society for Heart and Lung Transplant Meeting, supporting both HeartMate 2 and 3, including HeartMate 3 CE Mark 12-month data and real world experience in the Kazakhstan study.

Turning to our CRT portfolio. We recently received FDA Approval for our MultiPoint Pacing, or MPP, technology for our Quadra CRT-D and CRT-P devices, along with two complementary Quartet Left Ventricular Leads, further strengthening our differentiation in the treatment of heart failure. MPP is a first-to-market technology provided only by St. Jude Medical , which we believe will become the next standard of care in CRT therapy and builds upon our success as the leader in CRT therapy options.

In addition to MPP, we intend on adding a feature to our CRT portfolio called Sync AV, which is in response to the growing importance of CRT optimization. We expect this technology to be available to customers in the US during the second quarter of 2016.

Our European experience has shown that MPP can provide improved acute hemodynamic response as

well as an improved chronic responder rate for CRT therapy.

Recent data presented at ACC demonstrated optimization of LV pacing sites by means of hemodynamic and electrical delay, plus MPP resulted in significantly significant improvements in New York Heart Association class Heart Failure Packer Index and remodeling versus standard CRT therapy.

We will present data at the upcoming Heart Rhythm Society Meeting in May, as we were recently informed that the results from our IDE trial have been accepted to be presented as a late-breaking clinical trial session.

We also recently completed enrollment in our 1,800-patient MORE CRT MPP study, which will provide the largest data set regarding the ability of MPP to reduce the percentage of patients or non-responders to CRT. Other studies are also expected to be published in the near term that demonstrate MPP's effectiveness in improving the response to CRT at one year.

With MPP, we have continued to advance CRT therapy by delivering better outcomes for patients and physicians. We believe this is an important next generation technology that differentiates St. Jude Medical and will allow us to grow our market share in this important segment as well as in CRT-P, where we are already the clear market leader.

Moving to our traditional CRM business. First quarter dynamics were similar to those experienced in the fourth quarter of 2015. While we continue to experience challenge in this business, particularly in the US, we continue to believe our competitive position will improve throughout the year. In Japan, we launched our MRI safe ICD, which drove strong high-voltage performance in that geography and we expect our pending launch of MPP to continue to strengthen our CRM business in Japan.

Turning to our US high-voltage business. I would like to highlight that we are still on track to begin our global IDE trial for the MRI-safe ICD with first implants in Europe later this month and remain on track for a US launch during the first half of 2017. Earlier this quarter, Nanostim received its CE Mark for MRI compatibility. St. Jude Medical has long been at the forefront of leadless pacing technology. We look forward to bringing Nanostim, the world's longest-lasting leadless pacemaker with the industry's least invasive and smallest delivery system to the market to ensure broad patient access to this important therapy. We continue to work with FDA regarding our Nanostim leadless pacemaker and continue to expect FDA approval of Nanostim in the second half of 2016.

In the US, we remain in discussions with FDA regarding approval of our Assurity MRI pacemaker, which is the smallest and longest-lasting device in the market. Based on these discussions, we now expect approval and launch of our Assurity MRI pacemakers in the second half of 2016.

We think not having an MRI compatible pacemaker, until the second half of 2016, will cost us approximately $15 million to $20 million in 2016 revenue. However, we are not changing our total sales guidance because we believe continued improvement in US field execution and our strong expected product cadence and our broader electrophysiology business will offset that gap.

The CRM market remains an important area of our business and is a vital part of the care continuum for patients who suffer from a variety of cardiovascular diseases. I want to emphasize that we think about our traditional CRM products in context of the overall Electrophysiology business because that is how our customers make purchasing decisions. Both our sales organization and our customers are excited about the strength of our entire Electrophysiology pipeline that is expected yet this year.

For instance, while sales from our next generation Confirm Insertable Cardiac Monitor, or ICM, will not be reported in our traditional CRM category, once approved, we believe this product will be a driver for our CRM business.

As a reminder, we believe this next generation Confirm will be a disrupter in the market and a significant differentiator for St. Jude Medical . We anticipate this device will be the first commercially available Bluetooth-enabled and smart phone-capable ICM. We are on track to submit for US and European regulatory approvals in the second half of 2016.

