Johnson & Johnson (JNJ) CEO Discusses Q2 2013 Results - Earnings Call Transcript

Executives

Louise Mehrotra - Vice President, Investor Relations

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sandra Peterson - Group Worldwide Chairman

Dominic Caruso - Chief Financial Officer, Vice President - Finance

Analysts

Mike Weinstein - JPMorgan

Rajeev Jashnani - UBS

Matthew Dodds - Citigroup

Kristen Stewart - Deutsche Bank

Larry Biegelsen - Wells Fargo

Derrick Sung - Sanford Bernstein

Jami Rubin - Goldman Sachs

Danielle Antalffy - Leerink Swann

Tony Butler - Barclays Capital

Glenn Navarro - RBC Capital Markets

Matt Miksic - Piper Jaffray

Jeff Holford - Jefferies

Bob Hopkins - Bank of America Merrill Lynch

David Lewis - Morgan Stanley

Johnson & Johnson (JNJ) Q2 2013 Earnings Call July 16, 2013 8:30 AM ET

Operator

Good morning, and welcome to the Johnson & Johnson second quarter 2013 earnings conference call. All participants will be able to listen-only until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections you may disconnect at this time. (Operator Instructions).

I will now turn the call over to Johnson & Johnson. You may begin.

Louise Mehrotra

Good morning and welcome. I am Louise Mehrotra, Vice President of Investor Relations for Johnson & Johnson and it is my pleasure this morning to review our business results for the second quarter of 2013. Joining me on the call today are Alex Gorsky, Chairman of the Board and Chief Executive Officer and Sandy Peterson, Group Worldwide Chairman and Dominic Caruso, Vice President Finance and Chief Financial Officer.

A few logistics before we get into the details. This review is being made available to a broader audience via a webcast accessible through the Investor Relations section of the Johnson & Johnson website. I will begin by briefly reviewing highlights of the second quarter for the corporation and highlights for our three business segments.

Following my remarks, Alex will provide some additional commentary on our results and an update on our near term priorities and Sandy will provide an update on our consumer business and our global supply chain. Please note, the presentation for the company's, Sandy's and Alex's remarks are available on our website. Dominic will provide some additional commentary on the financial results and guidance for 2013.

We will then open the call to your questions. We expect the call to last approximately one and a half hour. Included with the press release that was issued earlier this morning is the schedule of sales for key products and/or businesses to facilitate updating your models. These schedules are available on the Johnson & Johnson website as is the press release.

Before I get into the results, let me remind you that some of the statements made during this review may be considered forward-looking statements. The 10-K for the fiscal year 2012 identifies certain factors that could cause the company's actual results to differ materially from those projected in any forward-looking statements made today. 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 is available through the company and online.

During the review, non-GAAP financial measures are used to provide information pertinent to ongoing business performance. These non-GAAP financial measures should not be considered replacements for GAAP results. Tables reconciling these measures to the most comparable GAAP measures are available in the press release and on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com.

Now, we would like to review our results for the second quarter of 2013. If you would refer to your copy of the press release, let's begin with the schedule titled, supplementary sales data by geographic area. Worldwide sales to customers were $17.9 billion for the second quarter of 2013, up 8.5% as compared to the second quarter of 2012. On an operational basis, sales were up 10% and currency had a negative impact of 1.5%.

In the U.S., sales were up 8%. In regions outside the U.S., our operational growth was 11.8%, while the effect of currency exchange rates negatively impacted our recorded results by 2.8 points. Sales included the impact of the acquisition of Synthes, net of the divestiture of the DePuy trauma business. Excluding this impact, worldwide operational sales growth was 5.6%.

The western hemisphere, excluding the U.S. grew by 14% operationally while Europe grew 11.4% on an operational basis. Asia-Pacific, Africa region grew 11% operationally. The success of new product launches and Synthes sales made strong contributions to the results in all regions.

If you will now turn to the consolidated statement of earnings. Net earnings were $3.8 billion compared to $1.4 billion in the same period in 2012. Earnings per share were $1.33 versus $0.50 a year ago. Please direct your attention to the box section of the schedule where we have provided earnings adjusted to exclude special items. As a reference to the accompanying table reconciling non-GAAP measures, 2013 second quarter net earnings were adjusted to exclude special items related to increases in litigation expense accrual, integration and transaction cost related to the acquisition of Synthes and cost associated with the DePuy ASR Hip program.

Second quarter 2012 net earnings included after-tax special items of approximately $2.2 billion as shown in the accompanying reconciliation of non-GAAP financial measures. Excluding these special items for both periods, net earnings for the current quarter were $4.3 billion and diluted earnings per share were $1.48, representing increases of 17.7% and 13.8%, respectively, as compared to the same period in 2012.

I would now like to make some additional comments relative to the components leading to earnings before we move onto the segment highlights. For the second quarter of 2013, cost of goods sold at 30.7% was down 50 basis points from the same period last year, primarily due mix, lower cost associated with strong volume growth in our

pharmaceutical business and cost improvement initiatives across all the businesses. This was partially offset by incremental amortization expense related to Synthes of approximately $140 million, or 80 basis points and the impact of the medical device excise tax.

Second quarter selling, marketing and administrative expenses were 30.1% of sales consistent with our 2012 results. Our investment in research and development as a percent of sales was 10.9%, up 20 basis points due to milestone payments.

Interest expense net of interest income of $101 million was down $28 million versus the second quarter of 2012, due to a lower average debt level. Other expense, net of other income was $172 million in the second quarter of 2013, compared to $2 billion in the same period last year.

Excluding special items, other income net of other expense of $394 million was $220 million favorable compared to 2012, the gain on sale of the ECHELON investment is reflected in this amount.

Excluding special items, the effective tax rate was 20% in the second quarter of 2013, compared to 21.6% in the same period last year. Dominic will provide commentary on taxes in his remarks.

Turning now to business segment highlights, please refer to the supplementary sales schedule highlighting key products or businesses for the second quarter of 2013. I will begin with the consumer segment.

Worldwide consumer segment sales for the second quarter of 2013 of $3.7 billion, increased 1.1% as compared to the same period, last year. On an operational basis, sales increased 1.7%, while the impact of currency was negative 0.6% U.S. sales were up 1%, while international sales grew 2% on an operational basis.

Excluding the impact of divestitures net of acquisitions operational growth was approximately 2.5%. Baby Care products increased on an operational basis by 3.1% when compared to the second quarter of 2012, primarily due to hair care and cleansers. Sales in the Oral Care business increased operationally 0.2%. Results were driven by strong international sales of LISTERINE, due to the continued success of new product launches partially offset by the impact of the divestiture of manual toothbrushes in North America.

Beginning this quarter, we are reporting OTC Pharmaceuticals separately and have moved Nutritionals to the other line. To assist in updating your models, a summary under the new format is included in the sales schedule that accompany the press release.

For the second quarter of 2013, sales for OTC pharmaceuticals increased 5.4% on an operational basis compared to the same period in 2012. U.S. sales were up 17.4% driven by strong growth in analgesics and other key brands as we continue to make progress in returning a reliable supply products to the marketplace.

International sales were up 0.9% operationally. Our Skin Care business was down 0.4% on an operational basis in the second quarter of 2013. Strong results for [renal] were offset by the impact of divestitures. Excluding divestitures, operational growth was approximately 1%.

Women's health grew 3.6% on an operational basis due to strong growth in women's sanitary protection products. Wound Care other sales decreased 4.3% on an operational basis, impacted by competitive pressures as well as a divestiture and nutritionals.

That completes the review of the Consumer segment, and I will now review highlights for the pharmaceutical segment.

Worldwide net sales for the second quarter of $7 billion increased 11.7% versus the same period last year. On an operational basis, sales increased 12.9% with a negative currency impact of 1.2 points. Sales in the U.S. increased 9.1%, while sales outside the U.S. increased on an operational basis by 16.5%.

Now reviewing sales for major therapeutic areas. Immunology products were 17.6% operationally, with sales in the U.S. up 7.3% and sales outside the U.S. up 51.5% operationally. During the quarter, the company made certain supply chain changes from for REMICADE, resulting in sales to distributors previously recorded as U.S. exports sales now being international sales. Adjusting for this impact, the U.S. immunology growth was approximately 14% with REMICADE excluding expert sales up approximately 4%, SIMPONI up 38.1% and STELARA up 53.3%. Results were driven by market growth across the major products, complemented by increased market share for both STELARA and SIMPONI.

With the strength of our portfolio, we continue to be the U.S. market leader in immunology. Adjusted immunology

sales outside the U.S. increased by over 25% operationally, with REMICADE up approximately 20% due to strong growth in Canada and the emerging markets including a tender shipment. STELARA made significant contributions due to market share gains and market growth across the major regions, while very strong growth in Japan drove the results for SIMPONI.

Sales of infectious disease products increased 23.9% on an operational basis. INCIVO, a treatment for Hepatitis C grew 71.8% on an operational basis due to the success of the continued rollout most notably in Latin America as well as a shipment for tender business. Continued momentum in market share growth of PREZISTA made notable contributions to the results as did the combined sales of COMPLERA and EDURANT.

Neuroscience product sales increased 0.4% operationally. U.S. sales declined 4.9% impacted by generic competition primarily for CONCERTA. The long-acting injectable antipsychotics, RISPERDAL CONSTA and INVEGA SUSTENNA or XEPLION achieved operational growth of approximately 15% due to an increase in combined market share.

Sales of oncology products increased 53.2% on an operational basis due to the very strong results for ZYTIGA and VELCADE. ZYTIGA is now approved to treat both chemo refractory and chemo naïve metastatic castration resistant prostate cancer. In the quarter, ZYTIGA achieved operational sales growth of 70% with U.S. sales growing 54% due to very strong market growth of over 20% and increased market share in the combined metastatic castrate resistant prostate cancer market. ZYTIGA has captured over 30% of that market and is up approximately 3.5 points sequentially. Operational sales outside the U.S. grew 85.2% versus second quarter 2012 and on a sequential basis, ZYTIGA was up over 20%. Additional country rollouts and the expansion of the label to chemo naïve patients drove the strong results. ZYTIGA is approved in more than 80 countries.

VELCADE is a treatment for multiple myeloma. Sales increased 22.7% on an operational basis. Strong performance in patient share in the frontline setting and the launch of the subcutaneous version continue to drive sales growth.

Other oncology increased primarily due to DOXIL/CAELYX. Other pharmaceutical products declined 2.7% on an operational basis with lower sales for ACIPHEX and PARIET, related primarily to generic competition. PROCRIT sales declined 18.1%, due primarily to a market decline. Positively impacting results, XARELTO sales grew over 20% on a sequential basis capturing nearly 39% of new to brand scripts in cardiology, surpassing warfarin. Total prescription share in the broader anticoagulant market grew 1.7 points on a sequential basis to 7.4%.

As an update on the pipeline, during the quarter, in immunology the FDA approved SIMPONI for the treatment of moderately to severely active ulcerative colitis and the EMA application for SIMPONI IV for the treatment of adults with moderately to severely active RA was resubmitted. In infectious diseases, a marketing authorization application was submitted to the European Medicines Agency seeking approval for simeprevir for Hepatitis C, and it was granted U.S. priority review status by the FDA with a PDUFA in late November. The European Commission approved a new twice daily dosing for INCIVO. In neuroscience, regarding bapineuzumab, JANSSEN Alzheimer Immunotherapy and its alliance partner Pfizer have decided to discontinue development of the subcutaneous formulation.

Studies with other compounds in earlier stages of development in the alliance portfolio are ongoing and future development strategies will be discussed jointly by the alliance partners. We remain committed to our efforts to discover and develop promising new treatments for people with Alzheimer's disease.

Regarding the stent thrombosis sNDA for XARELTO, a complete response letter was received from the FDA. We remain confident in the results of the ATLAS ACS trial and are in ongoing discussions with the FDA regarding this sNDA.

In oncology, Breakthrough Therapy Designation for daratumumab, for the treatment of certain patients with multiple myeloma was granted by the FDA and the positive opinion from the European authorities on two variations relating to the use of VELCADE were received.

The first recommendations for the use of VELCADE as retreatment in adult who had previously responded to the treatment with the same medicine, the second recommendation was for using induction combination therapy for certain adult patients. And, ibrutinib was submitted to the FDA for use in the treatment of previously treated patients with chronic lymphocytic leukemia or CLL, and small lymphocytic lymphoma or SLL and for its use in treatment of previously treated patients with mantle cell lymphoma or MCL.

That completes the review of the Pharmaceutical segment. I will now review the Medical Devices and Diagnostics segment results. Worldwide Medical Devices and Diagnostics segment sales of $7.2 billion grew 12% operationally as compared to the same period in 2012.

Currency had a negative impact of 2.4 points resulting in a total sales increase of 9.6%. Sales excluding the net impact of Synthes were up 0.5% on an operational basis, with U.S. sales down 3.3% and sales outside the U.S. up 3.5% on an operational basis. Adjusted for divestitures and exits from certain businesses, underlying growth was approximately 1.5%, reflecting continued market and pricing pressures. I will provide more commentary on these factors in the franchise reviews.

Now, turning to the MD&D businesses starting with, Cardiovascular Care. Cardiovascular Care sales were up 7.7% operationally, with U.S. up 4.6% and sales outside the U.S. up 9.6%, operationally, driven by Biosense Webster, our electrophysiology business with worldwide operational growth of over 16% in the quarter.

The success of a number of catheter launches made strong contributions to the results. The Diabetes Care business operational sales declined 11.8% in the second quarter of 2013 with U.S. business down 23.1%, due to the impact of lower price, competitive pressures and softness in the retail market. The business outside the U.S. was down 0.5%, operationally, with strong growth in the emerging markets offset by lower sales in many of the developed markets.

The Diagnostics business declined 4% on an operational basis. Excluding the impact of divestitures of RhoGAM and Theracos businesses operational sales grew approximately 2.5%, primarily due to growth and donors screening in the U.S. and emerging markets outside the U.S.

Infection Prevention increased 5.2% on an operational basis, with sales in the U.S. down 4% due to lower sales of capital equipment. Outside the U.S. operational growth of 12.3% was driven by both, consumables and capital item sales.

Orthopedic sales were up 48.9% on an operational basis when compared to the same period in 2012. Excluding the net impact of Synthes, operational sales were up approximately 3% with U.S. up approximately 2% and outside the U.S. up approximately 3.5%, operationally.

Operationally, Hips were up 4% worldwide driven by 5% growth in the U.S., due to strong results in primary stent platform sales, partially offset by continued pricing pressure. Hips outside the U.S. were up 4% on an operational basis, driven mainly by heads and acetabular products.

Knees worldwide increased 2% on an operational basis with the U.S. up 3% driven by the ATTUNE fixed bearing knee as well as revision platforms offset by lower sales of rotating platforms. Sales outside the U.S. were up 1%. Including the Synthes business in both periods and excluding the divested DePuy trauma business in both periods, trauma grew approximately 4% on an operational basis due to both, new products and stronger underlying demand.

Growth in the U.S. was 2% and 7%, operational outside the U.S. Including the Synthes business in both periods, worldwide spine was down 2% on an operational basis, with U.S. down approximately 7%, impacted by continued softness in the market, as well as the impact of the attrition of the commercial sales organization as we integrate the businesses. Outside the U.S., sales were up approximately 6% operationally with strong growth in Latin America, Canada and Asia-Pacific.

Specialty surgery operational growth was 2.8% in the second quarter of 2013. U.S. Sales were down 1.5% and sales outside the U.S. were up 7.5% on an operational basis. Strong sales of balloon sinuplasty products from Acclarent and biosurgical products were partially offset by lower sales of Mentor products due to competitive and pricing pressures. Sales of energy products were flat on an operational basis with new product launches and continued penetration driving strong sales outside the U.S. offset by softer sales of HARMONIC products in the U.S. Surgical care worldwide sales were down 1.2% on an operational basis with the U.S. down 4.2% and sales outside the U.S. up 0.6% operationally.

Negatively impacting growth were divestitures and business exits. Excluding these items, the underlying business was flat with lower sales of women's health and urology offset by strong demand for endocutter products, with the ECHELON FLEX Powered ENDOPATH Stapler.

Rounding out the review, the medical devices and diagnostics segment, our Vision Care business achieved operational sales growth of 5.4% in the second quarter with the U.S. up 3.6% and sales outside the U.S. up 6.4% operationally. Growth was driven by daily lenses and astigmatism lenses. That completes highlights for the medical devices and diagnostics segment and concludes the segment highlights for Johnson & Johnson second quarter of 2013.

It is now my pleasure to turn the call over to Alex Gorsky. Alex?

Alex Gorsky

Well, hello everyone and thank you, Louise, and thanks to everyone for joining us on this call today. Now it is really my pleasure to review our results for the first half of the year and also the progress we made under near-term priorities. Now, you recall, in January, that I discussed the framework for managing our business. The success of our enterprise is built first on Our Credo, which unites Johnson & Johnson as a global enterprise. Our strategic operating principles continue to service well in the evolving marketplace and with our four growth drivers, we have a sound approach to sustaining and driving growth in today's dynamic global healthcare environment.

At the mid-year point, we have achieved strong growth across our enterprise. A year ago, our team established a set of critical near-term priorities for moving the business forward. As part of our commitment to keeping you appraised of how we are doing against them, I am pleased to say that with the laser focus approach we have taken, we have made solid demonstrable progress in delivering on our financial commitments, restoring a reliable supply of OTC products to consumers, continuing the successful integration of Synthes and building on the strong momentum in our pharmaceutical business.

Reflecting our broad base of leadership in healthcare, we have generated sales of $35.4 billion thus far in 2013, up a strong 9.9% operationally versus this time a year ago, 4.8% operationally, excluding the net impact of Synthes. Medical devices and diagnostics represents 40% of our total sales, generating $14.3 billion in sales year-to-date. Sales grew 12% operationally driven by the positive growth contribution of the Synthes acquisition.

Excluding Synthes, overall growth in this segment was impacted by portfolio decisions to divest and exit certain businesses as well as the continued economic and pricing pressures within these markets. Underlying growth was essentially flat year-to-date. With $13.8 billion, the pharmaceutical segment represented 39% of our total sales and has continued its strong momentum reporting operational growth of 12.1%. Our consumer segment generated 21% of our total sales at $7.3 billion in revenue at an operational growth rate of 2.4%.

Now as the global economy evolves, more people are entering the middle-class in emerging markets and increasing demands on the healthcare system. As I outlined at our year-end earnings meeting in January, we are investing in growth and expansion in the broader emerging markets by leveraging our strong iconic brands as well as acquiring market specific products and to-date they account for nearly a quarter of our sales. As a subset of the emerging markets, we are also seeing growth in the brick nations, which account for approximately 10% of our overall sales this year.

We are encouraged by the double-digit growth rates we are seeing in these countries driven by our core pharmaceutical and the Indian consumer brands as well as the complementary acquisitions we have made in Russia and China. As our global reach with local focus, strategy for driving growth matures, we will overtime be introducing more products that will increase options for consumers in these fast-growing parts of the world.