So while our traditional CRM business continues to be under pressure, particularly in the US, we are continuing to work on getting MRI-compatible low-voltage approved in 2016 and high-voltage products to market in the first half of 2017.

At the same time, we are continuing to grow other related segments of our business.

In Electrophysiology, this pipeline includes our next-generation Confirm Insertable Cardiac Monitor, MultiPoint Pacing, EnSite Precision, Nanostim and Sync AV product launches, which are all on track and will allow us to continue to contract competitively with hospitals, offset traditional CRM share loss and set the stage for traditional CRM share recapture in 2017.

Turning to our AF business, where our comprehensive product portfolio is, again, a key differentiator for St. Jude Medical . We saw a 9% growth in the quarter. We're excited about our AF position given the strong cadence of new launches and consistent double-digit growth across our TactiCath and FlexAbility ablation catheters.

We expect to continue our successful limited launch of EnSite Precision in Europe and will initiate a full launch in Europe during the second quarter. In the US, we filed our regulatory submissions associated with EnSite Precision in the first quarter and expect to initiate a full launch of our new EnSite Precision System in the US in the second half of 2016. This will be the largest and most comprehensive launch in the history of our AF portfolio and stands to revolutionize the cardiac mapping segment with a flexible, precise, and automated mapping system.

To date, more than 600 procedures have been performed with EnSite Precision in Europe with existing EnSite users as well as by KOLs who have historically favored competitive systems. Feedback on the use of EnSite Precision has been overwhelmingly positive in regards to stability, reliability, speed and unique features including the auto map system. Included in this launch will be a series of sensor-enabled catheters that will allow further penetration of our proprietary MediGuide platform.

We continue to view our AF business as a highlight in 2016 as we gain share with the successful launch of EnSite Precision and the continued adoption of both TactiCath and FlexAbility. We expect to leverage this strong portfolio of new products in conjunction with our CRM business to strengthen our contracting position with US hospitals.

Our first quarter neuromodulation results represent another bright spot in the quarter, as we continued to successfully execute against our strategy of surrounding chronic pain with Spinal Cord Stimulation, or SCS, as well as DRG and radio-frequency ablation. We grew 10% in the first quarter and believe we took share with our innovative SCS platform. Plans are underway to establish St. Jude Medical's proprietary Burst therapy as a new standard advanced wave form in SCS and to achieve superior pain relief across rechargeable and recharge-free devices.

We saw strong growth in our international SCS business with continued adoption of Burst therapy, growing approximately twice the international SCS market growth rate. We remain on track and are preparing to bring our Burst technology to the US in the second half of 2016.

We are pleased with the progress we are making with the launch of Proclaim, the only upgradeable, recharge-free device on the market which is expanding the SCS market as the adoption of this technology is moving more quickly than originally modeled. In fact, we are noticing a significant shift in

our SCS product mix to Proclaim. This momentum signals to us that physicians are highly interested in implanting products that provide them the ability to upgrade software platforms to instantly access new technology upon regulatory approval and that customers realize the benefits of a device that does not require recharging.

Our Axium Neurostimulator System for DRG, or Dorsal Root Ganglion Stimulation expands our chronic pain portfolio in the almost $2 billion chronic pain market to treat patients who suffer from complex regional pain syndrome and positions DRG therapy as a clinically validated market expansion story. The recent 12-month follow-up data on DRG presented at NANS last December demonstrated DRG stimulations sustain superior pain relief and improve therapeutic targeting.

Since our commercial launch in the US a few weeks ago, we have received strong enthusiasm from the clinical community and are on track to complete approximately 100 cases in the first month. We have implanted a successful training program with initial case experiences going very smoothly, providing life-changing results for patients. We have begun to implant our innovative Infinity DBS platform in Europe, with the first cases happening earlier this month. We continue to expect FDA approval in the second half of 2016.

We believe our Infinity platform is the first platform engineered to fuel patient independence with an app-based Bluetooth wireless communication platform and our directional lead technology. This is a first-of-its-kind technology, providing a more patient-centric intuitive technology for patients battling Parkinson's disease, essential tremor, and dystonia. We continue to be excited with the potential that our neuromodulation business offers, as these products are launched and adopted worldwide.

Turning to our cardiovascular portfolio. We continue to execute on our innovation strategy with a focus of bringing to market new technology that will allow us to take share while supporting market growth in our more traditional business segments. We remain encouraged by the momentum of our Portico TAVR System, which continued from last year into the first quarter. We saw implants per week increase throughout the past two quarters and continue to receive positive reviews regarding Portico's ease of delivery, hemodynamic performance and reduced need for pacemaker implants relative to next-generation valves.

The IDE study continues to enroll and we are targeting complete enrollment in the study in the second half of 2016. Additionally, our next-generation tissue valve, Trifecta with Glide Technology, just launched this month in Europe, and with an expected launch in the US during the second quarter.

In regards to our PFO closure device, we look forward to the FDA panel meeting that has now been scheduled for May 24. Recall that at last year's Transcatheter Cardiovascular Therapeutics Conference, 10-year follow-up RESPECT data showed in the intent-to-treat arm of the study that when subsequent strokes were restricted to cryptogenic stroke, there was a 54% relative risk reduction in recurrent cryptogenic stroke for the PFO closure group as compared to medical management. This compelling data was statistically significant.

Our HeartMate Percutaneous Heart Pump, or PHP, device addresses a large growing market and provides meaningful enhancements to the available competitive offerings.

Enrolling patients in this IDE study continues to be a high priority for us and we are gaining traction as we are adding several high-volume centers in the US. In addition, we continue to have good discussions with the FDA regarding our Renal Denervation IDE study and we continue to expect to begin that study later this year.

During the first quarter, we demonstrate our ability to execute against our strategy, deliver on our investment in innovation, and drive market demand for our products. With 10 product approvals and

major product launches in key regions in the first quarter, we are off to a good start in 2016. We're on track to do what we said we were going to do in terms of delivering sales and adjusted EPS growth.

We continue to gain momentum in heart failure with our recent launch of MPP and strong results from our HeartMate portfolio. In AF, we are demonstrating strong growth, with continued share gain in ablation catheters and unprecedented opportunity with the launch of EnSite Precision.

Our Neuromodulation business continues to be a bright spot with above-market growth due to our innovative product portfolio. We have a path for traditional CRM share recapture and believe our expected product cadence in our Electrophysiology business sets the stage for a momentum in 2017.

This is a challenging but exciting time for St. Jude Medical . I believe that we are focused on the right objectives. As the healthcare environment continues to evolve, we're building new capabilities and expanding our comprehensive solutions for the treatment of expensive epidemic disease.

Our focus on innovation and execution is driving results and we have never been better positioned for worldwide market leadership in atrial fibrillation, heart failure and neuromodulation.

Thank you for joining us today.

With that, I'd like to open the call up for questions.

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Matthew Taylor with Barclays.

Matthew Taylor (Analyst - Barclays Capital):

Good morning. Thanks for taking the question. I guess I wanted to see if you could give us a little bit more color on your expectation for the arc of the recovery in CRM and just how important the different product approvals are, MultiPoint, MRI Pacers and MRI high-voltage and why the delay in the pacer here?

Mike Rousseau (President & CEO):

So Matt, I'll start with the importance of the product cadence and how that's going to impact us through the year. The thing to remember about our traditional CRM business is you have to look at it in context of the overall EP business. And that's the way the EP is looking at this business.

So product launches across EP are just critically important. And of course, MPP would be a great example. We've talked a lot about MPP and we really need to work to make sure that this technology is fully appreciated by our customers and frankly, by the Street. It's not simply an iteration of Quadripolar technology.

MPP was developed to really solve a significant problem that the EP has in the CRT-D and CRT-P space, which is the non-responder group. This, in some centers, they will tell you it's as high as 30%. So the idea that there is now a technology that will help reduce the amount of non-responders, it's significant, not just in patient care but also as it relates to the cost of care.