Moving now to the segment highlights. I will start with pharmaceuticals. Our pharmaceutical segment continues to drive robust growth by delivering meaningful innovations that will improve patient care, demonstrating the effect of the transformation we made in this segment. I am very proud of the accomplishments that our pharma team has exhibited in this process.

Our market leading execution in support of the 11 new products we've launched since 2009 has led our Pharmaceuticals business to a record 13 consecutive quarters of operational growth. That pace positions us as the fastest growing, top-10 global pharmaceutical company and U.S. leader in new product sales. Those new products, which includes ZYTIGA, STELARA and INVEGA SUSTENNA comprise 24% of our global pharmaceutical sales in the first half of 2013.

Now, we gave you a full review of our Pharmaceutical business in May, at which time we announced our intention to file more than 10 new molecular entities and 25 significant brand line extensions by 2017, so today I will just comment on two important developments we made in the quarter within our oncology division since the meeting which will really help to increase our leadership position in the category.

As we announced last week, ibrutinib became one of the first medicines to be filed with the FDA and the new breakthrough therapy designation. And if approved, it will be a first-in-class treatment option for patients who received prior therapy for chronic lymphocytic leukemia and small lymphocytic lymphoma, and also for patients who received prior therapy for mantle cell lymphoma, population today have very limited options.

Now recognizing this need, we and our strategic partners at Pharmacyclics are pleased to have been able to open an expand access program for relapsed or refractory MCL patients in the U.S. The program began enrolling in May. It is allowed by the FDA as a means of making an investigational drug available to patients with a serious or immediately

life-threatening disease without comparable or satisfactory alternatives.

We also announced a definitive agreement to acquire Aragon Pharmaceuticals, a move that will add their androgen receptor antagonist program to our R&D engine, including a lead development stage product ARN-509 for prostate cancer, which is attractive to us because the way it complements ZYTIGA were also increasing new options we can eventually offer patients in this important and growing segments of the oncology field.

So, now let's look at the market performance of some of our recent pharmaceutical launches. By combining superior science with best-in-class commercial capabilities, many of our newly launched products are delivering robust growth and outpacing our peers. As you can see, XARELTO, which is the broadest indication among novel oral anticoagulants is tracking well at of warfarin and the others in the category, in new to brand prescriptions among cardiologists and ZYTIGA is continuing on its strong growth trajectory gaining 22% in the U.S. chemo naïve market since its approval in this indication in December.

INVOKANA, our new treatment for Type 2 diabetes was launched in the U.S. in April, was demonstrating very strong early results with the primary care and endocrinologists. Access INVOKANA is also building steadily and we are seeing strong interest from payers. Overall, 80% of patients with commercial plans now have access to INVOKANA in either Tier 2 or Tier 3. The success coupled with the supported joining the forces our pharmaceutical group with our Diabetes Care business has helped INVOKANA overtake Januvia, Onglyza and Trajenta in share of new to brand prescriptions in the important Endocrinologists segment.

This type of early progress demonstrates the power of leveraging our enterprise-wide capabilities to offer patients a full solutions based approach to diabetes management, and we are looking at leveraging our broad capabilities across the enterprise to support the growth of our products in other categories in similar ways.

As I referred to earlier, the pace of growth in the global MD&D markets has slowed and competition is intensifying. In spite of the economic compression however, the medical device industry remains attractive and we are transforming our go-to-market approach to drive our competitiveness in this dynamic environment and ensure we continue to lead the sector.

With market-leading platforms and products, we succeeded in sustaining or grown share in the majority of our key platforms, holding number one or number two positions in about 85% of them. We are continuing to bring innovations to patients and providers through meaningful product launches that will help sustain and drive growth and we are especially excited about the steady cadence of innovation emerging across the segment.

For example, Biosense Webster, a business unit that's on track to deliver another year of double-digit growth as it has for more than 10 years in a row. Their nMARQ, circular ablation catheter is designed to reduce cardiac ablation procedure time and complexity to key customer needs. It launched last year in Europe and we began enrolling patients in the clinical trial that will support our regulatory filing in the U.S. planned for next year.

Also, the ThermoCool SmartTouch Catheter is an important innovative product that measures the catheter tip contact force and direction inside the heart during ablation procedures in real time. We launched this product in the EU in 2012 and compelling new safety and efficacy data were presented recently at the Heart Rhythm Society meeting. These data will be included in our application for U.S. approval that we plan to submit later this year.

We are also bringing products to patients to meet specific market needs. The Bioseal fibrin sealant in China is just one of many. We are Also focusing our resources to advance more strategic options in our portfolio that start with taking a comprehensive view on the disease like we have done in large chronic disease states such as diabetes. Now to help dim the cost curve in healthcare we are focusing our broad and diverse R&D approach and portfolio to deliver total solutions of products that will increase the clinical value we offer patients and providers as well as the economic value we offer for healthcare systems and payers across the globe.

Consider the ATTUNE knee system which DePuy Synthes has just recently launched. The development team conducted extensive research in its design to help improve functional outcomes for patients, performance for surgeons and efficiency for providers. From the patient perspective, ATTUNE is designed to provide better range of motion and address the unstable feeling some knee replacement patients experienced and also provides an extensive range of sizes for better patient matching. From the provider perspective, simply reducing the number of instruments used with ATTUNE in addition to several innovative design features flattens the learning curve and delivers more efficiencies for the surgeon and operating room staff.

Now an update on DePuy Synthes. We are a year into the integration and as we envisioned, by broadening our base of

offerings and expanding our reach in emerging markets, we have built a compelling growth combination that solidified our leadership in the $40 billion global orthopedics and neurologics marketplace. Our joint reconstruction business continues to do well especially with hips in the U.S. which have grown approximately 5% thus far in 2013. The ATTUNE knee that I just described has had a favorable initial response.

In trauma, we are encouraged by the second quarter results that generated mid single-digit operational growth in international markets, fueled by Europe as well as in emerging markets, notably China. In spine, disruption due to sales force attrition has improved and favorable increases in volume are being seen as the sales force continues to see momentum with cross-selling by the combined forces especially outside the U.S. with operational growth this past quarter in the mid-single digits.

While we still have work to do in certain areas of the integration, we are making good progress and we are seeing the benefits of bringing a broader portfolio of products to our customers to cross-selling including the collaboration between our cranio-maxillofacial and Codman businesses. We are also looking forward to similar results and to begin cross-selling products from our power tools and biomaterials platforms.

Now as we advance, we see additional growth in synergy opportunities within the organization and we are turning our attention to R&D and manufacturing and supply chain and to standardizing the IT infrastructure across the globe to improve our focus, speed and efficiency in order to realize them. You will hear more about the progress of our orthopedics business in the third quarter when Michel Orsinger, our worldwide chairman for DePuy Synthes will be on the call.

Our consumer segment is showing signs of its continued return to growth through its increasing momentum in returning a reliable supply of U.S. OTC products to the shelves, the continued expansion of iconic brands in the emerging markets and an overall focused portfolio and management approach. Sandy Peterson, who joined at the end of last year has already made an important impact on the organization. As group worldwide chairman, she holds a broad leadership role leading our supply chain, information technology and our consumer business sector. She is bringing a high level of broad and relative experience to our enterprise and I am pleased to be turning the call over to her in just a minute so that she can discuss her vision and plans for these vital areas of our business.

To recap, the year is off to a strong start. We have also made strong progress against our near-term priorities and long-term growth drivers to help sustain and drive growth in this dynamic global market. I will end by thanking our employees who work everyday on behalf of the patients, communities and shareholders that depend on us to deliver a high-quality and innovative products and solutions.

Now it is my pleasure to turn the call over to Sandy Peterson.

Sandra Peterson

Thanks, Alex. I have been with Johnson & Johnson now a little over seven months. It has been a great beginning and the longer I am here, the more excited I am about our ability to have a meaningful impact on people's lives around the globe. I have had the privilege to work at a number of well-respected companies, both inside and outside of healthcare and across geographies.

With that perspective, I am convinced that Johnson & Johnson is uniquely differentiated by its virtue of its broad portfolio, talented people and geographic reach to make a profound difference in health care. As you know, health care across the globe is changing as governments and consumers work to improve the quality of care and the rolls that providers, healthcare professionals and retailers also adapt and become more global.

I have spent much of my time so far meeting our customers and colleagues around the globe and learning our business. I have been to our major business and manufacturing campuses in the US, Brazil, Ireland, Puerto Rico, Belgium, China, Singapore, Vietnam and Thailand. I have met with numerous retail and provider payer customers in the U.S. and in our key other regions, both, large global customers as well as small mom-and-pop operation. What is most striking to me is the talent and diversity of our colleagues around the globe. And equally impressive is experiencing our credo as the source of constancy and inspiration in a time of remarkable change inside our company and in health care across the globe.

Our consumer brands are strong and resilient. Our breadth is a source of strength and competitive advantage. Although we have been challenged in recent years, our reputation with consumers, retailers, healthcare professionals and providers remain strong. As you know, I have accountability for some of the company's key enterprise functions, supply chain, including quality and information technology, as well as our consumer business sector. This integrated

portfolio affords us the capacity to leverage these important functions to help deliver innovation and value to our customers and company across sectors and across the globe. We have the opportunity to leverage our scale and breadth through world-class deployment of information technology services and supply chain to better serve the evolving needs of our customers and consumers.

Today, I will provide update related to our consumer businesses and the Johnson & Johnson supply chain. Let's start with what Alex had previously identified for you as one of our top enterprise-wide priorities, restoring a reliable supply of our U.S. OTC products. Our priorities in the U.S. OTC business are, first, to deliver on our consent decree milestones, second, to ensure reliable supply of OTC products to retailers and consumers. Third, to achieve both, brand leadership and sustained healthcare professional number one recommended status, fourth, to rebuild customer trust and become our customers' preferred partner and fifth to execute a return to market plan for core U.S. OTC brands and SKUs.

Our consent decree work plan was approved by the FDA without modification in the fourth quarter of 2012. We've achieved 100% on-time execution of the prescribed step through the second quarter. Additionally, all reports have been submitted to the FDA on time. We are making good progress on restoring our OTC brands to the shelf. We have achieve solid steady unit sale rates and consistent delivery commitments to customers and retailers.

By year end, our plan is to deliver reliable and consistent supply of three quarters of the product brands. In the first half of 2013, we achieved the U.S. OTC operational growth of 19.7%, which includes 26% growth in revenues in over-the-counter medicines, and we are winning the hearts of consumers as these products return to the shelves in all four segment cough, cold and flu, allergy, pain and digestive health. For instance, Extra Strength TYLENOL is the number one code in adult pain. Children's TYLENOL and MOTRIN are the top two SKUs in pediatric pain, and we are leading in other important categories such as allergy care with ZYRTEC and our digestive health brands IMODIUM and IMODIUM are returning the strength.

We are focusing on our top retail customers. We have achieved full distribution of key brands and point-of-sale has improved with all top retailers. We are partnering with them on strategic initiatives that are rebuilding our relationships and supporting their health and wellness strategies in order to educate consumers, simplify their purchasing experience and ultimately to help bring more consumers into their stores. Our strategic purpose for our consumer segment is caring for people around the world by anticipating their needs and creating solutions and experiences that help them and those they care for to live a healthy, vibrant lives and we are uniquely suited to do just that.

Our broad consumer portfolio, from well-being and beauty to health and (inaudible) is a competitive advantage as are our iconic brands. We have a legacy of innovation that leverages our scientific heritage and wins us unparalleled professional endorsements, trust-based relationships with healthcare professionals and deep consumer insights. We are applying the portfolio of discipline that calls on us to make choices that will drive global brand growth in key priority markets, including rationalizing SKUs and harmonizing formulations. With our long history in emerging markets, which represent a proportionately higher share of segment sales than elsewhere in Johnson & Johnson, we are globalizing existing brands such as Listerine, Motrin, Johnson's Baby and Carefree and complementing our portfolio with key local brands like Elsker in China and Rinzai and Dr. Mom brands in Russia.

Our consumer segment is not only a critical component of Johnson & Johnson's diverse portfolio and growth plan, our iconic brands are those that stakeholders most closely identify with Johnson & Johnson. We are pleased with the value creation opportunities ahead of us but we know, there is still work to be done to restore our OTC businesses to sustainable growth, while globalizing our remaining brand portfolio and investing in key market growth.

Let us now shift to how we are working to deliver a reliable and cost competitive supply of high quality products to our customers, consumers and patients across our businesses. Three years ago, we created a global enterprise supply chain. Our goal was to integrate into a network that would employ consistent quality standards and systems, leverage the scale and technological breadth of our portfolio and enable continuous production of cost-effective and high-quality products. This is a multiyear effort to integrate and leverage over 120 manufacturing sites, over 500 external manufacturers, 450 distribution centers and over 60 ERP systems that support about 275 operating companies. But the opportunity to leverage our scale and breadth to better meet our customers' evolving needs and maintain the highest quality and regulatory standards is significant.

We have implemented a new quality and compliance operating model to ensure consistent standards and capabilities across all products, businesses and geographies while strengthening independent oversight processes. For instance, we have adapted and are now deploying 34 common quality standards for all companies around the world. An independent internal audit program launched three years ago is ensuring that all Johnson & Johnson sites are in full compliance with health authority regulations and our own quality requirements.

Each of the three business segments has a chief quality officer responsible for developing the quality and compliance strategy and overseeing quality results for all companies in the segment globally. Each of the three business segments had the quality and compliance systems group to drive standardization and quality and compliance practices. We are evolving our supply chain model to enable leverage across our global network in sourcing, logistics, transportation and distribution management, and to strengthened business continuity plan.

Our improved product launch performance demonstrates tighter commercial integration. We have begun to consolidate and harmonize ours ERP landscape. This is a four-year program that will deliver efficiencies in terms of cost to offset pricing pressures and working capital improvements, supply reliability and flexibility for years to come.

We are integrating Synthes, into our global supply chain network and quality systems, and we are optimizing our products supply network both, internally and externally to meet our growth objectives for new product launches and emerging market growth.

Health care is a challenging, but intensely rewarding space. In a few months that I have been part of the Johnson & Johnson leadership team, I have gained even more conviction and we are making a real difference for consumers, for patients, for customers, providers and health care system. I see the enormous opportunity we have to do more and I am looking forward to growing our businesses and creating meaningful innovation for our customers and value for shareholders.

Thank you for the opportunity to share some of my thoughts with you today.

And now, I'll turn it over to Dominic.

Dominic Caruso

Thank you, Sandy, and good morning, everyone. It is really great to have Sandy join us today on the call and it's a real pleasure working with her as a new member of our executive committee,

I would like to now provide some brief comments about our results and also provide our guidance for you to consider in refining your models for the balance of 2013. I am pleased to say, we've had a strong first half of 2013. The breadth of our business, which provides balance and consistency to our overall performance, as well as the extraordinary achievements and dedication of our people in all of our locations around the world positions us well to sustain growth in this increasingly dynamic global health care market.

While there are some indicators of general economic improvement, the healthcare market data we see in terms of utilization is still relatively flat over the prior year, with just a modest sequential improvement over the first quarter utilization data. Overall, however, we continue to drive growth in many areas of our business, especially in the pharmaceutical segment with the launch of new products addressing unmet needs.

Alex and Louise already commented on our results for the quarter, so let me just mention the impact of special items this quarter. There were special items recorded in the other income and expense line during the second quarter of approximately $560 million on a pretax basis. That consisted of charges for litigation expense accruals related to various legal matters DePuy ASR hip program cost. And, as expected, continued costs associated with the global integration of Synthes. Excluding these special items, our adjusted earnings per share for the quarter of $1.48 exceeded the mean of the analyst estimates as published by first call. Now, let me provide some guidance for you to consider as you refine your models for 2013.

Let me begin with a discussion of cash and interest income and expense. At the end of the quarter, we had approximately $10 billion of net cash. This consists of approximately $25 billion of cash and marketable securities and $15 billion of debt. We continue to generate very strong cash flows. For purposes of your models assuming no major acquisitions, I suggest you consider modeling net interest expense of between $400 million and $450 million, a slight improvement from our previous guidance.

Turning now to other income and expense, as a reminder, this is the account where we record royalty income as well as gains and losses arising from such items as litigation, investments by our development corporation. and other divestitures, asset sales or write-offs. As previously disclosed, during the second quarter, we sold our equity interest in ECHELON and that gain is reflected in this line. This account is difficult to forecast, but we would be comfortable with your models for 2013, reflecting other income and expense as a net gain, excluding special items ranging from approximately $750 million to $850 million, which is consistent with our previous guidance and includes the gain from the sale of our equity interest in ECHELON.

Now, a word on taxes. Through the second quarter of 2013, the company's effective tax rate excluding special items was approximately 19.5%. We suggest that you model our effective tax rate for the full year 2013 at approximately between 19% and 20%, or slightly lower rate than our previous guidance. As always, we will continue to pursue opportunities in this area to improve upon this rate during the remainder of the year.

Now, turning to sales and earnings. We would be comfortable with your models reflecting operational sales growth on a constant currency basis of between approximately 6% and 7% for the year, which is higher than our previous guidance. This would result in estimated sales for 2013 on a constant currency basis of approximately $71.3 billion to $71.9 billion.

While we are not predicting the impact of currency movements, to give you an idea of the potential impact if currency exchange rates for the remainder of 2013 were to stay where they were as of last week, then our sales growth rate would be negatively impacted by approximately 2% for the year. Thus under this scenario, we would expect reported sales growth to be between approximately 4% and 5% for the year for an expected level of reported sales of approximately between $70 billion and $70.6 billion which is lower than our prior guidance simply due to the overall weakening of foreign currency rates versus the U.S. dollar, particularly the Japanese Yen, Brazilian Real and the British Pound.

Now, turning to earnings. Considering the strength we saw in our operating results for the first half, we suggest that you consider full year 2013 earnings per share estimates, excluding the impact of special items, of between $5.42 and $5.49 per share on an operational basis at constant currency rates or an operational growth rate of between 6.5% and 7.5%, which is higher than our previous guidance. As a reminder, the benefit from the Elan gain, as we noted, would largely be reinvested in the business and our other income guidance is unchanged. So this increase is related to the operational performance of the business which we see improving.

We are not predicting the impact of currency movements but to give you an idea of the potential impact on earnings per share if currency rates for the balance of 2013 were to remain where they were as of last week, then our reported EPS, excluding special items, would be negatively impacted by approximately $0.02 per share or $0.04 lower than the impact we had previously estimated in our guidance solely due to exchange rate fluctuations. We therefore suggest that you model our reported earnings per share excluding special items in the range between $5.40 and $5.47 per share or a growth rate of between 6% and 7%, resulting in a reported EPS guidance being higher than our previous reported EPS guidance, reflecting our strong operational performance somewhat offset by the movement in currency rates.

Overall, as you update your models for the guidance I just provided, you should see pretax operating margins will continue to show improvement over the prior year as we indicated at the beginning of this year and which we feel confident we can achieve, given the strength our operating performance while we continue to invest for future growth.

Now, Louise, back to you for the Q&A session.

Louise Mehrotra

Thank you, Dominic. Stephanie, can you please give the instructions for the Q&A session?

Question-and-Answer Session

Operator

(Operator Instructions) Your first question is from the line of Mike Weinstein with JPMorgan.

Mike Weinstein - JPMorgan

I wanted to ask that, at a recent event which was the allowance of the patent application on ZYTIGA in combination with prednisone and could you give us your updated view on the life of that ZYTRIGA in the U.S. and how ZYTIGA is going to fit with ARN-509 and the Aragon acquisition and where do you see the position in the two products? Thanks

Alex Gorsky

Hi, Mike, this is Alex. Thanks a lot for the questions. As you know, Janssen has got five years of data exclusivity in the U.S. from the date of approval which was April 2011 or until April 2016. We are also watching the Hatch-Waxman extension to December 2016. At this point in time, we believe that those are the correct dates of using. Obviously we are going to be looking at some of these other recent events closer to see what impact it may have. But at this time,

we are sticking with December 2016.

Regarding the Aragon, look we think it's a great complement to our portfolio. If you look at the great job, frankly, that our team has been able to do with Zetia in the launch regarding the clinical backup, actually the actual approval of the compound, the ongoing clinical development, very impressive, the commercial penetration that we have seen, as well as the care programs for the patients, we think it represents a significant capability. Now when you complement that with the Aragon compound, it will certainly enable us to leverage all of those skills on to a next phase. We think that there could be potentially complementary utilization of those compounds together and again as one another example of us continuing to really make a difference for patients and for our business and is very exciting oncology area.

Mike Weinstein - JPMorgan

Two quick follow ups if I can. One, is there an update on the plans for the Clinical Diagnostics. And, two, Dominic, where are you with the completion of last year's ASR and could you just talk about thoughts on additional share repurchase following that? Thanks.

Alex Gorsky

Sure, Mike. I'll take the first half of that question and then I'll ask Dominic to follow up on the second part. As you remember, earlier this year we announced that we were going to be exploring the future. The Diagnostics group at an enterprise level. And the initiation of this process was really part of a broader strategic planning process across Johnson & Johnson. Recognizing that we wanted to be very disciplined and decisive about what we are going to do with our businesses and our capabilities going forward.

Now, as we stated back in January, we expect that this process could take anywhere from about 12 months to 24 months. We're on track for that. We're still in the early-stages and we think it's premature at this time to speculate about specific impact, but we are continuing to look at our options. Dominic?

Dominic Caruso

Yes. Hi, Michael. On the ASR program, we expect it will be completed in early August, and we are near of the completion of it. As soon as we complete that programs then we will be permitted to recommence the share purchases that we normally do in a normal course of business, which as I think you all know, we repurchase all the shares that are issued in connection with any employee compensation programs, so we'll obviously commence that right after the ASR program is completed in early August.

As far as any larger, more significant share buyback program, as we said before, we always evaluate that in the spirit of utilizing our strong cash flows, but quite frankly in the priority, we've always said, first our dividend, second to use in building our businesses to generate even more sustainable cash flows for the future, and then finally, considering an additional return to shareholders as appropriate given the first two.

Louise Mehrotra

Okay. Next question, please.

Operator

Your next question is from the line of Rajeev Jashnani, UBS.

Rajeev Jashnani - UBS

My first question was on consumer business, Sandy. And, I was hoping you would talk a little bit about the margins in that business and clearly there is some cost associated with compliance that are ongoing now. But, maybe if you talk about how you see that playing out over the next few years and some of the investments you had to make on the brand. Thanks.

Sandra Peterson

Thanks for the question. As you know, we are still in the process of remediating the OTC business, which is an ongoing effort. And, clearly, we will spend what it takes to ensure that we are completely compliant with the CD, and we are bringing all of the products back.

Our expectation is that that will continue for the near-term. But, in addition to all of the remediation efforts, we also are going to ensure that we are investing sufficiently to bring these brands back and bring them back fully to consumers and retailers and that our current estimation is that we will probably be spending at a higher rate than our historical averages as we are bringing all of these brands back. So, that clearly in the near-term, will have some impact on our margins. But at the same time, we are also working very hard to you globalize our core brand portfolio, and by doing that that will improve our margins over time across the total consumer portfolio. And, we have also, the team has put a lot of effort in the last couple of years in reducing overheads and driving efficiencies throughout the business.

So, I think what you will see that over time, we will start seeing improvements in our margins as we bring the OTC portfolio back and as we globalize the rest of our core portfolio. And our expectation is that, our business will have similar margin in the consumer sectors as you see in the other parts of the JNJ portfolio, as we bring all of these businesses back and we will continue to improve the margins over time.

Louise Mehrotra

Okay. Next question, please?

Operator

Your next question is from the line of Matthew Dodds with Citigroup.

Matthew Dodds - Citigroup

Good morning, one for Alex and one for Sandy. Alex, if you look at the Pharma results, ZYTIGA, XARELTO and INCIVO were big drivers globally, but it looks like Europe accelerated again this quarter even if you back out adjustments one timers ZYTIGA, INCIVO. So, my question is whether one or two things that's changed in Europe is maybe going to gain all the share.

Alex Gorsky

I am sorry, Matt. Would you repeat the last part of that question?

Matthew Dodds - Citigroup

Yes. What's driving the share gains in Europe for kind of the base business not the new products, but the base? It seems like you continue to do better and better in Europe, in pharma.

Alex Gorsky

Yes. Well, Matt, really its strong performance across both base and launch brands. So if you take a look, for example, of how we are doing in the CNS area, continued growth with those products. We have had, of course, a number of new launches on top of that. I think, overall, our team is just executing extremely well. So I really think it’s a mix, both of some of the core brands combined with the new product launches that’s driving that kind of performance.

Matthew Dodds - Citigroup

Okay, then. Just to hear from Sandi. Sandi, one area you didn’t hit on was skincare, which is almost as big as OTC nutritionals and the last, I would say, three quarters even again, ex-divestitures, it looks like it slowed a little bit. Is that market share or market growth and is there anything coming there, innovation wise that could accelerate the growth?

Sandra Peterson

Matt, thanks for the question. Actually, the overall skin care market, as a category is improving, but it is still not what it used to be at our historical level. However, our own business is doing relatively well. So our Neutrogena portfolio, in the U.S., we have gained 0.5 share point in the first half of this year. Our Aveeno business is up almost 8%. Our LPN business in Europe is growing close to 10%. Our Johnson's adult business is growing in the mid-single digit level. So those are all very positive things and we are feeling good about our businesses in Asia as well.

The one thing that is impacting those that are in this category is the sun care business. The market category is down 11% in the first half of this year. We have actually been gaining share in the U.S. over 2% and we are now the number two global sun care provider in the world. So the impact of the sun care market clearly is having an impact on the overall business and while we are doing very well in it, a little over 2% is less than the historical rates that you would

see normally in that business. So that's a general sense of how we are doing in the skincare portfolio and that's why you see a relatively low overall growth rate because of market growth. But our shares are actually growing in our core brands.

Louise Mehrotra

Next question, please.

Operator

Your next question comes from Kristen Stewart, Deutsche Bank.

Kristen Stewart - Deutsche Bank

I just want to take a step back, I guess, and just discuss what gives you, I guess, the confidence to raise the overall operational outlook for the rest of the year? Is it coming more, and obviously you had a good first half, but is there anything kind of in the end markets either within medical devices that gives you some increased confidence or are you just having a higher level of mix on more of the pharma side with some the performance there?

Alex Gorsky

Hi, Kristen, this is Alex. Thanks for the question. I will start off and then I will ask Dominic to finish. But I think overall as we characterize our business, we are really pleased with what we have seen during the first six months. We have made a lot of progress around our top objectives that we have been very clear about from the very beginning delivering on our financial performance. Obviously accelerating the launch of our pharmaceutical products. As we look at that portfolio and particularly there is a couple of things, one is in spite of new competition, really all of our newly launched categories, we continue to see very good uptake.

We think that's driven, first of all, product profiles that really important for patients but they also have been very well-developed by our clinical development team. Two, by great commercial excellence. I think that's demonstrated in our ability to differentiate but also in our ability to ensure access for these products through managed care Medicaid in the United States but also through tendering processes outside the United States. We have also seen good performance in our pipeline and development by bringing in through licensing and acquisitions but also continued progress in our own. So, all around, our pharma business, we believe, is in a good place and certainly positioned well for future growth.

If we look at the MD&D, clearly we have been challenged by the macroeconomic situation that's having an impact on demand around the world. If I start in the United States, what we have seen is fairly flat performance overall. By the way, if we look at some of the leading indicators, for example, if we look at hospital admissions, if we look at inpatient procedures, we see relatively flat to even slightly negative statistics. The primary care physician visits are in the low single-digits. We have got you multiple quarters, consecutive quarters now, with those types of trends. We don't expect that to turn in the near-term. Longer-term, we will have to see the impact of the Affordable Care Act on that. That being said, we remain very committed to our MD&D business. In areas such as Biosense Webster, ENT, Vision Care, we have seen very positive performance this quarter. However, if you look at some of our other core businesses, surgical care for example, sutures and surgical instruments, we see the challenges associated with the macroeconomic environment.

We're also somewhat, I would say, I encouraged as well by what we are seeing in orthopedics, particularly in hips and knees and trauma over the past quarter. And, clearly, if we look at our consumer group, we see a very strong performance from our U.S. OTC business. Sandy took you through some of that earlier. I think around the rest of the world, we tend to follow more what we are seeing with GDP, but if we total all of that, we think that we are continuing to make good progress. We still see challenges ahead. At the same time, our teams and our employees, I think, continue to demonstrate that we are delivering on our commitments and that's the way we intend to finish out the rest of the year.

Dominic Caruso

So, I wouldn't add anything else except that we are not reading into our performance any uptick in utilization trends generally speaking, so I think that that still remains to be challenging for the balance of the year. But as Alex said, individual product performance is really pretty exceptional especially in the Pharma business.

Kristen Stewart - Deutsche Bank

And then just really quickly just the breaking out of the Nutritionals from the OTC business, what was the rationale for that as Nutritionals is an area where you might look to divest or how should we just think about that separation?

Alex Gorsky

Yes. We wanted to break it out, so actually for your benefit, so you can track the progress in our return of the OTC business. You know it's pretty significant in terms of our progress there. I think it sometimes gets buried by the groupies of different things in the same line, so really for your benefit in your modeling purposes we want to show you singularly what the U.S. an overall OTC business was doing. No other reason than that.

Louise Mehrotra

Next question, please?

Operator

Your next question is from Larry Biegelsen, Wells Fargo.

Larry Biegelsen - Wells Fargo

Good morning. Thanks for taking the question. One for Alex and one for Dominic. Alex, could you share with us your first and second quarter growth rates in emerging markets? Given the macroeconomic and political dynamics, could you give us your latest thoughts on the outlook in those markets for health care in general and your business? And, for Dominic, then after that I'll ask my question for Dominic.

Alex Gorsky

Larry, this Alex. Larry, we are not splitting it out specifically for all emerging markets, but if we take a look at our BRIC markets, Brazil, Russia, India, China, what are saying is about 19% growth. You can see obviously that that's a significant multiple of what we are seeing in developed markets. Again, I think it's built on the fact that we've been in these markets for a substantial period of time, particularly if you take a look at our consumer and our MD&D business in places like China, but even our pharmaceutical business as well as the other businesses in places like Brazil, we made investments over the last several years in our consumer and our MD&D business for example with (Inaudible) [Elsker], Bioseal in China, and so we see these markets as very important for our growth. We continue to see good uptake in health care. It's something that we are watching very closely in light of the larger macroeconomic environment.

But, overall, we believe that these markets represent a significant growth opportunity simply because more patients are receiving access to treatment. And, secondly, because we have solid positions in many of these areas.

Larry Biegelsen - Wells Fargo

That's helpful. Just to clarify the 19%, Alex, in the BRIC markets. Was that for Q2 or the first half of the year?

Alex Gorsky

That was Q2.

Sandra Peterson

And, it excludes Synthes.

Alex Gorsky

Larry, and it excludes Synthes.

Larry Biegelsen - Wells Fargo

Okay. And, Dominic, you grew, I think, 4.8% year-to-date ex-Synthes. I think, Alex talked about earlier in the presentation. Correct me if I am wrong, but the updated guidance implies about 2% to 4% in the second half of the year. Is my math correct and is this just conservatism or is there any reason why you would expect the second half to be slower than the first half. Thanks.

Alex Gorsky

Yes. So, we were looking at operational growth. Let's focus on that, because obviously currencies that have a negative impact on our sales growth. Operationally, for the first half, we had pretty strong growth, all related to the pharmaceutical business primarily and obviously the inclusion of Synthes. In the back half of the year, to get to about between 6% and 7% operational growth that I was referring to, we would expect about 4% overall growth for the back half of the year because the first half obviously was impacted by Synthes. So that's that math I have, Larry, about 10% this quarter, roughly 10% for the first half of the year, between 6% and 7% for the full year, which implies about 4% in the back half of the year on an operational basis, excluding any currency impacts.

Louise Mehrotra

Next question, please.

Operator

Your next question comes from Derrick Sung with Sanford Bernstein.

Derrick Sung - Sanford Bernstein

My question, to start off with just a couple of housekeeping items. Was there any impact to sales this quarter from either in the pharma, the Medicaid rebate adjustment or in medical devices, any extra selling days that might have inflated sales growth rates?

Alex Gorsky

So, Derrick, no Medicaid rebate adjustments in this particular quarter. We had a significant adjustment last quarter that we talked extensively about but nothing of that nature in this quarter. With selling days, we don't know if there is any real significant impact for selling days this quarter.

Louise Mehrotra

Really no significant impact. It's about 0.2 days. That's all OUS. It only really impacts our orthopedics business. Okay?

Derrick Sung - Sanford Bernstein

Great, and Louise, could you give us a sense for the breakout of pricing and mix, again for the orthopedic divisions?

Louise Mehrotra

Sure. So price worldwide, just price is about 1% decline and that's consistent U.S., OUS and total and that's as the same as the first quarter. Now if we get into the U.S. only, where I have a price and mix number. For hips, the price was down about 3.5% very consistent with the prior periods. Mix, however was up about 1.5%. So it netted to about a 2% decline. So that's a little bit more favorable than the first quarter. When you go into knees, the price number was down about 1%. We did have favorable mix again. For now we are about 0.5% favorable and that is very consistent with what we had in the first quarter.

Derrick Sung - Sanford Bernstein

How about spine?

Louise Mehrotra

Okay, so in terms of spine, price was about 3% negative for the second quarter and mix was about to 2.5% positive, netting to about 0.5% negative, very similar trend on the total between the first and the second quarter. However, just a little bit of changes between price and mix.

Derrick Sung - Sanford Bernstein

Great, thank you. Just one more for Sandi, if I could. Sandi, what are your expectations for how much share you will gain, once you get your products back into the market, now that you have seen how the initial relaunch of your OTC products is going. I understand that's 75% expectation for brands to market. But how much of that lost share do you recapture when you hit the market? Thank you.

Sandra Peterson

Thanks for the question. Quite honestly, we were still in early days. Our intent and we are on track to bring 75% of those brands back this year. We have others that we will be bringing back next year. But as we begin to get into the stores and interact with consumers again, we have had very positive responses from not only retailers but that consumers and healthcare professionals. It is a little early to be able to answer that question, but what I can tell you is that in the first half of the year, we have seen with the limited on distribution, now we have full distribution, but in the first half we only had limited distribution, we have seen things like our Extra Strength TYLENOL share double in the first half of the year. We have seen significant growth with most of our other products that we have brought back to the market. But it's a little early for us to actually give you a clear sense of what that number will be. Clearly, our intent and our desire is to get back to the share numbers that we had before we went in to the CD process and that's what we are really focused on doing.

Louise Mehrotra

Next question, please.

Operator

Next question comes from the line of Jami Rubin with Goldman Sachs.

Jami Rubin - Goldman Sachs

Just two questions to Dominic. I just want to follow up on an earlier question. That is the implied guidance for the second half of the year. Even if I assume the top end of the guidance, that still assumes a second half earnings growth of 4.5% versus 9% during the first half. So I can't imagine that having Synthes now fully annualized would affect the operational growth rate that much. May be it does, but if you just talk about what specific headwinds you expect in the second half that we did not see in the first half.

Then, Alex, a question for you, as long as we have the opportunity to have you on the call, if you could talk sort of bigger picture about business development, Dominic said that your priority is, number one, the dividend. Number two, business development or maybe you have that mixed up. And then number three share buybacks. But now with Synthes having fully annualized, just wondering if you could talk to what your business priorities are in terms of specific businesses, what sort of size we should anticipate. How are you thinking about business development? Thanks.

Alex Gorsky

So, Jamie, on the earnings part of the back half versus first half comparison, remember we did indicate that we expected this other income and expense line to be about $800 million for the year that's consistent with our guidance now, so no change there. But, of course, you with the Élan gain coming, all in one quarter, the vast majority of that has already happened in the first half of the year. So.

Sandra Peterson

That contributes this quarter?

Alex Gorsky

Yes. As you look at that, we released in April, we talked about the fact that we sold our Elan shares and we filed a registration statement concerning that and we indicated the estimated gain was going to be about $200 million from that sale we then sold some additional shares later in the year. So, think about it as a better $0.07 kind of number that we disclosed earlier, but to put one thing in perspective with this other income and expense line, your models, of course, have modeled one quarter of the $800 million, which is about what I had expected a model and this quarter we had within that line $400 million of other income and expense, right, because as the Élan gain in there. So, if you look at the impact just this quarter of the Élan gain versus the overall analyst models, I would say that that $200 million excess or roughly $150 million after-tax is worth about $0.05 compared to what the Street has been modeling.

Dominic Caruso

Okay. And, Jamie, for your first question, I think the way that I would frame our overall position is look, we are going to continue to look for internal and external opportunities that we feel is going to drive our growth going forward. We've been very consistent in saying that when there are new technologies, new innovations that give us a platform to build,

and I think a great example of that is what we have done in oncology over the past few years and our pharmaceutical business. There is a lot of unmet medical need and we've been able to do some great partnering to rapidly build what we feel is now a world-class platform in oncology both, from a pharmaceutical development but also from a commercial and access point of view.

The next area that we look at of course is, what businesses could be complementary to our existing businesses. What may round out some of our current portfolios or allow, build on capabilities that we currently have and there are other opportunities perhaps, where we look at vertical integration. What we've done for example in our biosurgicals business is a great example of that with OMRIX, and we are excited about the potential that has is we are in the process of launching that on a global level, but that's the way we look at it. But, regarding our pharmaceutical business, look, I am really proud of the work the team has done there in taking agreement such as what we've done with Pharmacyclics, what we've done with (Inaudible), what we have done with other organizations in partnering and adding on to our portfolio to bring forward great opportunities for patients, but also for our business.