Secondly, there's a technology that we're introducing, Sync AV, and when you take the combination of optimized location, optimization of the management of the device as well as optimized timing, we think the results can be even more promising than we're seeing now. So HRS will be an exciting time for us, the

paper has been accepted there and that's where the initial data will come out.

The other second factor is more CRT. That's going to be the largest study ever and over the years, as you look at technologies like Quad, where you begin to change the way medicine is practiced and actually set the standard of care, it often requires multiple studies and multiple trials. MPP will have two significant trials, with more CRT just completing and now going to the process of follow-up.

And over 60 publications and papers drafted about single-site performance of the product. So we think that, that cadence of products, going into the second half, will be extremely important for us to offset the delay in our labeling for MRI. And as we pointed out, we think that delay is approximately $5 million a quarter and with the cadence of products that we anticipate coming into the market, we're confident that we'll be able to offset that.

As it relates to the delay, we've been working closely with the FDA on this and remember, this is a full PMA requiring review from both the pharma and device side. We believe that we've been working very closely with them over the last several months, particularly, and think we're on a good track to meet the requirements that they've outlined.

I would say that as we look at the submission, we have high confidence that we'll get to the results that are required and we decided it would be prudent to move the time out and make sure that this submission is appropriate contract and will be successful. And so that's the delay that we have.

We think it's a manageable delay when you look at the overall product cadence and we also think that we will, in fact, achieve the labeling this year.

Matthew Taylor (Analyst - Barclays Capital):

Okay. Thanks for all the color.

Operator:

Mike Weinstein with JPMorgan .

Mike Weinstein (Analyst - JPMorgan):

Thank you. A couple questions. Unfortunately, the new categorization and disclosure doesn't help a lot in some of the businesses, so I was hoping you could maybe give us a little bit more color on the HeartMate performance, on the Thoratec performance this quarter? And then second, could you just talk about the data that we're going to see at ISHLT?

Mike Rousseau (President & CEO):

So I'll cover the performance that we're seeing in the field, Mike, and then I'll switch it to Eric to give you update on the study itself and what we're looking forward to at the meeting. (multiple speakers)

Mike Weinstein (Analyst - JPMorgan):

And Mike, you guys said double-digits but that, again, that's such a general comment. It does -- that's just not specific enough to help the Street.

Mike Rousseau (President & CEO):

Okay. So I could characterize that as high teens, Mike, to help you with your modeling.

Mike Weinstein (Analyst - JPMorgan):

Thank you.

Mike Rousseau (President & CEO):

The performance of HeartMate 3, it's in the study has been, not only very well received but it -- I think is really setting the standard here and we're looking forward to the data being presented and clarifying just how good the performance of the product has been. The -- as it relates to building out our sales force, specifically targeted in Europe, we're moving from an independent to direct on a country by country basis.

That process and progress is ahead of schedule. We specifically targeted Germany. It's the most important market in Europe and the team, the sales team over there has really executed at very high level, and now in the four key sites are contracting or in Europe, the tender process is being developed and we think that we're on track to continue to take share in Europe as well as the US.

The last comment I'd like to make about the Thoratec integration. The hard part of acquisitions is always in the outcome associated with the integration. And it's really been a very successful integration with excellent results, both internationally, US, and in the division itself.

In the US, we're so pleased with the performance of that team that we thought it would be a good idea and we're seeing the early results here of actually combining our CardioMEMS team in with that Heart Failure Group, led by that senior executive, Ed Rieflin, who's done a great job in transition. The results so far have indicated that our implant rates continue to improve, giving us confidence that we can achieve the target of $65 million by year end.

So I think we were on a good track from both a product standpoint, the combination of heart failure and access to the top labs, and sales forces around the world that are very focused at launching new technology and taking share. So with that, let me turn it over to Eric. He's got laryngitis but he's going to --

Eric Fain (Group President):

Hey, Mike. Let me know if you can hear me.

Mike Weinstein (Analyst - JPMorgan):

My goodness, Eric, you don't sound too good there.

Eric Fain (Group President):

No, but here, let me help you out with the study. So there's two main abstracts for HeartMate 3 at ISHLT. As you know, one's from Kazakhstan, that has 39 patients, and then the CE Mark study that has 50 patients at 10 centers.