In MD&D, obviously, the Synthes transaction was very large transaction. Michel and his team are doing a very nice job through the integration process, but we realize that that does take some time. We remain committed to having the broadest and most comprehensive orthopedics platform. We are seeing that happening right now as those businesses come together.

In consumer, we think the consumer area [level]-one consumerism will also be very important as we go forward in healthcare. And, we have made some select acquisition they are particular in China over the past couple of years. We have also done some other divestments in our business as we really focus more in certain areas of our portfolio and as we have also done in MD&D, so I think that's overall our approach. We want to continue to look for technologies and innovations that really make a difference for patients, we want to continue to look for opportunities to that can be complementary add-on, give us additional customer offerings or if we see other brand-new areas that we think can really be transformational, obviously we would be interested in that as well.

Louise Mehrotra

Next question, please.

Operator

Your next question is from the line of Danielle Antalffy with Leerink Swann.

Danielle Antalffy - Leerink Swann

Good morning, everyone. Thanks so much for taking my question. I just wanted to touch on the diabetes business a little bit. You mentioned some of the impacts on competitive bidding. Can you talk a little bit, Alex, about your commitment to that business going forward and how we think about the business now in the context of competitive bidding? Louise, if you could remind us the impact of competitive bidding to the business? How much of the business is as opposed to Medicare?

Alex Gorsky

Hi, Danielle, thank you vey much for the question. Look, overall, what I would say is that J&J and our diabetes companies, we still feel we are very uniquely positioned for strong leadership and success in the category based on a great track record that we have had in technology innovation scale and brand equity. If you just look at diabetes, of course, its one of the largest and most significant issues in healthcare today. I think there is somewhat around 370 million people with diabetes today, projected to go to almost 500 million by 2020. So the need is great. It is a very difficult area to control.

Now what I would say is that with the recent launch of Invokana, our sales and marketing efforts are broadly targeting both endocrinologists and primary care physician to treat a vast majority of these Type 2 patients. Both Janssen and LifeScan Animas are partnering to accomplish this objective. It is the first time where LifeScan Animas have been involved in promoting an oral therapeutic agent of any kind. That really helps to expand their reach and it strengthens basically their commercial and clinical relevance beyond just glucose monitoring and insulin delivery among those healthcare professionals.

Then when you compound that with the Calibra acquisition that we recently did, it’s the Wearable Insulin Patch technology, we feel that that’s going to be a very good opportunity for patients making it easier for them. If they are currently on basal only insulin therapy and they need an easy to administer mealtime dosing option, that certainly

provides that. But while we look at all that, we also acknowledge the realities of the market and now with a competitive bidding process, the 72% reduction in pricing that we are experiencing in the United States, we are having to adapt our business model to meet that challenge.

But again it's a diabetes, we think, is a very important space of a lot of unmet medical need. We think we have a number of offerings across our MD&D, pharmaceutical and consumer segment that can address them. But clearly we will adapt to those changing dynamics as events unfold and as we predict they will unfold in the coming years.

Louise Mehrotra

And Medicare sales are just over 20% of the U.S. business.

Danielle Antalffy - Leerink Swann

Okay, great. Thanks so much. Then on Synthes, if I could dig a little bit deeper on that. You mentioned a stable or some positive momentum and fine procedures. I am wondering how much of that is underlying market growth versus specific to Synthes and how is Synthes doing relative to your internal expectations as far as sales force attrition goes and how are you managing that going forward? Thanks so much, guys.

Alex Gorsky

Sure. Let me start with Synthes. Overall, look, we are really pleased with the way the integration is going. Taking on a company the size of Synthes with a reputation that scale its capabilities is no small undertaking. Bringing those together the way that our teams have, I think, they are really to be commended for it. We have got a multi-phased program in place to bring it together commercially, the entire research and development organization as well as all the supporting functional areas. When you look at, for example, our hip and knee performance in the United States, we saw growth in our hip area up 5%, again based on new products being introduced, things like (inaudible), CORAIL, other things, our knee business being helped by the introduction of the ATTUNE new knee system.

If we compare those to the U.S. growth rates, we are estimating and this is first quarter data because we don't have all second quarter data yet, of 1% in hips and slightly down in knees. We think that's very favorable performance and again keeping those segments focused, keeping them delivering while going through the integration is no small feat. If we look at trauma, we are up 2% in the U.S. versus the market that we think is probably going around 6%. We have seen some loss of share due to the nail recall that we experienced early in the earlier. We think it's being managed well, we think we will see our way through that on a worldwide basis, so we think we are you growing commensurate with what we are seeing with the market, so continued strong emerging market growth, the globalization that we offer to some of those businesses we think is real opportunity.

Now last, but not least in spine, on a worldwide basis what we see the market is down about 2%. We think we are down about 1%, so we think we are commensurate. In the U.S., we have seen the performance when we were down about 7% versus the market that was down about three. We were clearly impacted by some transitional issues with our sales force during that period. They put a comprehensive plan in place, where we think that we project that will do much better going forward.

And more importantly, when you look at the offerings that our representatives have across the minimally invasive segment, degenerative, spine, a number of other areas combined with the rest of our portfolio is going to put us in a very good position in that marketplace. So, we remain very optimistic, pleased with the performance around the integration and feel that DePuy Synthes again is going to be good for patients and also be good for our business.

Louise Mehrotra

Next question please?

Operator

The next question is from the line of Tony Butler with Barclays Capital.

Tony Butler - Barclays Capital

Good morning and thank you very much for the time. Really two questions and one is two parts. Alex, a question for you first, clearly some discussion not only in the press today, which has been in the press for some time about the ministry of public security looking into business practices principally in China. And, I am concerned that that you'd

spread not only to Glaxo, but to other companies, including JNJ. Just simply looking business practices, can you comment on what you know today maybe going on what sort of investigations and whether or not your practices are being discussed.

Then two product questions. One, clearly around the very strong growth of PREZISTA, up 80%, sequentially, Louise or Dominic, any commentary that you can make regarding that very strong growth, sequentially. Then second on XARELTO, if I understand 20% sequential growth, but you believe that's solely driven by DTC. Thanks very much.

Alex Gorsky

Sure, Tony. Let me start up. Look, on the first question what I would is that, we are absolutely committed to ensuring that our businesses are run in a highly compliant manner around the world. And, we have a very active compliance program in place in the country such as China little on all the BRIC countries. We continue to update our policies and procedures as we get more information. At the same time, we recognize that these countries are very important markets going forward.

By that there is still a lot of unmet medical need with patients. And, clearly, we know that these governments are also very committed to ensuring that they have a compliant environment at the same time they are getting access for their citizens to important health care options. So, we remain very diligent on it. We've made significant investments in these areas in compliance and we want to work closely with these countries and governments to ensure that we are working together in a collaborative way to ensure we have a very compliant environment going forward. Louise?

Louise Mehrotra

Charlie, more in PREZISTA, we have seen just the basic market share improvement over the quarter. I mean, PREZISTA is doing very well. Our sales team is doing an excellent job and the product has become quite frankly a mainstay in HIV therapy, so it's really just we saw pretty strong market share growth, sequentially.

Then on XARELTO, we did do some DTC there, but I think that product as we've talked about before with the breadth of its indications is becoming much more recognized as a standard of care in that marketplace. And as Alex pointed out earlier, you know, we've now surpassed warfarin in the new to brand share. So, I think the breadth and our strategy around the breadth of that compound in the market that needs that kind of therapy that has both, exceptional efficacy and obviously safety is what's driving that growth. I wouldn't just pin it on overall DTC advertising. I would say just a breadth of the overall indications for the product as we expected. That's what our strategy was and looks like to playing out.

Alex Gorsky

Yes, Tony, I would just add one other thing on to that because I think Dominic gave a really comprehensive answer. That is in addition to the clinical development program which resulted in numerous indications, it's really gives physicians a very broad application of the product. They have also done a great job done by our access team in ensuring broad formulary access in our managed care in places here in the United States. So I think now we have got more than 85% access of Tier 2 in both private as well as Medicare customers. That’s very important for them. It relates to an issue of affordability, of convenience and of course the reason that we are able to get that kind of access is because our team has done a great job of demonstrating the clinical and overall economic value of XARELTO to those patients and in those settings.

Louise Mehrotra

Next question, please.

Operator

Your next question is from the line of Glenn Navarro with RBC Capital Markets.

Glenn Navarro - RBC Capital Markets

Thanks for taking my question. A question for Alex. Alex, I would like your view on the CapEx environment in the United States. It appears the environment remains challenging. I know you spend a lot of time visiting hospitals and hospital executives. Is the CapEx challenged environment a function of utilization? Is it a function of healthy health care reform? So just curious of your views.

Then, as a follow-up, what do you think turns the CapEx environment to the positive in the U.S.? Thanks.

Alex Gorsky

Hi, thank you very much, Glenn. Look, I would say, in discussions that I have had with hospital CEOs and with other people in the marketplace, I have seen a couple of things. One is, clearly there has been a recession now for, I believe, almost 10 to 12 consecutive quarters, where we see that admissions in the hospitals as well as numbers of procedures being flat to negative. Now clearly we are seeing some shift to the outpatient setting but when it comes to inpatient procedures and additions, that market is obviously being impacted by the macroeconomic conditions.

I think secondly, people are waiting to see the full impact of the Affordable Care Act. They are still working their way through the details and how that might affect. There is certainly changes regarding risk bearing areas such as hospital acquired infections and other procedures. So I think that's also having an impact.

Third, we are seeing is that patients, frankly, and customers as being more demanding about the data that is supporting justification for new approaches, new procedures and innovation.

So that's the way I would describe the overall CapEx environment as it related to hospitals.

Glenn Navarro - RBC Capital Markets

And just as one quick follow-up. Do you have a view on Europe? Europe has remained very challenging from a utilization and a capital point of view? That appears to be stable. Is that correct?

Alex Gorsky

What I would say, Glenn, is it's a bit of a tale of two cities. I think on one hand what we see in CapEx, particularly if you go to Southern Europe, it's a very challenging environment and it's because of, again, the macro economic situation they are facing. I don't think we have seen a pronounced decrease or improvement. We have seen it fairly steady quarter-to-quarter but we expect that to remain a very challenging environment going forward. On the other hand, what we have seen, is that when you introduce new innovations such as our pharmaceutical group has done, over the past 12 months they can really make a difference for patients that you can get reimbursement and get access for patients.

Louise Mehrotra

Next question, please.

Operator

Your next question is from Matt Miksic with Piper Jaffray.

Matt Miksic - Piper Jaffray

Thanks, good morning. So, Alex, I very much appreciate the update in perspective. There is a lot to talk about here. But I was wondering if you could expand a little bit on your thoughts on innovation as you had just mentioned and earlier in the call, particularly as it pertains to MD&D and a few different factors, just the first, to a degree towards new technologies, smart instruments and your competitors in different areas of putting that out. You have put that out obviously effectively with Biosense Webster over time. Number two, whether these opportunities are greater in areas where you have an established business like orthopedics, like cardio or whether new platforms and opportunities are as attractive.

Then finally, I you think you just mentioned again presenting innovations in a way that hospital and caregivers can recognize the value and are willing to pay for them. So, maybe just your broad thoughts as to factors pertaining to MD&D, and I have one follow-up for Sandy.

Alex Gorsky

Sure. Matt, thanks a lot for the question. If I reflect on it at a very broad level, what I would say around MD&D is that, look innovation is going to continue to be important. However, I think that the bar will be raised on the data will be required to describe and represent that innovation, so let me give you a few examples.

I think, overall what we are saying is incremental innovation while still clearly an important part of the overall portfolio and ultimately that can help you lead a path a significant breakthrough innovation is not being rewarded with, for example increased pricing or improved pricing in the marketplace and we would expect over time that we will need to have more transformational innovation or more significant innovation. We recognize that that's going to require additional clinical development and investments. At the same time, we think at Johnson & Johnson, we are uniquely positioned in that category. Given the broad breadth and scale capabilities that we have at our pharmaceutical group and in our medical device group.

So, for example, what we've done in our biosurgicals area, as we are getting ready to launch Fibrin Pad, the way that we are having our cardiovascular team, even the for example, work with XARELTO, and some of the things that we are doing Biosense Webster, it gives us a unique opportunity for convergence. And, in fact, we see opportunities in some of these segments to look innovation differently and frankly raise the bar with innovation from a clinical point of view, but also from a regulatory point of view that's in the best interest of patients as well as for our business.

We look at areas going forward. I think it's going to be a combination. We still think that in areas such as general surgery, when we look at biosurgicals, when we look at your areas such as energy, there's a lot of opportunity to make procedures less invasive, to simplify the procedures, particularly in emerging markets that will ultimately lead to better overall outcomes and reducing morbidity.

We think in other areas, there is great technology opportunity. Such in Biosense Webster, so in the in the general surgery category, I think there is a lot of opportunity for growth in orthopedics. We are working on innovation with products like the ATTUNE Knee, like a number of things that we are doing in spine and hip as of late. We're also looking at innovation from a commercial model standpoint.

What can we do around having a broader offering, a different kind of relationship and partnership with hospitals and other large payers, again in a way that's good for patients that helps to improve outcomes, but also is better for the institution and we think again there too we are uniquely position given the breadth, the depth, the scale and size of our business.

Matt Miksic - Piper Jaffray

That's great. Thank you for that. And then for Sandy, and maybe Alex you may want to chime in on this as well, but around the quality and regulatory and we tend to have focused over the past couple of years on the pathway and the process for OTC in sort of managing through the OTC-specific challenges that have come up, but it would be very helpful if you touch a little bit on this with respect to the supply chain but it would be great to hear and maybe some of the changes you made proactive in ongoing at your other major businesses and facilities, and maybe if you could provide some examples or anecdotes, it would help illustrate the progress that you are making across the organization in terms of quality.

Sandra Peterson

So, Matt, thanks for the question. As I mentioned in the opening remarks, our quality effort is across the enterprise, across all of our businesses, our manufacturing sites as well as all of our R&D sites, because they are under the scope of trying to ensure that we have the highest standard of quality for the safety and care of our patients and consumers. So, when we launched the quality initiative a number of years ago, the focus really was ensuring that we have got consistent quality standards.

We went through a three-year cycle that were just ending the first of the cycle over a three year period, where we have gone through all of our manufacturing facilities, all of our core strategic suppliers as well as all of our R&D site to ensure that all of them are living up to the appropriate regulatory standards in those countries that also are standard that at J&J, we believe is one of the highest in the industry and its across all of our sectors.

So there has been an immense amount of work and focus in ensuring that we have consistency across our operations, across our product lines and across all of the countries in which we operate. We have, obviously, as we gone through all of this work, we have identified corrective actions and we have immediately taken those corrective actions. We are harmonizing systems. We are putting in place processes and systems so that we have early warning. Systems in place to understand if there is, we think, may be something going on with a product, so we identify it early and we go out and correct it.

In addition to that, an important component of all of this is how we are managing our global supply chain. So one of the very important changes that we have been making with our global supply chain is ensuring that all of our external

suppliers, so our material suppliers are thoroughly reviewed, are thoroughly managed and that they are living up to our quality standards. In that process in the last three years, we have actually consolidated our external manufacturing, our external material suppliers by about a third. So we have a third less than we had three years ago. That means that we an ability to manage them much more effectively and ensure that we are reviewing their quality of their products coming into our facilities.

We have also looked at our external manufacturers, those that provide finished products to us and we manage those across the enterprise now in a very rigorously manner with thorough and thorough audits and we are learning across the enterprise how to share best practice from business to business and technology to technology. So this effort is not just focus on the OTC business, it is really across all of our businesses in all of our countries globally. We are ensuring that we independent audits and independent approach to managing this but we are ensuring that we also are putting the right systems, processes and capital and automation in place in all of our facilities around the globe.

So we have made significant progress. I think one other indication of that progress is that over the last couple of years, we recently closed out a number of warning letters and we are making very good progress on the ones that are remaining but we are feeling good about where we are. Always things can happen. We have 300,000 SKUs around the globe. So that's where our vigilance has to be, as ensuring every single one of those SKUs are meeting our high standards.

Louise Mehrotra

Next question, please.

Operator

Your next question is from the line of Jeff Holford with Jefferies.

Jeff Holford - Jefferies

Just wanted to get a little bit more of an update on the diabetes care businesses where you have been progressing to in terms of market share versus your key competitors and just what you think outside of reimbursement changes what the underlying growth rate here just for expectations going forward? Thank you.

Alex Gorsky

Jeff, are you referring to which of our businesses? Our MD&D diabetes business or Invokana?

Jeff Holford - Jefferies

Sorry, MD&D diabetes.

Alex Gorsky

Okay. We believe that we have been relatively flat in share this last quarter. We think that there may have been a slight downtick based upon some of the pricing changes that are being made and particularly intrusion of store brands and other offerings. Obviously it's something that we are watching very closely.

Dominic Caruso

Jeff, I want to add, our estimation is that the overall market is declining there. So overall market trends are negative in the diabetes test strips. The market volumes are declining overall.

Louise Mehrotra

Next question, please.

Operator

Your next question is from the line of Bob Hopkins, Bank of America.

Bob Hopkins - Bank of America Merrill Lynch

I know its getting late. So two very quick ones. Thanks for taking the call. First, there hasn't been a lot of commentary

on your general surgery franchises within medical technology. So I am wondering if you can just comment a little bit more specifically on of those businesses and what you are seeing there because the growth rate in general surgery and especially surgery did look like it was a little better than last quarter. So just a little bit of a commentary there on what you are seeing in those markets and what you are seeing competitively? Is the uptick more of a little better market or is it a little bit more little better market or is it little bit more or less share loss more you can think?

Alex Gorsky

Sure. Look, there's a number of things driving our performance over there. I think, first of all, we saw modest growth overall in the specialty surgery category for the quarter. Our biosurgicals platform had solid growth, particularly outside the United States. We also saw good growth in the U.S. in our ENT business. And while the worldwide energy business continues to grow driven by the continued expansion in new emerging markets and new product launches, we were challenged in the U.S. with our energy business with low cost competitors, as well as some competitive pressures. So, that's the way I would described specialty surgery. In general surgery, of course, our business was impacted by what has taken place and women's health and our decision to exit some of those businesses, so that had negative. We look at suture and some of those basic platforms we are seeing very consistent growth with the overall market that we think it is basically up about 1% or 2%.

Bob Hopkins - Bank of America Merrill Lynch

Okay. Then just one quick follow up on an earlier question on emerging markets. I know you talked a lot about how well position you think change is, but just in terms of the outlook for growth of the markets in emerging markets, especially as relates to MD&D, how confident are you that the current growth trends in the market can continue as we look forward over the couple of years. So, again, it's really question of gauging confidence in light of some of the things that have gone on in these economies, in your confidence and abilities of these market, specifically medical devices to continued growth, nice pace we've seen over the last year or so.