So just to take a step back, there were no stroke events in the Kazakhstan study and a total of nine stroke events in the CE Mark study at one-year follow-up. Since the presentations are still upcoming, I don't want to give too many details but I'd recommend that you -- that everybody attend the sessions and read about that to get a better idea of the details surrounding the strokes, as we've looked at the individual events.

We don't see any systematic trends that are concerning. Also, keep in mind that the CE Mark study represents the very initial experience with HeartMate 3. There's always a learning curve with all devices but especially with LVADs and getting a feel for the appropriate implant techniques --

Mike Weinstein (Analyst - JPMorgan):

Go ahead, Eric.

Eric Fain (Group President):

Okay. (laughter) I'd also say that just in our commercial experience, we're monitoring that, as you might imagine, very, very carefully and we don't see any signals that would raise any concerns.

Mike Weinstein (Analyst - JPMorgan):

Okay. Just two quick follow-ups, guys. So the push out on the timing for the MRI Compatible Pacers, does that have any impact at all on the timing for MRI Compatible ICDs and CRT-Ds in 2017? And then two, when you guys talked about moving Confirm -- downsizing Confirm Loop Recorder to a much smaller device at the Analyst Meeting, you didn't talk about changes to the detection algorithms. I know when Medtronic with Confirm revealed to LINQ, they had to modify their detection algorithms because of the different size of the device. So could you just spend a minute on that? What you're doing to the existing algorithms that have been published on and whether there will be any changes required to get to a much smaller device? Thanks.

Mike Rousseau (President & CEO):

Mike, I'll take the first question and then we'll let Eric start. If he can't finish, I'll try my best to finish for him. But on HV timing, we don't see any impact from one versus the other. As a matter of fact, we think that we're going to start here in weeks and that trial is clearly defined.

We've got -- done a lot of work to make sure that we're prepared to execute on that study. Remember, it's scans, so we have to go collect a number of scans. One of the things about the size of the trial is the actual rate of scans for these patients are somewhere between 3% and 5%.

And so as big as the MRI labeling has become, the actual use and the importance in the market is at that 3% to 5% rate. So there's going to be a lot of scans required to meet the threshold and that's why the timing.

Eric Fain (Group President):

So Mike, on the Confirm. It's the same algorithms. We did not need to change that at all based on the work that we've done with the design. So we're going forward with the same algorithms that we had in the original Confirm.

Mike Weinstein (Analyst - JPMorgan):

Okay. Thank you, Eric. Feel better.

Eric Fain (Group President):

Thanks.

Operator:

Bob Hopkins with Bank of America .

Bob Hopkins (Analyst - BofA Merrill Lynch):

Thanks. Good morning. Can you hear me okay?

Mike Rousseau (President & CEO):

Yes, good morning, Bob.

Bob Hopkins (Analyst - BofA Merrill Lynch):

Great. Good morning, Mike. So two quick questions here. First, just again on the pipeline and I appreciate the update you guys gave on a bunch of different products. One thing I heard though was on EnSite Precision in the US, it sounds like timeline for that has maybe slipped a little bit. Could you just talk about the reason for the slip and confidence that you'll have an approval in the second half? Just want to understand what happened there?

Mike Rousseau (President & CEO):

Okay. So Mike, it's actually six separate submissions, and with a lot of moving parts, as it relates to how that all fits together. So it's a complex submission. It's been thorough. We've met extensively with the FDA and we think that we're on track. It is -- the delay -- and we don't think it will be significant, but the delay is really around the review of the six systems and how they all come together.

It's software, hardware, some peripheral changes and some new catheters that are also involved here that are sensor-enabled catheters that are brand new to the industry. And so that's the challenge. And again, we're working very closely with the FDA.

It's just the significance and the size of the overall submission. So you're -- we're literally talking about a completely updated system across the board and so therein lies the delay in the process. But we're still confident that we'll be in the market with a full release in 2016.

Bob Hopkins (Analyst - BofA Merrill Lynch):

Okay. Thank you for that. And then the second question I wanted to ask was just back on the traditional ICD business, as you guys are breaking it out. Obviously, from a year-over-year perspective, still pretty weak but you did see in the United States a sequential improvement in the traditional ICD business. And so I was wondering if you could just talk about what drove that sequential improvement?