Alex Gorsky

Sure. Look, I think there is a couple of forces and dynamics that will be impacting it. You know, first of all, you've got a significant increase in the middle-class populations in those countries. So, for example in China, I think most of the recent statistics would suggest you have about 150 million people in the middle-class. That could go as high as north of 500 million, close to 800 million people over the next 10 years. And, what we also know is that these people move up the economic ladder, they generally consume more health care. And, so we think that the urbanization trend, the trend towards an increasing middle-class does offer a significant growth opportunity.

Now, of course, offsetting that will be pressure put on governments on how they are going to control overall healthcare spending. But if you look at the healthcare spending levels in places like Brazil, Russia, India and China, it's very low single digits. We think that it's an opportunity for them to invest in their society even have a more stable society as well as a more productive society, so we think that the growth opportunities there will continue. We recognize that it's going to take perhaps a different portfolio of products that are really targeted towards specific disease states areas of unmet medical need for those markets. It will take time for different commercial approaches, but overall we do think that emerging markets will be a major source of growth for the next several years.

Louise Mehrotra

With respect to everybody's time, we will take one more question and then we'll have some closing remarks by Alex.

Operator

Your next question is from the line of David Lewis, Morgan Stanley.

David Lewis - Morgan Stanley

Good morning. Maybe two quick ones here, Louise, to keep on the time schedule here. First, Dominic, on the cash flow, free cash specifically got better in 2012 versus 2011, I believe. How do you feel about first half free cash generation. I know you don't give specific guidance, but if you just think about free cash versus net income, how do you expect back half '13 and '13 general to shape up relative to '12. And then I had a quick follow-up maybe for Louise, just on ibrutinib any timing expectations can could we see that approval for year end. Thank you.

Dominic Caruso

David, we are pleased with our cash flow generation. And, for the first half of the year, free cash flow is little over $6 billion, so we expect to be well north of $12 billion, which is where we ended last year's free cash flow, so I think we will see '13 overall free cash flow generation better than we saw in '12, and that we are off to a good start already.

Alex Gorsky

Yes. And, regarding ibrutinib, look the NDA, the new drug application for ibrutinib was submitted June 2013, which was announced recently and this was announced by the FDA. We do have the Breakthrough Therapy designation, which we are very excited about for the treatment of patients with chronic lymphocytic leukemia CLL, SLL, and we have received at least one prior therapy in patients also with mantle cell lymphoma MCL who have received at least one prior therapy. We got to two pivotal trials that we think are both the very strong and the FDA has not communicated the PDUFA date and the review period is not dictated in the existing breakthrough therapy guidelines from the FDA. Now that being said, we have requested a priority review designation which has an FDA goal for completion of six months after a two-month validation period but we really cannot comment beyond that at this time. All that being said, we think this is going to really offer a great option for patients and for physicians in a very difficult to treat area and be a tremendous extension of our emerging oncology portfolio and franchise.

Louise Mehrotra

So some final remarks, Alex?

Alex Gorsky

Okay. So thanks for your time everybody. On behalf of Dominic, Sandi, Louise and myself and even more importantly from the 128,000 employees of Johnson & Johnson around the world, I would like to close today's conference call by thanking you for participating in the meeting. Your engagement in our business is much appreciated. We look forward to discussing our future results as we move through the rest of the year. So enjoy the rest of summer and thank you very much.

Operator

Thank you. This concludes today's Johnson & Johnson second quarter earnings conference call. You may now disconnect.

Executives

Louise Mehrotra - Vice President, Investor Relations

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sandra Peterson - Group Worldwide Chairman

Dominic Caruso - Chief Financial Officer, Vice President - Finance

Analysts

Mike Weinstein - JPMorgan

Rajeev Jashnani - UBS

Matthew Dodds - Citigroup

Kristen Stewart - Deutsche Bank

Larry Biegelsen - Wells Fargo

Derrick Sung - Sanford Bernstein

Jami Rubin - Goldman Sachs

Danielle Antalffy - Leerink Swann

Tony Butler - Barclays Capital

Glenn Navarro - RBC Capital Markets

Matt Miksic - Piper Jaffray

Jeff Holford - Jefferies

Bob Hopkins - Bank of America Merrill Lynch

David Lewis - Morgan Stanley

Johnson & Johnson (JNJ) Q2 2013 Earnings Call July 16, 2013 8:30 AM ET

Operator

Good morning, and welcome to the Johnson & Johnson second quarter 2013 earnings conference call. All participants will be able to listen-only until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections you may disconnect at this time. (Operator Instructions).

I will now turn the call over to Johnson & Johnson. You may begin.

Louise Mehrotra - Vice President, Investor Relations

Good morning and welcome. I am Louise Mehrotra, Vice President of Investor Relations for Johnson & Johnson and it is my pleasure this morning to review our business results for the second quarter of 2013. Joining me on the call today are Alex Gorsky, Chairman of the Board and Chief Executive Officer and Sandy Peterson, Group Worldwide Chairman and Dominic Caruso, Vice President Finance and Chief Financial Officer.

A few logistics before we get into the details. This review is being made available to a broader audience via a webcast accessible through the Investor Relations section of the Johnson & Johnson website. I will begin by briefly reviewing highlights of the second quarter for the corporation and highlights for our three business segments.

Following my remarks, Alex will provide some additional commentary on our results and an update on our near term priorities and Sandy will provide an update on our consumer business and our global supply chain. Please note, the presentation for the company's, Sandy's and Alex's remarks are available on our website. Dominic will provide some additional commentary on the financial results and guidance for 2013.

We will then open the call to your questions. We expect the call to last approximately one and a half hour. Included with the press release that was issued earlier this morning is the schedule of sales for key products and/or businesses to facilitate updating your models. These schedules are available on the Johnson & Johnson website as is the press release.

Before I get into the results, let me remind you that some of the statements made during this review may be considered forward-looking statements. The 10-K for the fiscal year 2012 identifies certain factors that could cause the company's actual results to differ materially from those projected in any forward-looking statements made today. 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 is available through the company and online.

During the review, non-GAAP financial measures are used to provide information pertinent to ongoing business performance. These non-GAAP financial measures should not be considered replacements for GAAP results. Tables reconciling these measures to the most comparable GAAP measures are available in the press release and on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com.

Now, we would like to review our results for the second quarter of 2013. If you would refer to your copy of the press release, let's begin with the schedule titled, supplementary sales data by geographic area. Worldwide sales to customers were $17.9 billion for the second quarter of 2013, up 8.5% as compared to the second quarter of 2012. On an operational basis, sales were up 10% and currency had a negative impact of 1.5%.

In the U.S., sales were up 8%. In regions outside the U.S., our operational growth was 11.8%, while the effect of currency exchange rates negatively impacted our recorded results by 2.8 points. Sales included the impact of the acquisition of Synthes, net of the divestiture of the DePuy trauma business. Excluding this impact, worldwide operational sales growth was 5.6%.

The western hemisphere, excluding the U.S. grew by 14% operationally while Europe grew 11.4% on an operational basis. Asia-Pacific, Africa region grew 11% operationally. The success of new product launches and Synthes sales made strong contributions to the results in all regions.

If you will now turn to the consolidated statement of earnings. Net earnings were $3.8 billion compared to $1.4 billion in the same period in 2012. Earnings per share were $1.33 versus $0.50 a year ago. Please direct your attention to the box section of the schedule where we have provided earnings adjusted to exclude special items. As a reference to the accompanying table reconciling non-GAAP measures, 2013 second quarter net earnings were adjusted to exclude special items related to increases in litigation expense accrual, integration and transaction cost related to the acquisition of Synthes and cost associated with the DePuy ASR Hip program.

Second quarter 2012 net earnings included after-tax special items of approximately $2.2 billion as shown in the accompanying reconciliation of non-GAAP financial measures. Excluding these special items for both periods, net earnings for the current quarter were $4.3 billion and diluted earnings per share were $1.48, representing increases of 17.7% and 13.8%, respectively, as compared to the same period in 2012.

I would now like to make some additional comments relative to the components leading to earnings before we move onto the segment highlights. For the second quarter of 2013, cost of goods sold at 30.7% was down 50 basis points from the same period last year, primarily due mix, lower cost associated with strong volume growth in our pharmaceutical business and cost improvement initiatives across all the businesses. This was partially offset by incremental amortization expense related to Synthes of approximately $140 million, or 80 basis points and the impact of the medical device excise tax.

Second quarter selling, marketing and administrative expenses were 30.1% of sales consistent with our 2012 results. Our investment in research and development as a percent of sales was 10.9%, up 20 basis points due to milestone payments.

Interest expense net of interest income of $101 million was down $28 million versus the second quarter of 2012, due to a lower average debt level. Other expense, net of other income was $172 million in the second quarter of 2013, compared to $2 billion in the same period last year.

Excluding special items, other income net of other expense of $394 million was $220 million favorable compared to 2012, the gain on sale of the ECHELON investment is reflected in this amount.

Excluding special items, the effective tax rate was 20% in the second quarter of 2013, compared to 21.6% in the same period last year. Dominic will provide commentary on taxes in his remarks.

Turning now to business segment highlights, please refer to the supplementary sales schedule highlighting key products or businesses for the second quarter of 2013. I will begin with the consumer segment.

Worldwide consumer segment sales for the second quarter of 2013 of $3.7 billion, increased 1.1% as compared to the

same period, last year. On an operational basis, sales increased 1.7%, while the impact of currency was negative 0.6% U.S. sales were up 1%, while international sales grew 2% on an operational basis.

Excluding the impact of divestitures net of acquisitions operational growth was approximately 2.5%. Baby Care products increased on an operational basis by 3.1% when compared to the second quarter of 2012, primarily due to hair care and cleansers. Sales in the Oral Care business increased operationally 0.2%. Results were driven by strong international sales of LISTERINE, due to the continued success of new product launches partially offset by the impact of the divestiture of manual toothbrushes in North America.

Beginning this quarter, we are reporting OTC Pharmaceuticals separately and have moved Nutritionals to the other line. To assist in updating your models, a summary under the new format is included in the sales schedule that accompany the press release.

For the second quarter of 2013, sales for OTC pharmaceuticals increased 5.4% on an operational basis compared to the same period in 2012. U.S. sales were up 17.4% driven by strong growth in analgesics and other key brands as we continue to make progress in returning a reliable supply products to the marketplace.

International sales were up 0.9% operationally. Our Skin Care business was down 0.4% on an operational basis in the second quarter of 2013. Strong results for [renal] were offset by the impact of divestitures. Excluding divestitures, operational growth was approximately 1%.

Women's health grew 3.6% on an operational basis due to strong growth in women's sanitary protection products. Wound Care other sales decreased 4.3% on an operational basis, impacted by competitive pressures as well as a divestiture and nutritionals.

That completes the review of the Consumer segment, and I will now review highlights for the pharmaceutical segment.

Worldwide net sales for the second quarter of $7 billion increased 11.7% versus the same period last year. On an operational basis, sales increased 12.9% with a negative currency impact of 1.2 points. Sales in the U.S. increased 9.1%, while sales outside the U.S. increased on an operational basis by 16.5%.

Now reviewing sales for major therapeutic areas. Immunology products were 17.6% operationally, with sales in the U.S. up 7.3% and sales outside the U.S. up 51.5% operationally. During the quarter, the company made certain supply chain changes from for REMICADE, resulting in sales to distributors previously recorded as U.S. exports sales now being international sales. Adjusting for this impact, the U.S. immunology growth was approximately 14% with REMICADE excluding expert sales up approximately 4%, SIMPONI up 38.1% and STELARA up 53.3%. Results were driven by market growth across the major products, complemented by increased market share for both STELARA and SIMPONI.

With the strength of our portfolio, we continue to be the U.S. market leader in immunology. Adjusted immunology sales outside the U.S. increased by over 25% operationally, with REMICADE up approximately 20% due to strong growth in Canada and the emerging markets including a tender shipment. STELARA made significant contributions due to market share gains and market growth across the major regions, while very strong growth in Japan drove the results for SIMPONI.

Sales of infectious disease products increased 23.9% on an operational basis. INCIVO, a treatment for Hepatitis C grew 71.8% on an operational basis due to the success of the continued rollout most notably in Latin America as well as a shipment for tender business. Continued momentum in market share growth of PREZISTA made notable contributions to the results as did the combined sales of COMPLERA and EDURANT.

Neuroscience product sales increased 0.4% operationally. U.S. sales declined 4.9% impacted by generic competition primarily for CONCERTA. The long-acting injectable antipsychotics, RISPERDAL CONSTA and INVEGA SUSTENNA or XEPLION achieved operational growth of approximately 15% due to an increase in combined market share.

Sales of oncology products increased 53.2% on an operational basis due to the very strong results for ZYTIGA and VELCADE. ZYTIGA is now approved to treat both chemo refractory and chemo naïve metastatic castration resistant prostate cancer. In the quarter, ZYTIGA achieved operational sales growth of 70% with U.S. sales growing 54% due to very strong market growth of over 20% and increased market share in the combined metastatic castrate resistant prostate cancer market. ZYTIGA has captured over 30% of that market and is up approximately 3.5 points sequentially. Operational sales outside the U.S. grew 85.2% versus second quarter 2012 and on a sequential basis, ZYTIGA was up over 20%. Additional country rollouts and the expansion of the label to chemo naïve patients drove

the strong results. ZYTIGA is approved in more than 80 countries.

VELCADE is a treatment for multiple myeloma. Sales increased 22.7% on an operational basis. Strong performance in patient share in the frontline setting and the launch of the subcutaneous version continue to drive sales growth.

Other oncology increased primarily due to DOXIL/CAELYX. Other pharmaceutical products declined 2.7% on an operational basis with lower sales for ACIPHEX and PARIET, related primarily to generic competition. PROCRIT sales declined 18.1%, due primarily to a market decline. Positively impacting results, XARELTO sales grew over 20% on a sequential basis capturing nearly 39% of new to brand scripts in cardiology, surpassing warfarin. Total prescription share in the broader anticoagulant market grew 1.7 points on a sequential basis to 7.4%.

As an update on the pipeline, during the quarter, in immunology the FDA approved SIMPONI for the treatment of moderately to severely active ulcerative colitis and the EMA application for SIMPONI IV for the treatment of adults with moderately to severely active RA was resubmitted. In infectious diseases, a marketing authorization application was submitted to the European Medicines Agency seeking approval for simeprevir for Hepatitis C, and it was granted U.S. priority review status by the FDA with a PDUFA in late November. The European Commission approved a new twice daily dosing for INCIVO. In neuroscience, regarding bapineuzumab, JANSSEN Alzheimer Immunotherapy and its alliance partner Pfizer have decided to discontinue development of the subcutaneous formulation.

Studies with other compounds in earlier stages of development in the alliance portfolio are ongoing and future development strategies will be discussed jointly by the alliance partners. We remain committed to our efforts to discover and develop promising new treatments for people with Alzheimer's disease.

Regarding the stent thrombosis sNDA for XARELTO, a complete response letter was received from the FDA. We remain confident in the results of the ATLAS ACS trial and are in ongoing discussions with the FDA regarding this sNDA.

In oncology, Breakthrough Therapy Designation for daratumumab, for the treatment of certain patients with multiple myeloma was granted by the FDA and the positive opinion from the European authorities on two variations relating to the use of VELCADE were received.

The first recommendations for the use of VELCADE as retreatment in adult who had previously responded to the treatment with the same medicine, the second recommendation was for using induction combination therapy for certain adult patients. And, ibrutinib was submitted to the FDA for use in the treatment of previously treated patients with chronic lymphocytic leukemia or CLL, and small lymphocytic lymphoma or SLL and for its use in treatment of previously treated patients with mantle cell lymphoma or MCL.

That completes the review of the Pharmaceutical segment. I will now review the Medical Devices and Diagnostics segment results. Worldwide Medical Devices and Diagnostics segment sales of $7.2 billion grew 12% operationally as compared to the same period in 2012.

Currency had a negative impact of 2.4 points resulting in a total sales increase of 9.6%. Sales excluding the net impact of Synthes were up 0.5% on an operational basis, with U.S. sales down 3.3% and sales outside the U.S. up 3.5% on an operational basis. Adjusted for divestitures and exits from certain businesses, underlying growth was approximately 1.5%, reflecting continued market and pricing pressures. I will provide more commentary on these factors in the franchise reviews.

Now, turning to the MD&D businesses starting with, Cardiovascular Care. Cardiovascular Care sales were up 7.7% operationally, with U.S. up 4.6% and sales outside the U.S. up 9.6%, operationally, driven by Biosense Webster, our electrophysiology business with worldwide operational growth of over 16% in the quarter.

The success of a number of catheter launches made strong contributions to the results. The Diabetes Care business operational sales declined 11.8% in the second quarter of 2013 with U.S. business down 23.1%, due to the impact of lower price, competitive pressures and softness in the retail market. The business outside the U.S. was down 0.5%, operationally, with strong growth in the emerging markets offset by lower sales in many of the developed markets.

The Diagnostics business declined 4% on an operational basis. Excluding the impact of divestitures of RhoGAM and Theracos businesses operational sales grew approximately 2.5%, primarily due to growth and donors screening in the U.S. and emerging markets outside the U.S.

Infection Prevention increased 5.2% on an operational basis, with sales in the U.S. down 4% due to lower sales of capital equipment. Outside the U.S. operational growth of 12.3% was driven by both, consumables and capital item

sales.

Orthopedic sales were up 48.9% on an operational basis when compared to the same period in 2012. Excluding the net impact of Synthes, operational sales were up approximately 3% with U.S. up approximately 2% and outside the U.S. up approximately 3.5%, operationally.

Operationally, Hips were up 4% worldwide driven by 5% growth in the U.S., due to strong results in primary stent platform sales, partially offset by continued pricing pressure. Hips outside the U.S. were up 4% on an operational basis, driven mainly by heads and acetabular products.

Knees worldwide increased 2% on an operational basis with the U.S. up 3% driven by the ATTUNE fixed bearing knee as well as revision platforms offset by lower sales of rotating platforms. Sales outside the U.S. were up 1%. Including the Synthes business in both periods and excluding the divested DePuy trauma business in both periods, trauma grew approximately 4% on an operational basis due to both, new products and stronger underlying demand.

Growth in the U.S. was 2% and 7%, operational outside the U.S. Including the Synthes business in both periods, worldwide spine was down 2% on an operational basis, with U.S. down approximately 7%, impacted by continued softness in the market, as well as the impact of the attrition of the commercial sales organization as we integrate the businesses. Outside the U.S., sales were up approximately 6% operationally with strong growth in Latin America, Canada and Asia-Pacific.

Specialty surgery operational growth was 2.8% in the second quarter of 2013. U.S. Sales were down 1.5% and sales outside the U.S. were up 7.5% on an operational basis. Strong sales of balloon sinuplasty products from Acclarent and biosurgical products were partially offset by lower sales of Mentor products due to competitive and pricing pressures. Sales of energy products were flat on an operational basis with new product launches and continued penetration driving strong sales outside the U.S. offset by softer sales of HARMONIC products in the U.S. Surgical care worldwide sales were down 1.2% on an operational basis with the U.S. down 4.2% and sales outside the U.S. up 0.6% operationally.

Negatively impacting growth were divestitures and business exits. Excluding these items, the underlying business was flat with lower sales of women's health and urology offset by strong demand for endocutter products, with the ECHELON FLEX Powered ENDOPATH Stapler.

Rounding out the review, the medical devices and diagnostics segment, our Vision Care business achieved operational sales growth of 5.4% in the second quarter with the U.S. up 3.6% and sales outside the U.S. up 6.4% operationally. Growth was driven by daily lenses and astigmatism lenses. That completes highlights for the medical devices and diagnostics segment and concludes the segment highlights for Johnson & Johnson second quarter of 2013.

It is now my pleasure to turn the call over to Alex Gorsky. Alex?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Well, hello everyone and thank you, Louise, and thanks to everyone for joining us on this call today. Now it is really my pleasure to review our results for the first half of the year and also the progress we made under near-term priorities. Now, you recall, in January, that I discussed the framework for managing our business. The success of our enterprise is built first on Our Credo, which unites Johnson & Johnson as a global enterprise. Our strategic operating principles continue to service well in the evolving marketplace and with our four growth drivers, we have a sound approach to sustaining and driving growth in today's dynamic global healthcare environment.

At the mid-year point, we have achieved strong growth across our enterprise. A year ago, our team established a set of critical near-term priorities for moving the business forward. As part of our commitment to keeping you appraised of how we are doing against them, I am pleased to say that with the laser focus approach we have taken, we have made solid demonstrable progress in delivering on our financial commitments, restoring a reliable supply of OTC products to consumers, continuing the successful integration of Synthes and building on the strong momentum in our pharmaceutical business.

Reflecting our broad base of leadership in healthcare, we have generated sales of $35.4 billion thus far in 2013, up a strong 9.9% operationally versus this time a year ago, 4.8% operationally, excluding the net impact of Synthes. Medical devices and diagnostics represents 40% of our total sales, generating $14.3 billion in sales year-to-date. Sales grew 12% operationally driven by the positive growth contribution of the Synthes acquisition.

Excluding Synthes, overall growth in this segment was impacted by portfolio decisions to divest and exit certain businesses as well as the continued economic and pricing pressures within these markets. Underlying growth was

essentially flat year-to-date. With $13.8 billion, the pharmaceutical segment represented 39% of our total sales and has continued its strong momentum reporting operational growth of 12.1%. Our consumer segment generated 21% of our total sales at $7.3 billion in revenue at an operational growth rate of 2.4%.

Now as the global economy evolves, more people are entering the middle-class in emerging markets and increasing demands on the healthcare system. As I outlined at our year-end earnings meeting in January, we are investing in growth and expansion in the broader emerging markets by leveraging our strong iconic brands as well as acquiring market specific products and to-date they account for nearly a quarter of our sales. As a subset of the emerging markets, we are also seeing growth in the brick nations, which account for approximately 10% of our overall sales this year.

We are encouraged by the double-digit growth rates we are seeing in these countries driven by our core pharmaceutical and the Indian consumer brands as well as the complementary acquisitions we have made in Russia and China. As our global reach with local focus, strategy for driving growth matures, we will overtime be introducing more products that will increase options for consumers in these fast-growing parts of the world.

Moving now to the segment highlights. I will start with pharmaceuticals. Our pharmaceutical segment continues to drive robust growth by delivering meaningful innovations that will improve patient care, demonstrating the effect of the transformation we made in this segment. I am very proud of the accomplishments that our pharma team has exhibited in this process.

Our market leading execution in support of the 11 new products we've launched since 2009 has led our Pharmaceuticals business to a record 13 consecutive quarters of operational growth. That pace positions us as the fastest growing, top-10 global pharmaceutical company and U.S. leader in new product sales. Those new products, which includes ZYTIGA, STELARA and INVEGA SUSTENNA comprise 24% of our global pharmaceutical sales in the first half of 2013.

Now, we gave you a full review of our Pharmaceutical business in May, at which time we announced our intention to file more than 10 new molecular entities and 25 significant brand line extensions by 2017, so today I will just comment on two important developments we made in the quarter within our oncology division since the meeting which will really help to increase our leadership position in the category.

As we announced last week, ibrutinib became one of the first medicines to be filed with the FDA and the new breakthrough therapy designation. And if approved, it will be a first-in-class treatment option for patients who received prior therapy for chronic lymphocytic leukemia and small lymphocytic lymphoma, and also for patients who received prior therapy for mantle cell lymphoma, population today have very limited options.

Now recognizing this need, we and our strategic partners at Pharmacyclics are pleased to have been able to open an expand access program for relapsed or refractory MCL patients in the U.S. The program began enrolling in May. It is allowed by the FDA as a means of making an investigational drug available to patients with a serious or immediately life-threatening disease without comparable or satisfactory alternatives.

We also announced a definitive agreement to acquire Aragon Pharmaceuticals, a move that will add their androgen receptor antagonist program to our R&D engine, including a lead development stage product ARN-509 for prostate cancer, which is attractive to us because the way it complements ZYTIGA were also increasing new options we can eventually offer patients in this important and growing segments of the oncology field.

So, now let's look at the market performance of some of our recent pharmaceutical launches. By combining superior science with best-in-class commercial capabilities, many of our newly launched products are delivering robust growth and outpacing our peers. As you can see, XARELTO, which is the broadest indication among novel oral anticoagulants is tracking well at of warfarin and the others in the category, in new to brand prescriptions among cardiologists and ZYTIGA is continuing on its strong growth trajectory gaining 22% in the U.S. chemo naïve market since its approval in this indication in December.

INVOKANA, our new treatment for Type 2 diabetes was launched in the U.S. in April, was demonstrating very strong early results with the primary care and endocrinologists. Access INVOKANA is also building steadily and we are seeing strong interest from payers. Overall, 80% of patients with commercial plans now have access to INVOKANA in either Tier 2 or Tier 3. The success coupled with the supported joining the forces our pharmaceutical group with our Diabetes Care business has helped INVOKANA overtake Januvia, Onglyza and Trajenta in share of new to brand prescriptions in the important Endocrinologists segment.

This type of early progress demonstrates the power of leveraging our enterprise-wide capabilities to offer patients a full solutions based approach to diabetes management, and we are looking at leveraging our broad capabilities across the enterprise to support the growth of our products in other categories in similar ways.

As I referred to earlier, the pace of growth in the global MD&D markets has slowed and competition is intensifying. In spite of the economic compression however, the medical device industry remains attractive and we are transforming our go-to-market approach to drive our competitiveness in this dynamic environment and ensure we continue to lead the sector.

With market-leading platforms and products, we succeeded in sustaining or grown share in the majority of our key platforms, holding number one or number two positions in about 85% of them. We are continuing to bring innovations to patients and providers through meaningful product launches that will help sustain and drive growth and we are especially excited about the steady cadence of innovation emerging across the segment.

For example, Biosense Webster, a business unit that's on track to deliver another year of double-digit growth as it has for more than 10 years in a row. Their nMARQ, circular ablation catheter is designed to reduce cardiac ablation procedure time and complexity to key customer needs. It launched last year in Europe and we began enrolling patients in the clinical trial that will support our regulatory filing in the U.S. planned for next year.

Also, the ThermoCool SmartTouch Catheter is an important innovative product that measures the catheter tip contact force and direction inside the heart during ablation procedures in real time. We launched this product in the EU in 2012 and compelling new safety and efficacy data were presented recently at the Heart Rhythm Society meeting. These data will be included in our application for U.S. approval that we plan to submit later this year.

We are also bringing products to patients to meet specific market needs. The Bioseal fibrin sealant in China is just one of many. We are Also focusing our resources to advance more strategic options in our portfolio that start with taking a comprehensive view on the disease like we have done in large chronic disease states such as diabetes. Now to help dim the cost curve in healthcare we are focusing our broad and diverse R&D approach and portfolio to deliver total solutions of products that will increase the clinical value we offer patients and providers as well as the economic value we offer for healthcare systems and payers across the globe.

Consider the ATTUNE knee system which DePuy Synthes has just recently launched. The development team conducted extensive research in its design to help improve functional outcomes for patients, performance for surgeons and efficiency for providers. From the patient perspective, ATTUNE is designed to provide better range of motion and address the unstable feeling some knee replacement patients experienced and also provides an extensive range of sizes for better patient matching. From the provider perspective, simply reducing the number of instruments used with ATTUNE in addition to several innovative design features flattens the learning curve and delivers more efficiencies for the surgeon and operating room staff.

Now an update on DePuy Synthes. We are a year into the integration and as we envisioned, by broadening our base of offerings and expanding our reach in emerging markets, we have built a compelling growth combination that solidified our leadership in the $40 billion global orthopedics and neurologics marketplace. Our joint reconstruction business continues to do well especially with hips in the U.S. which have grown approximately 5% thus far in 2013. The ATTUNE knee that I just described has had a favorable initial response.

In trauma, we are encouraged by the second quarter results that generated mid single-digit operational growth in international markets, fueled by Europe as well as in emerging markets, notably China. In spine, disruption due to sales force attrition has improved and favorable increases in volume are being seen as the sales force continues to see momentum with cross-selling by the combined forces especially outside the U.S. with operational growth this past quarter in the mid-single digits.

While we still have work to do in certain areas of the integration, we are making good progress and we are seeing the benefits of bringing a broader portfolio of products to our customers to cross-selling including the collaboration between our cranio-maxillofacial and Codman businesses. We are also looking forward to similar results and to begin cross-selling products from our power tools and biomaterials platforms.

Now as we advance, we see additional growth in synergy opportunities within the organization and we are turning our attention to R&D and manufacturing and supply chain and to standardizing the IT infrastructure across the globe to improve our focus, speed and efficiency in order to realize them. You will hear more about the progress of our orthopedics business in the third quarter when Michel Orsinger, our worldwide chairman for DePuy Synthes will be on the call.

Our consumer segment is showing signs of its continued return to growth through its increasing momentum in returning a reliable supply of U.S. OTC products to the shelves, the continued expansion of iconic brands in the emerging markets and an overall focused portfolio and management approach. Sandy Peterson, who joined at the end of last year has already made an important impact on the organization. As group worldwide chairman, she holds a broad leadership role leading our supply chain, information technology and our consumer business sector. She is bringing a high level of broad and relative experience to our enterprise and I am pleased to be turning the call over to her in just a minute so that she can discuss her vision and plans for these vital areas of our business.

To recap, the year is off to a strong start. We have also made strong progress against our near-term priorities and long-term growth drivers to help sustain and drive growth in this dynamic global market. I will end by thanking our employees who work everyday on behalf of the patients, communities and shareholders that depend on us to deliver a high-quality and innovative products and solutions.

Now it is my pleasure to turn the call over to Sandy Peterson.

Sandra Peterson - Group Worldwide Chairman

Thanks, Alex. I have been with Johnson & Johnson now a little over seven months. It has been a great beginning and the longer I am here, the more excited I am about our ability to have a meaningful impact on people's lives around the globe. I have had the privilege to work at a number of well-respected companies, both inside and outside of healthcare and across geographies.

With that perspective, I am convinced that Johnson & Johnson is uniquely differentiated by its virtue of its broad portfolio, talented people and geographic reach to make a profound difference in health care. As you know, health care across the globe is changing as governments and consumers work to improve the quality of care and the rolls that providers, healthcare professionals and retailers also adapt and become more global.

I have spent much of my time so far meeting our customers and colleagues around the globe and learning our business. I have been to our major business and manufacturing campuses in the US, Brazil, Ireland, Puerto Rico, Belgium, China, Singapore, Vietnam and Thailand. I have met with numerous retail and provider payer customers in the U.S. and in our key other regions, both, large global customers as well as small mom-and-pop operation. What is most striking to me is the talent and diversity of our colleagues around the globe. And equally impressive is experiencing our credo as the source of constancy and inspiration in a time of remarkable change inside our company and in health care across the globe.

Our consumer brands are strong and resilient. Our breadth is a source of strength and competitive advantage. Although we have been challenged in recent years, our reputation with consumers, retailers, healthcare professionals and providers remain strong. As you know, I have accountability for some of the company's key enterprise functions, supply chain, including quality and information technology, as well as our consumer business sector. This integrated portfolio affords us the capacity to leverage these important functions to help deliver innovation and value to our customers and company across sectors and across the globe. We have the opportunity to leverage our scale and breadth through world-class deployment of information technology services and supply chain to better serve the evolving needs of our customers and consumers.

Today, I will provide update related to our consumer businesses and the Johnson & Johnson supply chain. Let's start with what Alex had previously identified for you as one of our top enterprise-wide priorities, restoring a reliable supply of our U.S. OTC products. Our priorities in the U.S. OTC business are, first, to deliver on our consent decree milestones, second, to ensure reliable supply of OTC products to retailers and consumers. Third, to achieve both, brand leadership and sustained healthcare professional number one recommended status, fourth, to rebuild customer trust and become our customers' preferred partner and fifth to execute a return to market plan for core U.S. OTC brands and SKUs.

Our consent decree work plan was approved by the FDA without modification in the fourth quarter of 2012. We've achieved 100% on-time execution of the prescribed step through the second quarter. Additionally, all reports have been submitted to the FDA on time. We are making good progress on restoring our OTC brands to the shelf. We have achieve solid steady unit sale rates and consistent delivery commitments to customers and retailers.

By year end, our plan is to deliver reliable and consistent supply of three quarters of the product brands. In the first half of 2013, we achieved the U.S. OTC operational growth of 19.7%, which includes 26% growth in revenues in over-the-counter medicines, and we are winning the hearts of consumers as these products return to the shelves in all four segment cough, cold and flu, allergy, pain and digestive health. For instance, Extra Strength TYLENOL is the number

one code in adult pain. Children's TYLENOL and MOTRIN are the top two SKUs in pediatric pain, and we are leading in other important categories such as allergy care with ZYRTEC and our digestive health brands IMODIUM and IMODIUM are returning the strength.

We are focusing on our top retail customers. We have achieved full distribution of key brands and point-of-sale has improved with all top retailers. We are partnering with them on strategic initiatives that are rebuilding our relationships and supporting their health and wellness strategies in order to educate consumers, simplify their purchasing experience and ultimately to help bring more consumers into their stores. Our strategic purpose for our consumer segment is caring for people around the world by anticipating their needs and creating solutions and experiences that help them and those they care for to live a healthy, vibrant lives and we are uniquely suited to do just that.

Our broad consumer portfolio, from well-being and beauty to health and (inaudible) is a competitive advantage as are our iconic brands. We have a legacy of innovation that leverages our scientific heritage and wins us unparalleled professional endorsements, trust-based relationships with healthcare professionals and deep consumer insights. We are applying the portfolio of discipline that calls on us to make choices that will drive global brand growth in key priority markets, including rationalizing SKUs and harmonizing formulations. With our long history in emerging markets, which represent a proportionately higher share of segment sales than elsewhere in Johnson & Johnson, we are globalizing existing brands such as Listerine, Motrin, Johnson's Baby and Carefree and complementing our portfolio with key local brands like Elsker in China and Rinzai and Dr. Mom brands in Russia.

Our consumer segment is not only a critical component of Johnson & Johnson's diverse portfolio and growth plan, our iconic brands are those that stakeholders most closely identify with Johnson & Johnson. We are pleased with the value creation opportunities ahead of us but we know, there is still work to be done to restore our OTC businesses to sustainable growth, while globalizing our remaining brand portfolio and investing in key market growth.

Let us now shift to how we are working to deliver a reliable and cost competitive supply of high quality products to our customers, consumers and patients across our businesses. Three years ago, we created a global enterprise supply chain. Our goal was to integrate into a network that would employ consistent quality standards and systems, leverage the scale and technological breadth of our portfolio and enable continuous production of cost-effective and high-quality products. This is a multiyear effort to integrate and leverage over 120 manufacturing sites, over 500 external manufacturers, 450 distribution centers and over 60 ERP systems that support about 275 operating companies. But the opportunity to leverage our scale and breadth to better meet our customers' evolving needs and maintain the highest quality and regulatory standards is significant.

We have implemented a new quality and compliance operating model to ensure consistent standards and capabilities across all products, businesses and geographies while strengthening independent oversight processes. For instance, we have adapted and are now deploying 34 common quality standards for all companies around the world. An independent internal audit program launched three years ago is ensuring that all Johnson & Johnson sites are in full compliance with health authority regulations and our own quality requirements.

Each of the three business segments has a chief quality officer responsible for developing the quality and compliance strategy and overseeing quality results for all companies in the segment globally. Each of the three business segments had the quality and compliance systems group to drive standardization and quality and compliance practices. We are evolving our supply chain model to enable leverage across our global network in sourcing, logistics, transportation and distribution management, and to strengthened business continuity plan.

Our improved product launch performance demonstrates tighter commercial integration. We have begun to consolidate and harmonize ours ERP landscape. This is a four-year program that will deliver efficiencies in terms of cost to offset pricing pressures and working capital improvements, supply reliability and flexibility for years to come.

We are integrating Synthes, into our global supply chain network and quality systems, and we are optimizing our products supply network both, internally and externally to meet our growth objectives for new product launches and emerging market growth.

Health care is a challenging, but intensely rewarding space. In a few months that I have been part of the Johnson & Johnson leadership team, I have gained even more conviction and we are making a real difference for consumers, for patients, for customers, providers and health care system. I see the enormous opportunity we have to do more and I am looking forward to growing our businesses and creating meaningful innovation for our customers and value for shareholders.

Thank you for the opportunity to share some of my thoughts with you today.

And now, I'll turn it over to Dominic.

Dominic Caruso - Chief Financial Officer, Vice President

Thank you, Sandy, and good morning, everyone. It is really great to have Sandy join us today on the call and it's a real pleasure working with her as a new member of our executive committee,

I would like to now provide some brief comments about our results and also provide our guidance for you to consider in refining your models for the balance of 2013. I am pleased to say, we've had a strong first half of 2013. The breadth of our business, which provides balance and consistency to our overall performance, as well as the extraordinary achievements and dedication of our people in all of our locations around the world positions us well to sustain growth in this increasingly dynamic global health care market.

While there are some indicators of general economic improvement, the healthcare market data we see in terms of utilization is still relatively flat over the prior year, with just a modest sequential improvement over the first quarter utilization data. Overall, however, we continue to drive growth in many areas of our business, especially in the pharmaceutical segment with the launch of new products addressing unmet needs.

Alex and Louise already commented on our results for the quarter, so let me just mention the impact of special items this quarter. There were special items recorded in the other income and expense line during the second quarter of approximately $560 million on a pretax basis. That consisted of charges for litigation expense accruals related to various legal matters DePuy ASR hip program cost. And, as expected, continued costs associated with the global integration of Synthes. Excluding these special items, our adjusted earnings per share for the quarter of $1.48 exceeded the mean of the analyst estimates as published by first call. Now, let me provide some guidance for you to consider as you refine your models for 2013.