Because it actually is a sequentially, normally a seasonally weak quarter for you and yet you drove a little bit of upside in the business relative to Q4. So can you just talk about what the drivers of that improvement were in Q1 and maybe just talk about some of the changes in the business that you've made that make you think you're on the right track? So I'm talking now besides the pipeline.

Mike Rousseau (President & CEO):

Yes. So the international numbers were strong and, driven to a large extent, by the expansion of MPP and the execution of that sales force has been very good in that space. And I would characterize that as a true international upside. So Europe, Asia and Latin America all had a pretty strong performance and in the markets where we had MPP, we clearly had an advantage in growth.

On the -- in the US, it came down to a series of changes that we made both organizationally, refocusing on the field, and a resetting the expectations around what we want to achieve in 2016 and one of the big factors in the national sales meeting that we conducted was laying out the pipeline and getting people ready to go into the market with significant series of new products.

And so this is always exciting to the EP community when they have an opportunity to meet with our sales reps and our sales management and we lay out the product cadence and we talk about how we can bring that technology into their site. And one of the areas that's probably most exciting is the lab, now, the fully integrated lab. So when you think about the technology required to do that, it is unique to St. Jude Medical .

We are the only Company that can provide a full highly-advanced, the most advanced EP lab in the world and going in and talking about our product portfolio in that context re-energizes the electrophysiologist and reminds them of the innovation St. Jude Medical's bringing into the market. So I think that probably has helped us from an execution standpoint.

And again, we absolutely believe that in the context of these product approvals and the achievement of that MRI labeling, if you look in Japan, for instance, where they received the labeling, they're up high double-digits in the aftermath of the approval of that label. So we think as we get towards the end of 2016, and we develop our momentum going into 2017, we will be a share recapture story in the traditional CRM space.

Bob Hopkins (Analyst - BofA Merrill Lynch):

Great. Thanks, Mike.

Operator:

Bruce Nudell with SunTrust.

Bruce Nudell (Analyst - SunTrust Robinson Humphrey):

Good morning. Thanks for taking the question. Mike, just to start off on, people have consternation about the prospects for CardioMEMS reimbursement, given the local intermediary responses. Could you just kind of explain your level of confidence regarding the ultimate CMS disposition at the NCD? And perhaps explain why the local reimbursement rate path has been rockier than you might expect, given the quality of the data.

Mike Rousseau (President & CEO):

Yes, so -- and you've really characterized the issues well there, Bruce. The -- and I'll start first with where we are on the NCD process. We've had very positive discussions with the CMS organization. We put together with their guidance and with the guidance of several different advocacies and constituents, physicians and ACC and so forth. The heart failure community have all stepped up and are participating in this process and the data, as I know you know, the data continues to get better.

What we're caught in here is not unusual. I think on a go-forward basis, it's our understanding that CMS is very busy. It's one of the reasons that our submission hasn't been accepted yet is that the local MACs are becoming more and more restrictive as it relates to cost management and innovation is now going to either be delayed or go through a more torturous path to get to the patient community.

The local MACs, not all of them, but some of the local MACs look at an annual budget and they're managing within an annual budget. When you look at the value proposition of a product like CardioMEMS, it's two, three, five, 10 years of value at working against a system that's looking at an annual perspective. So if you want to put in context why we have the problem, well, that's the cause of the problem.

The idea that we'll go through the process, one point that we just learned is that CMS has extended the add-on payment in their latest ruling, so they remain committed and positive about the technology. And we think that we'll have to go through this process and quite frankly, unless there's some changes from a legislative perspective, other companies are going to have to go through this same process as it relates to reimbursement.

On the more positive side, I'd say that some of the private payers are starting to show interest and are beginning to work with us as well as the VA and so we have not completely abandoned those areas with

Novitas and FCSO. There are still people that are committed to the technology and are using it. So the fact is, that we're going to go through the process.