Let me begin with a discussion of cash and interest income and expense. At the end of the quarter, we had approximately $10 billion of net cash. This consists of approximately $25 billion of cash and marketable securities and $15 billion of debt. We continue to generate very strong cash flows. For purposes of your models assuming no major acquisitions, I suggest you consider modeling net interest expense of between $400 million and $450 million, a slight improvement from our previous guidance.

Turning now to other income and expense, as a reminder, this is the account where we record royalty income as well as gains and losses arising from such items as litigation, investments by our development corporation. and other divestitures, asset sales or write-offs. As previously disclosed, during the second quarter, we sold our equity interest in ECHELON and that gain is reflected in this line. This account is difficult to forecast, but we would be comfortable with your models for 2013, reflecting other income and expense as a net gain, excluding special items ranging from approximately $750 million to $850 million, which is consistent with our previous guidance and includes the gain from the sale of our equity interest in ECHELON.

Now, a word on taxes. Through the second quarter of 2013, the company's effective tax rate excluding special items was approximately 19.5%. We suggest that you model our effective tax rate for the full year 2013 at approximately between 19% and 20%, or slightly lower rate than our previous guidance. As always, we will continue to pursue opportunities in this area to improve upon this rate during the remainder of the year.

Now, turning to sales and earnings. We would be comfortable with your models reflecting operational sales growth on a constant currency basis of between approximately 6% and 7% for the year, which is higher than our previous guidance. This would result in estimated sales for 2013 on a constant currency basis of approximately $71.3 billion to $71.9 billion.

While we are not predicting the impact of currency movements, to give you an idea of the potential impact if currency exchange rates for the remainder of 2013 were to stay where they were as of last week, then our sales growth rate would be negatively impacted by approximately 2% for the year. Thus under this scenario, we would expect reported sales growth to be between approximately 4% and 5% for the year for an expected level of reported sales of approximately between $70 billion and $70.6 billion which is lower than our prior guidance simply due to the overall weakening of foreign currency rates versus the U.S. dollar, particularly the Japanese Yen, Brazilian Real and the British Pound.

Now, turning to earnings. Considering the strength we saw in our operating results for the first half, we suggest that you consider full year 2013 earnings per share estimates, excluding the impact of special items, of between $5.42 and $5.49 per share on an operational basis at constant currency rates or an operational growth rate of between 6.5% and

7.5%, which is higher than our previous guidance. As a reminder, the benefit from the Elan gain, as we noted, would largely be reinvested in the business and our other income guidance is unchanged. So this increase is related to the operational performance of the business which we see improving.

We are not predicting the impact of currency movements but to give you an idea of the potential impact on earnings per share if currency rates for the balance of 2013 were to remain where they were as of last week, then our reported EPS, excluding special items, would be negatively impacted by approximately $0.02 per share or $0.04 lower than the impact we had previously estimated in our guidance solely due to exchange rate fluctuations. We therefore suggest that you model our reported earnings per share excluding special items in the range between $5.40 and $5.47 per share or a growth rate of between 6% and 7%, resulting in a reported EPS guidance being higher than our previous reported EPS guidance, reflecting our strong operational performance somewhat offset by the movement in currency rates.

Overall, as you update your models for the guidance I just provided, you should see pretax operating margins will continue to show improvement over the prior year as we indicated at the beginning of this year and which we feel confident we can achieve, given the strength our operating performance while we continue to invest for future growth.

Now, Louise, back to you for the Q&A session.

Louise Mehrotra - Vice President, Investor Relations

Thank you, Dominic. Stephanie, can you please give the instructions for the Q&A session?

Question-and-Answer Session

Operator

(Operator Instructions) Your first question is from the line of Mike Weinstein with JPMorgan.

Mike Weinstein - JPMorgan

I wanted to ask that, at a recent event which was the allowance of the patent application on ZYTIGA in combination with prednisone and could you give us your updated view on the life of that ZYTRIGA in the U.S. and how ZYTIGA is going to fit with ARN-509 and the Aragon acquisition and where do you see the position in the two products? Thanks

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Hi, Mike, this is Alex. Thanks a lot for the questions. As you know, Janssen has got five years of data exclusivity in the U.S. from the date of approval which was April 2011 or until April 2016. We are also watching the Hatch-Waxman extension to December 2016. At this point in time, we believe that those are the correct dates of using. Obviously we are going to be looking at some of these other recent events closer to see what impact it may have. But at this time, we are sticking with December 2016.

Regarding the Aragon, look we think it's a great complement to our portfolio. If you look at the great job, frankly, that our team has been able to do with Zetia in the launch regarding the clinical backup, actually the actual approval of the compound, the ongoing clinical development, very impressive, the commercial penetration that we have seen, as well as the care programs for the patients, we think it represents a significant capability. Now when you complement that with the Aragon compound, it will certainly enable us to leverage all of those skills on to a next phase. We think that there could be potentially complementary utilization of those compounds together and again as one another example of us continuing to really make a difference for patients and for our business and is very exciting oncology area.

Mike Weinstein - JPMorgan

Two quick follow ups if I can. One, is there an update on the plans for the Clinical Diagnostics. And, two, Dominic, where are you with the completion of last year's ASR and could you just talk about thoughts on additional share repurchase following that? Thanks.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure, Mike. I'll take the first half of that question and then I'll ask Dominic to follow up on the second part. As you remember, earlier this year we announced that we were going to be exploring the future. The Diagnostics group at an enterprise level. And the initiation of this process was really part of a broader strategic planning process across

Johnson & Johnson. Recognizing that we wanted to be very disciplined and decisive about what we are going to do with our businesses and our capabilities going forward.

Now, as we stated back in January, we expect that this process could take anywhere from about 12 months to 24 months. We're on track for that. We're still in the early-stages and we think it's premature at this time to speculate about specific impact, but we are continuing to look at our options. Dominic?

Dominic Caruso - Chief Financial Officer, Vice President

Yes. Hi, Michael. On the ASR program, we expect it will be completed in early August, and we are near of the completion of it. As soon as we complete that programs then we will be permitted to recommence the share purchases that we normally do in a normal course of business, which as I think you all know, we repurchase all the shares that are issued in connection with any employee compensation programs, so we'll obviously commence that right after the ASR program is completed in early August.

As far as any larger, more significant share buyback program, as we said before, we always evaluate that in the spirit of utilizing our strong cash flows, but quite frankly in the priority, we've always said, first our dividend, second to use in building our businesses to generate even more sustainable cash flows for the future, and then finally, considering an additional return to shareholders as appropriate given the first two.

Louise Mehrotra - Vice President, Investor Relations

Okay. Next question, please.

Operator

Your next question is from the line of Rajeev Jashnani, UBS.

Rajeev Jashnani - UBS

My first question was on consumer business, Sandy. And, I was hoping you would talk a little bit about the margins in that business and clearly there is some cost associated with compliance that are ongoing now. But, maybe if you talk about how you see that playing out over the next few years and some of the investments you had to make on the brand. Thanks.

Sandra Peterson - Group Worldwide Chairman

Thanks for the question. As you know, we are still in the process of remediating the OTC business, which is an ongoing effort. And, clearly, we will spend what it takes to ensure that we are completely compliant with the CD, and we are bringing all of the products back.

Our expectation is that that will continue for the near-term. But, in addition to all of the remediation efforts, we also are going to ensure that we are investing sufficiently to bring these brands back and bring them back fully to consumers and retailers and that our current estimation is that we will probably be spending at a higher rate than our historical averages as we are bringing all of these brands back. So, that clearly in the near-term, will have some impact on our margins. But at the same time, we are also working very hard to you globalize our core brand portfolio, and by doing that that will improve our margins over time across the total consumer portfolio. And, we have also, the team has put a lot of effort in the last couple of years in reducing overheads and driving efficiencies throughout the business.

So, I think what you will see that over time, we will start seeing improvements in our margins as we bring the OTC portfolio back and as we globalize the rest of our core portfolio. And our expectation is that, our business will have similar margin in the consumer sectors as you see in the other parts of the JNJ portfolio, as we bring all of these businesses back and we will continue to improve the margins over time.

Louise Mehrotra - Vice President, Investor Relations

Okay. Next question, please?

Operator

Your next question is from the line of Matthew Dodds with Citigroup.

Matthew Dodds - Citigroup

Good morning, one for Alex and one for Sandy. Alex, if you look at the Pharma results, ZYTIGA, XARELTO and INCIVO were big drivers globally, but it looks like Europe accelerated again this quarter even if you back out adjustments one timers ZYTIGA, INCIVO. So, my question is whether one or two things that's changed in Europe is maybe going to gain all the share.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

I am sorry, Matt. Would you repeat the last part of that question?

Matthew Dodds - Citigroup

Yes. What's driving the share gains in Europe for kind of the base business not the new products, but the base? It seems like you continue to do better and better in Europe, in pharma.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes. Well, Matt, really its strong performance across both base and launch brands. So if you take a look, for example, of how we are doing in the CNS area, continued growth with those products. We have had, of course, a number of new launches on top of that. I think, overall, our team is just executing extremely well. So I really think it's a mix, both of some of the core brands combined with the new product launches that's driving that kind of performance.

Matthew Dodds - Citigroup

Okay, then. Just to hear from Sandi. Sandi, one area you didn't hit on was skincare, which is almost as big as OTC nutritionals and the last, I would say, three quarters even again, ex-divestitures, it looks like it slowed a little bit. Is that market share or market growth and is there anything coming there, innovation wise that could accelerate the growth?

Sandra Peterson - Group Worldwide Chairman

Matt, thanks for the question. Actually, the overall skin care market, as a category is improving, but it is still not what it used to be at our historical level. However, our own business is doing relatively well. So our Neutrogena portfolio, in the U.S., we have gained 0.5 share point in the first half of this year. Our Aveeno business is up almost 8%. Our LPN business in Europe is growing close to 10%. Our Johnson's adult business is growing in the mid-single digit level. So those are all very positive things and we are feeling good about our businesses in Asia as well.

The one thing that is impacting those that are in this category is the sun care business. The market category is down 11% in the first half of this year. We have actually been gaining share in the U.S. over 2% and we are now the number two global sun care provider in the world. So the impact of the sun care market clearly is having an impact on the overall business and while we are doing very well in it, a little over 2% is less than the historical rates that you would see normally in that business. So that's a general sense of how we are doing in the skincare portfolio and that's why you see a relatively low overall growth rate because of market growth. But our shares are actually growing in our core brands.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question comes from Kristen Stewart, Deutsche Bank.

Kristen Stewart - Deutsche Bank

I just want to take a step back, I guess, and just discuss what gives you, I guess, the confidence to raise the overall operational outlook for the rest of the year? Is it coming more, and obviously you had a good first half, but is there anything kind of in the end markets either within medical devices that gives you some increased confidence or are you just having a higher level of mix on more of the pharma side with some the performance there?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Hi, Kristen, this is Alex. Thanks for the question. I will start off and then I will ask Dominic to finish. But I think overall

as we characterize our business, we are really pleased with what we have seen during the first six months. We have made a lot of progress around our top objectives that we have been very clear about from the very beginning delivering on our financial performance. Obviously accelerating the launch of our pharmaceutical products. As we look at that portfolio and particularly there is a couple of things, one is in spite of new competition, really all of our newly launched categories, we continue to see very good uptake.

We think that's driven, first of all, product profiles that really important for patients but they also have been very well-developed by our clinical development team. Two, by great commercial excellence. I think that's demonstrated in our ability to differentiate but also in our ability to ensure access for these products through managed care Medicaid in the United States but also through tendering processes outside the United States. We have also seen good performance in our pipeline and development by bringing in through licensing and acquisitions but also continued progress in our own. So, all around, our pharma business, we believe, is in a good place and certainly positioned well for future growth.

If we look at the MD&D, clearly we have been challenged by the macroeconomic situation that's having an impact on demand around the world. If I start in the United States, what we have seen is fairly flat performance overall. By the way, if we look at some of the leading indicators, for example, if we look at hospital admissions, if we look at inpatient procedures, we see relatively flat to even slightly negative statistics. The primary care physician visits are in the low single-digits. We have got you multiple quarters, consecutive quarters now, with those types of trends. We don't expect that to turn in the near-term. Longer-term, we will have to see the impact of the Affordable Care Act on that. That being said, we remain very committed to our MD&D business. In areas such as Biosense Webster, ENT, Vision Care, we have seen very positive performance this quarter. However, if you look at some of our other core businesses, surgical care for example, sutures and surgical instruments, we see the challenges associated with the macroeconomic environment.

We're also somewhat, I would say, I encouraged as well by what we are seeing in orthopedics, particularly in hips and knees and trauma over the past quarter. And, clearly, if we look at our consumer group, we see a very strong performance from our U.S. OTC business. Sandy took you through some of that earlier. I think around the rest of the world, we tend to follow more what we are seeing with GDP, but if we total all of that, we think that we are continuing to make good progress. We still see challenges ahead. At the same time, our teams and our employees, I think, continue to demonstrate that we are delivering on our commitments and that's the way we intend to finish out the rest of the year.

Dominic Caruso - Chief Financial Officer, Vice President

So, I wouldn't add anything else except that we are not reading into our performance any uptick in utilization trends generally speaking, so I think that that still remains to be challenging for the balance of the year. But as Alex said, individual product performance is really pretty exceptional especially in the Pharma business.

Kristen Stewart - Deutsche Bank

And then just really quickly just the breaking out of the Nutritionals from the OTC business, what was the rationale for that as Nutritionals is an area where you might look to divest or how should we just think about that separation?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes. We wanted to break it out, so actually for your benefit, so you can track the progress in our return of the OTC business. You know it's pretty significant in terms of our progress there. I think it sometimes gets buried by the groupies of different things in the same line, so really for your benefit in your modeling purposes we want to show you singularly what the U.S. an overall OTC business was doing. No other reason than that.

Louise Mehrotra - Vice President, Investor Relations

Next question, please?

Operator

Your next question is from Larry Biegelsen, Wells Fargo.

Larry Biegelsen - Wells Fargo

Good morning. Thanks for taking the question. One for Alex and one for Dominic. Alex, could you share with us your first and second quarter growth rates in emerging markets? Given the macroeconomic and political dynamics, could

you give us your latest thoughts on the outlook in those markets for health care in general and your business? And, for Dominic, then after that I'll ask my question for Dominic.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Larry, this Alex. Larry, we are not splitting it out specifically for all emerging markets, but if we take a look at our BRIC markets, Brazil, Russia, India, China, what are saying is about 19% growth. You can see obviously that that's a significant multiple of what we are seeing in developed markets. Again, I think it's built on the fact that we've been in these markets for a substantial period of time, particularly if you take a look at our consumer and our MD&D business in places like China, but even our pharmaceutical business as well as the other businesses in places like Brazil, we made investments over the last several years in our consumer and our MD&D business for example with (Inaudible) [Elsker], Bioseal in China, and so we see these markets as very important for our growth. We continue to see good uptake in health care. It's something that we are watching very closely in light of the larger macroeconomic environment.

But, overall, we believe that these markets represent a significant growth opportunity simply because more patients are receiving access to treatment. And, secondly, because we have solid positions in many of these areas.

Larry Biegelsen - Wells Fargo

That's helpful. Just to clarify the 19%, Alex, in the BRIC markets. Was that for Q2 or the first half of the year?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

That was Q2.

Sandra Peterson - Group Worldwide Chairman

And, it excludes Synthes.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Larry, and it excludes Synthes.

Larry Biegelsen - Wells Fargo

Okay. And, Dominic, you grew, I think, 4.8% year-to-date ex-Synthes. I think, Alex talked about earlier in the presentation. Correct me if I am wrong, but the updated guidance implies about 2% to 4% in the second half of the year. Is my math correct and is this just conservatism or is there any reason why you would expect the second half to be slower than the first half. Thanks.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes. So, we were looking at operational growth. Let's focus on that, because obviously currencies that have a negative impact on our sales growth. Operationally, for the first half, we had pretty strong growth, all related to the pharmaceutical business primarily and obviously the inclusion of Synthes. In the back half of the year, to get to about between 6% and 7% operational growth that I was referring to, we would expect about 4% overall growth for the back half of the year because the first half obviously was impacted by Synthes. So that's that math I have, Larry, about 10% this quarter, roughly 10% for the first half of the year, between 6% and 7% for the full year, which implies about 4% in the back half of the year on an operational basis, excluding any currency impacts.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question comes from Derrick Sung with Sanford Bernstein.

Derrick Sung - Sanford Bernstein

My question, to start off with just a couple of housekeeping items. Was there any impact to sales this quarter from either in the pharma, the Medicaid rebate adjustment or in medical devices, any extra selling days that might have

inflated sales growth rates?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

So, Derrick, no Medicaid rebate adjustments in this particular quarter. We had a significant adjustment last quarter that we talked extensively about but nothing of that nature in this quarter. With selling days, we don't know if there is any real significant impact for selling days this quarter.

Louise Mehrotra - Vice President, Investor Relations

Really no significant impact. It's about 0.2 days. That's all OUS. It only really impacts our orthopedics business. Okay?

Derrick Sung - Sanford Bernstein

Great, and Louise, could you give us a sense for the breakout of pricing and mix, again for the orthopedic divisions?

Louise Mehrotra - Vice President, Investor Relations

Sure. So price worldwide, just price is about 1% decline and that's consistent U.S., OUS and total and that's as the same as the first quarter. Now if we get into the U.S. only, where I have a price and mix number. For hips, the price was down about 3.5% very consistent with the prior periods. Mix, however was up about 1.5%. So it netted to about a 2% decline. So that's a little bit more favorable than the first quarter. When you go into knees, the price number was down about 1%. We did have favorable mix again. For now we are about 0.5% favorable and that is very consistent with what we had in the first quarter.

Derrick Sung - Sanford Bernstein

How about spine?

Louise Mehrotra - Vice President, Investor Relations

Okay, so in terms of spine, price was about 3% negative for the second quarter and mix was about to 2.5% positive, netting to about 0.5% negative, very similar trend on the total between the first and the second quarter. However, just a little bit of changes between price and mix.

Derrick Sung - Sanford Bernstein

Great, thank you. Just one more for Sandi, if I could. Sandi, what are your expectations for how much share you will gain, once you get your products back into the market, now that you have seen how the initial relaunch of your OTC products is going. I understand that's 75% expectation for brands to market. But how much of that lost share do you recapture when you hit the market? Thank you.

Sandra Peterson - Group Worldwide Chairman

Thanks for the question. Quite honestly, we were still in early days. Our intent and we are on track to bring 75% of those brands back this year. We have others that we will be bringing back next year. But as we begin to get into the stores and interact with consumers again, we have had very positive responses from not only retailers but that consumers and healthcare professionals. It is a little early to be able to answer that question, but what I can tell you is that in the first half of the year, we have seen with the limited on distribution, now we have full distribution, but in the first half we only had limited distribution, we have seen things like our Extra Strength TYLENOL share double in the first half of the year. We have seen significant growth with most of our other products that we have brought back to the market. But it's a little early for us to actually give you a clear sense of what that number will be. Clearly, our intent and our desire is to get back to the share numbers that we had before we went in to the CD process and that's what we are really focused on doing.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Next question comes from the line of Jami Rubin with Goldman Sachs.