We've scheduled a number that we think is achievable and again, I talked about positive implant rates, a nice reduction in stock shelf. That ratio has now crossed over and we're feeling positive about the centers that are open beginning to use CardioMEMS in their normal course of treatment. And that was the goal.

And so we'll build the beachhead. We'll work to achieve the NCD and I think that we will truly end up with the standard of care in heart failure management with CardioMEMS.

Bruce Nudell (Analyst - SunTrust Robinson Humphrey):

And my follow-up pertains -- and maybe you could answer this in a portfolio context, because that was the theme I thought I was detecting in your commentary regarding both AF and neuromodulation. But could you just speak to generally how you feel about the strength of those portfolios versus the cryoablation results that you saw at ACC as well as Nevro's very strong performance in the marketplace with their high frequency and just how competitively you're responding to those entrants.

Mike Rousseau (President & CEO):

Yes, good question, Bruce, and spot on, quite frankly. The strategy we refer to often is surrounding these disease states where we want the deepest and broadest portfolios and we are certainly on track to achieve that. In AF, we will be first to market with advanced sensor-enabled catheters.

We have both the FlexAbility and the TactiCath and I'd like to remind you that we do not have TactiCath in Japan until the second half of 2016 and we do not have TactiCath or FlexAbility in China until the end of the year, beginning of 2017, depending on how the regulatory process rolls out. So the results have been, to a large extent, in Europe and the US and we're talking about mid-teens growth in the ablation segment with right now a pause, if you will, on the capital side as physicians and hospitals are waiting for Precision.

But the depth and breadth of the AF and the ability to sit and meet with physicians. I had a team in, I got to meet some personally about a week and-a-half ago and just how impressed they are when they come in and we have an entire lab. And they're working in an entire suite and every component that they require to do an AF case, including all of the tools. And at this point, I'd say we have the most advanced tools, are all there and will be introduced into the market this year and next year.

The -- so on AF, we're extremely positive. We do think the EP does look at their specialty as device and AF in many cases and so there is the pull-through opportunity. There is the collective contracting opportunity and so there's areas for us to exercise strategically across that -- the broadest platform available in the market.

In Nevro, it's a real success story for us because we have not fully launched the entire portfolio and if you look at our growth in Europe with Burst, you're talking about high double-digit growth in Europe with Burst technology. The platform, both the rechargeable and the recharge-free technologies, the peripherals are now on a smart technology, so patients are using and doctors are using iPads and iTouch, all far advanced from a Bluetooth capability of any of our competitors.

The DBS System and the opportunity to get into the DBS System with another breakthrough technology in the infinity lead, where we can steer the energy and provide the physician more options and opportunities to work with patients, a lot of excitement about that launch yet this year. So we think those two portfolios are exactly -- define our long-term strategy.

Bruce Nudell (Analyst - SunTrust Robinson Humphrey):

Thanks so much.

Mike Rousseau (President & CEO):

You're welcome, Bruce.

Operator:

David Roman with Goldman Sachs .

David Roman (Analyst - Goldman Sachs):

Thank you and good morning, everyone. I had one question on the commercial strategy, then one on currency. First on the commercial strategy, Mike, you talked a lot about wrapping different disease states around -- to drive your sales organization but maybe if you could go into a little bit more detail on CRM and specifically, what I'm wondering is I look at the share loss that you guys have experienced in -- during this MRI product gap.

It's the most share that's ever moved since the recall, whereas Boston Scientific has not experienced the same amount of share shift. So I'm just hoping you could grow through your thoughts on it. If there's anything that's changed in the commercial landscape and whether your competitors are being more successful with bundling across multiple specialities and how you might respond to that once you do fill that product gap and if that is, in fact, a relevant point of discussion.

Mike Rousseau (President & CEO):

When we talk about the bundle, that's actually an area that we want to talk about. The idea that we can bundle in the entire lab and here shortly, we'll be talking about updating all of our EnSite Systems and again, the customer relationship between devices and AF go hand in hand. And so those are discussions we're actually looking forward to having and I think will be very effective for us.

The share loss really came rapidly in Q3. We experienced in Q4. We've made some substantial changes in our leadership team and in our refocusing of our marketing messages and training associated with the new product launches. And I think what the result is that we have a re-energized sales force that has some expectations about what we need to achieve in 2016.

So I think that Boston, obviously also under stress without the label, has managed that over the last two quarters better than we have. I think we've done a better job in Q1. I think that we'll do a better job as we go through the year.

And again, we modeled and planned to be able to manage the product gap until we get it. So we remain on track and our guidance is also on track. As it relates to FX, Don, you want to --

David Roman (Analyst - Goldman Sachs):

Yes, Don, my question on currency was, it looks like you're taking down the dollar impact for the year at the midpoint by roughly $85 million from what you had provided on the January earnings call. So why wouldn't there be a proportional benefit on the EPS line?

Does that have to do with timing of inventories or the hedging programs? You're only taking up by $0.06. I would have thought it could have been higher given the dollar relief that you're getting here.

Don Zurbay (CFO):

It's really the hedging program. Most of the currency impact has been on the Euro and Yen which is where we're heavily hedged, David.

David Roman (Analyst - Goldman Sachs):

Okay. That's helpful. Thank you.

Mike Rousseau (President & CEO):

I guess we'll take one more question.

Operator:

David Lewis with Morgan Stanley .

David Lewis (Analyst - Morgan Stanley):

Great. Thanks for fitting me in. Just two quick ones. First, Mike, for you on neuromodulation. Just 10% constant currency growth prior to US Burst, prior to DRG therapy. From these levels, is there a reason we shouldn't expect acceleration. That's a pretty big number before big product launches and the competition so I'm just wondering how you see that business progressing from here?

And then Don, just trying to get a better sense. I think you just answered David's question on currency. But considering the currency and your better SG&A controls in the first quarter, how are you thinking about sort of margin progression throughout the balance of the year? Thank you.

Mike Rousseau (President & CEO):

So I'll start with neuro. A good way to look at this is, are the performance of our team six months into their Burst launch or so and the results of a 17% in that space. That's a big number. That's twice the growth rate in Europe. And the wave of interest is really around Burst.

It's around our lead technology and it's around upgradability. And then you add into that, DRG. And the DRG story is still really unfolding here. The US demand for DRG, it's a little bit more complicated relative to reimbursement outside the US, a little bit more straightforward in the US, and the -- we are struggling to keep up with the training demand from patients, from physicians who want to treat patients.

I'll also say that -- and it's north of 60%, we're estimating early on here, are patients that would not be considered for standard SCS devices. And so you're looking at the potential of a true market expansion story that could develop here over the year. So when you look at that portfolio, you look at where we are, just like in AF and what we're building out in heart failure, we're at the early end of the process in RF ablation.

We've got the most advanced SCS system. We're bringing advanced wave forms in. We're the only Company that can upgrade wave form technology and advances in the industry without an explant and we're doing this all on cutting edge peripherals, using our Bluetooth capability.

You put DRG in there and then you add DBS which puts us into the deep brain space with brand-new platform hardware as well as software and peripherals, and we had an excited sales force. This is a sales force that has always performed even in the most difficult of times and it's great fun to be with them and around them because they're as excited, as you can imagine and looking forward to the competition.

As it relates to neuro, it's an underpenetrated space. The idea that Nevro is going to help be an expander. There will be some share loss in the market. We're working to not be one of the companies that are giving up some share loss but the idea that there's innovation coming into the space and driving the

total size of the market which is so underpenetrated long term, this is probably a good outcome.

Don Zurbay (CFO):

David, on the margin question, obviously, we maintained our guidance on the gross margin side. We think the currency gives us an opportunity to get more toward the higher end of that. We did bring down, or improve our SG&A guidance given that we had a pretty good first quarter. I think all that gives us confidence that as we look at our EPS guidance for the year, we can start focusing on the upper half of that number.

David Roman (Analyst - Goldman Sachs):

Okay. Thank you very much.

Mike Rousseau (President & CEO):

Okay. Thank you.

Operator:

We have no further --

Mike Rousseau (President & CEO):

If there aren't any further questions, I'd like to thank everybody that attended the meeting and look forward to seeing you next quarter.

Operator:

Today's call is being recorded and will be available for replay beginning at approximately 12