Jami Rubin - Goldman Sachs

Just two questions to Dominic. I just want to follow up on an earlier question. That is the implied guidance for the second half of the year. Even if I assume the top end of the guidance, that still assumes a second half earnings growth of 4.5% versus 9% during the first half. So I can't imagine that having Synthes now fully annualized would affect the operational growth rate that much. May be it does, but if you just talk about what specific headwinds you expect in the second half that we did not see in the first half.

Then, Alex, a question for you, as long as we have the opportunity to have you on the call, if you could talk sort of bigger picture about business development, Dominic said that your priority is, number one, the dividend. Number two, business development or maybe you have that mixed up. And then number three share buybacks. But now with Synthes having fully annualized, just wondering if you could talk to what your business priorities are in terms of specific businesses, what sort of size we should anticipate. How are you thinking about business development? Thanks.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

So, Jamie, on the earnings part of the back half versus first half comparison, remember we did indicate that we expected this other income and expense line to be about $800 million for the year that's consistent with our guidance now, so no change there. But, of course, you with the Élan gain coming, all in one quarter, the vast majority of that has already happened in the first half of the year. So.

Sandra Peterson - Group Worldwide Chairman

That contributes this quarter?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes. As you look at that, we released in April, we talked about the fact that we sold our Elan shares and we filed a registration statement concerning that and we indicated the estimated gain was going to be about $200 million from that sale we then sold some additional shares later in the year. So, think about it as a better $0.07 kind of number that we disclosed earlier, but to put one thing in perspective with this other income and expense line, your models, of course, have modeled one quarter of the $800 million, which is about what I had expected a model and this quarter we had within that line $400 million of other income and expense, right, because as the Élan gain in there. So, if you look at the impact just this quarter of the Élan gain versus the overall analyst models, I would say that that $200 million excess or roughly $150 million after-tax is worth about $0.05 compared to what the Street has been modeling.

Dominic Caruso - Chief Financial Officer, Vice President

Okay. And, Jamie, for your first question, I think the way that I would frame our overall position is look, we are going to continue to look for internal and external opportunities that we feel is going to drive our growth going forward. We've been very consistent in saying that when there are new technologies, new innovations that give us a platform to build, and I think a great example of that is what we have done in oncology over the past few years and our pharmaceutical business. There is a lot of unmet medical need and we've been able to do some great partnering to rapidly build what we feel is now a world-class platform in oncology both, from a pharmaceutical development but also from a commercial and access point of view.

The next area that we look at of course is, what businesses could be complementary to our existing businesses. What may round out some of our current portfolios or allow, build on capabilities that we currently have and there are other opportunities perhaps, where we look at vertical integration. What we've done for example in our biosurgicals business is a great example of that with OMRIX, and we are excited about the potential that has is we are in the process of launching that on a global level, but that's the way we look at it. But, regarding our pharmaceutical business, look, I am really proud of the work the team has done there in taking agreement such as what we've done with Pharmacyclics, what we've done with (Inaudible), what we have done with other organizations in partnering and adding on to our portfolio to bring forward great opportunities for patients, but also for our business.

In MD&D, obviously, the Synthes transaction was very large transaction. Michel and his team are doing a very nice job through the integration process, but we realize that that does take some time. We remain committed to having the broadest and most comprehensive orthopedics platform. We are seeing that happening right now as those businesses come together.

In consumer, we think the consumer area [level]-one consumerism will also be very important as we go forward in healthcare. And, we have made some select acquisition they are particular in China over the past couple of years. We

have also done some other divestments in our business as we really focus more in certain areas of our portfolio and as we have also done in MD&D, so I think that's overall our approach. We want to continue to look for technologies and innovations that really make a difference for patients, we want to continue to look for opportunities to that can be complementary add-on, give us additional customer offerings or if we see other brand-new areas that we think can really be transformational, obviously we would be interested in that as well.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question is from the line of Danielle Antalffy with Leerink Swann.

Danielle Antalffy - Leerink Swann

Good morning, everyone. Thanks so much for taking my question. I just wanted to touch on the diabetes business a little bit. You mentioned some of the impacts on competitive bidding. Can you talk a little bit, Alex, about your commitment to that business going forward and how we think about the business now in the context of competitive bidding? Louise, if you could remind us the impact of competitive bidding to the business? How much of the business is as opposed to Medicare?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Hi, Danielle, thank you vey much for the question. Look, overall, what I would say is that J&J and our diabetes companies, we still feel we are very uniquely positioned for strong leadership and success in the category based on a great track record that we have had in technology innovation scale and brand equity. If you just look at diabetes, of course, its one of the largest and most significant issues in healthcare today. I think there is somewhat around 370 million people with diabetes today, projected to go to almost 500 million by 2020. So the need is great. It is a very difficult area to control.

Now what I would say is that with the recent launch of Invokana, our sales and marketing efforts are broadly targeting both endocrinologists and primary care physician to treat a vast majority of these Type 2 patients. Both Janssen and LifeScan Animas are partnering to accomplish this objective. It is the first time where LifeScan Animas have been involved in promoting an oral therapeutic agent of any kind. That really helps to expand their reach and it strengthens basically their commercial and clinical relevance beyond just glucose monitoring and insulin delivery among those healthcare professionals.

Then when you compound that with the Calibra acquisition that we recently did, it’s the Wearable Insulin Patch technology, we feel that that’s going to be a very good opportunity for patients making it easier for them. If they are currently on basal only insulin therapy and they need an easy to administer mealtime dosing option, that certainly provides that. But while we look at all that, we also acknowledge the realities of the market and now with a competitive bidding process, the 72% reduction in pricing that we are experiencing in the United States, we are having to adapt our business model to meet that challenge.

But again it’s a diabetes, we think, is a very important space of a lot of unmet medical need. We think we have a number of offerings across our MD&D, pharmaceutical and consumer segment that can address them. But clearly we will adapt to those changing dynamics as events unfold and as we predict they will unfold in the coming years.

Louise Mehrotra - Vice President, Investor Relations

And Medicare sales are just over 20% of the U.S. business.

Danielle Antalffy - Leerink Swann

Okay, great. Thanks so much. Then on Synthes, if I could dig a little bit deeper on that. You mentioned a stable or some positive momentum and fine procedures. I am wondering how much of that is underlying market growth versus specific to Synthes and how is Synthes doing relative to your internal expectations as far as sales force attrition goes and how are you managing that going forward? Thanks so much, guys.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure. Let me start with Synthes. Overall, look, we are really pleased with the way the integration is going. Taking on a company the size of Synthes with a reputation that scale its capabilities is no small undertaking. Bringing those together the way that our teams have, I think, they are really to be commended for it. We have got a multi-phased program in place to bring it together commercially, the entire research and development organization as well as all the supporting functional areas. When you look at, for example, our hip and knee performance in the United States, we saw growth in our hip area up 5%, again based on new products being introduced, things like (inaudible), CORAIL, other things, our knee business being helped by the introduction of the ATTUNE new knee system.

If we compare those to the U.S. growth rates, we are estimating and this is first quarter data because we don't have all second quarter data yet, of 1% in hips and slightly down in knees. We think that's very favorable performance and again keeping those segments focused, keeping them delivering while going through the integration is no small feat. If we look at trauma, we are up 2% in the U.S. versus the market that we think is probably going around 6%. We have seen some loss of share due to the nail recall that we experienced early in the earlier. We think it's being managed well, we think we will see our way through that on a worldwide basis, so we think we are you growing commensurate with what we are seeing with the market, so continued strong emerging market growth, the globalization that we offer to some of those businesses we think is real opportunity.

Now last, but not least in spine, on a worldwide basis what we see the market is down about 2%. We think we are down about 1%, so we think we are commensurate. In the U.S., we have seen the performance when we were down about 7% versus the market that was down about three. We were clearly impacted by some transitional issues with our sales force during that period. They put a comprehensive plan in place, where we think that we project that will do much better going forward.

And more importantly, when you look at the offerings that our representatives have across the minimally invasive segment, degenerative, spine, a number of other areas combined with the rest of our portfolio is going to put us in a very good position in that marketplace. So, we remain very optimistic, pleased with the performance around the integration and feel that DePuy Synthes again is going to be good for patients and also be good for our business.

Louise Mehrotra - Vice President, Investor Relations

Next question please?

Operator

The next question is from the line of Tony Butler with Barclays Capital.

Tony Butler - Barclays Capital

Good morning and thank you very much for the time. Really two questions and one is two parts. Alex, a question for you first, clearly some discussion not only in the press today, which has been in the press for some time about the ministry of public security looking into business practices principally in China. And, I am concerned that that you'd spread not only to Glaxo, but to other companies, including JNJ. Just simply looking business practices, can you comment on what you know today maybe going on what sort of investigations and whether or not your practices are being discussed.

Then two product questions. One, clearly around the very strong growth of PREZISTA, up 80%, sequentially, Louise or Dominic, any commentary that you can make regarding that very strong growth, sequentially. Then second on XARELTO, if I understand 20% sequential growth, but you believe that's solely driven by DTC. Thanks very much.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure, Tony. Let me start up. Look, on the first question what I would is that, we are absolutely committed to ensuring that our businesses are run in a highly compliant manner around the world. And, we have a very active compliance program in place in the country such as China little on all the BRIC countries. We continue to update our policies and procedures as we get more information. At the same time, we recognize that these countries are very important markets going forward.

By that there is still a lot of unmet medical need with patients. And, clearly, we know that these governments are also very committed to ensuring that they have a compliant environment at the same time they are getting access for their citizens to important health care options. So, we remain very diligent on it. We've made significant investments in these areas in compliance and we want to work closely with these countries and governments to ensure that we are working together in a collaborative way to ensure we have a very compliant environment going forward. Louise?

Louise Mehrotra - Vice President, Investor Relations

Charlie, more in PREZISTA, we have seen just the basic market share improvement over the quarter. I mean, PREZISTA is doing very well. Our sales team is doing an excellent job and the product has become quite frankly a mainstay in HIV therapy, so it's really just we saw pretty strong market share growth, sequentially.

Then on XARELTO, we did do some DTC there, but I think that product as we've talked about before with the breadth of its indications is becoming much more recognized as a standard of care in that marketplace. And as Alex pointed out earlier, you know, we've now surpassed warfarin in the new to brand share. So, I think the breadth and our strategy around the breadth of that compound in the market that needs that kind of therapy that has both, exceptional efficacy and obviously safety is what's driving that growth. I wouldn't just pin it on overall DTC advertising. I would say just a breadth of the overall indications for the product as we expected. That's what our strategy was and looks like to playing out.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes, Tony, I would just add one other thing on to that because I think Dominic gave a really comprehensive answer. That is in addition to the clinical development program which resulted in numerous indications, it's really gives physicians a very broad application of the product. They have also done a great job done by our access team in ensuring broad formulary access in our managed care in places here in the United States. So I think now we have got more than 85% access of Tier 2 in both private as well as Medicare customers. That's very important for them. It relates to an issue of affordability, of convenience and of course the reason that we are able to get that kind of access is because our team has done a great job of demonstrating the clinical and overall economic value of XARELTO to those patients and in those settings.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question is from the line of Glenn Navarro with RBC Capital Markets.

Glenn Navarro - RBC Capital Markets

Thanks for taking my question. A question for Alex. Alex, I would like your view on the CapEx environment in the United States. It appears the environment remains challenging. I know you spend a lot of time visiting hospitals and hospital executives. Is the CapEx challenged environment a function of utilization? Is it a function of healthy health care reform? So just curious of your views.

Then, as a follow-up, what do you think turns the CapEx environment to the positive in the U.S.? Thanks.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Hi, thank you very much, Glenn. Look, I would say, in discussions that I have had with hospital CEOs and with other people in the marketplace, I have seen a couple of things. One is, clearly there has been a recession now for, I believe, almost 10 to 12 consecutive quarters, where we see that admissions in the hospitals as well as numbers of procedures being flat to negative. Now clearly we are seeing some shift to the outpatient setting but when it comes to inpatient procedures and additions, that market is obviously being impacted by the macroeconomic conditions.

I think secondly, people are waiting to see the full impact of the Affordable Care Act. They are still working their way through the details and how that might affect. There is certainly changes regarding risk bearing areas such as hospital acquired infections and other procedures. So I think that's also having an impact.

Third, we are seeing is that patients, frankly, and customers as being more demanding about the data that is supporting justification for new approaches, new procedures and innovation.

So that's the way I would describe the overall CapEx environment as it related to hospitals.

Glenn Navarro - RBC Capital Markets

And just as one quick follow-up. Do you have a view on Europe? Europe has remained very challenging from a

utilization and a capital point of view? That appears to be stable. Is that correct?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

What I would say, Glenn, is it's a bit of a tale of two cities. I think on one hand what we see in CapEx, particularly if you go to Southern Europe, it's a very challenging environment and it's because of, again, the macro economic situation they are facing. I don't think we have seen a pronounced decrease or improvement. We have seen it fairly steady quarter-to-quarter but we expect that to remain a very challenging environment going forward. On the other hand, what we have seen, is that when you introduce new innovations such as our pharmaceutical group has done, over the past 12 months they can really make a difference for patients that you can get reimbursement and get access for patients.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question is from Matt Miksic with Piper Jaffray.

Matt Miksic - Piper Jaffray

Thanks, good morning. So, Alex, I very much appreciate the update in perspective. There is a lot to talk about here. But I was wondering if you could expand a little bit on your thoughts on innovation as you had just mentioned and earlier in the call, particularly as it pertains to MD&D and a few different factors, just the first, to a degree towards new technologies, smart instruments and your competitors in different areas of putting that out. You have put that out obviously effectively with Biosense Webster over time. Number two, whether these opportunities are greater in areas where you have an established business like orthopedics, like cardio or whether new platforms and opportunities are as attractive.

Then finally, I you think you just mentioned again presenting innovations in a way that hospital and caregivers can recognize the value and are willing to pay for them. So, maybe just your broad thoughts as to factors pertaining to MD&D, and I have one follow-up for Sandy.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure. Matt, thanks a lot for the question. If I reflect on it at a very broad level, what I would say around MD&D is that, look innovation is going to continue to be important. However, I think that the bar will be raised on the data will be required to describe and represent that innovation, so let me give you a few examples.

I think, overall what we are saying is incremental innovation while still clearly an important part of the overall portfolio and ultimately that can help you lead a path a significant breakthrough innovation is not being rewarded with, for example increased pricing or improved pricing in the marketplace and we would expect over time that we will need to have more transformational innovation or more significant innovation. We recognize that that's going to require additional clinical development and investments. At the same time, we think at Johnson & Johnson, we are uniquely positioned in that category. Given the broad breadth and scale capabilities that we have at our pharmaceutical group and in our medical device group.

So, for example, what we've done in our biosurgicals area, as we are getting ready to launch Fibrin Pad, the way that we are having our cardiovascular team, even the for example, work with XARELTO, and some of the things that we are doing Biosense Webster, it gives us a unique opportunity for convergence. And, in fact, we see opportunities in some of these segments to look innovation differently and frankly raise the bar with innovation from a clinical point of view, but also from a regulatory point of view that's in the best interest of patients as well as for our business.

We look at areas going forward. I think it's going to be a combination. We still think that in areas such as general surgery, when we look at biosurgicals, when we look at your areas such as energy, there's a lot of opportunity to make procedures less invasive, to simplify the procedures, particularly in emerging markets that will ultimately lead to better overall outcomes and reducing morbidity.

We think in other areas, there is great technology opportunity. Such in Biosense Webster, so in the in the general surgery category, I think there is a lot of opportunity for growth in orthopedics. We are working on innovation with products like the ATTUNE Knee, like a number of things that we are doing in spine and hip as of late. We're also

looking at innovation from a commercial model standpoint.

What can we do around having a broader offering, a different kind of relationship and partnership with hospitals and other large payers, again in a way that's good for patients that helps to improve outcomes, but also is better for the institution and we think again there too we are uniquely position given the breadth, the depth, the scale and size of our business.

Matt Miksic - Piper Jaffray

That's great. Thank you for that. And then for Sandy, and maybe Alex you may want to chime in on this as well, but around the quality and regulatory and we tend to have focused over the past couple of years on the pathway and the process for OTC in sort of managing through the OTC-specific challenges that have come up, but it would be very helpful if you touch a little bit on this with respect to the supply chain but it would be great to hear and maybe some of the changes you made proactive in ongoing at your other major businesses and facilities, and maybe if you could provide some examples or anecdotes, it would help illustrate the progress that you are making across the organization in terms of quality.

Sandra Peterson - Group Worldwide Chairman

So, Matt, thanks for the question. As I mentioned in the opening remarks, our quality effort is across the enterprise, across all of our businesses, our manufacturing sites as well as all of our R&D sites, because they are under the scope of trying to ensure that we have the highest standard of quality for the safety and care of our patients and consumers. So, when we launched the quality initiative a number of years ago, the focus really was ensuring that we have got consistent quality standards.

We went through a three-year cycle that were just ending the first of the cycle over a three year period, where we have gone through all of our manufacturing facilities, all of our core strategic suppliers as well as all of our R&D site to ensure that all of them are living up to the appropriate regulatory standards in those countries that also are standard that at J&J, we believe is one of the highest in the industry and its across all of our sectors.

So there has been an immense amount of work and focus in ensuring that we have consistency across our operations, across our product lines and across all of the countries in which we operate. We have, obviously, as we gone through all of this work, we have identified corrective actions and we have immediately taken those corrective actions. We are harmonizing systems. We are putting in place processes and systems so that we have early warning. Systems in place to understand if there is, we think, may be something going on with a product, so we identify it early and we go out and correct it.

In addition to that, an important component of all of this is how we are managing our global supply chain. So one of the very important changes that we have been making with our global supply chain is ensuring that all of our external suppliers, so our material suppliers are thoroughly reviewed, are thoroughly managed and that they are living up to our quality standards. In that process in the last three years, we have actually consolidated our external manufacturing, our external material suppliers by about a third. So we have a third less than we had three years ago. That means that we an ability to manage them much more effectively and ensure that we are reviewing their quality of their products coming into our facilities.

We have also looked at our external manufacturers, those that provide finished products to us and we manage those across the enterprise now in a very rigorously manner with thorough and thorough audits and we are learning across the enterprise how to share best practice from business to business and technology to technology. So this effort is not just focus on the OTC business, it is really across all of our businesses in all of our countries globally. We are ensuring that we independent audits and independent approach to managing this but we are ensuring that we also are putting the right systems, processes and capital and automation in place in all of our facilities around the globe.

So we have made significant progress. I think one other indication of that progress is that over the last couple of years, we recently closed out a number of warning letters and we are making very good progress on the ones that are remaining but we are feeling good about where we are. Always things can happen. We have 300,000 SKUs around the globe. So that’s where our vigilance has to be, as ensuring every single one of those SKUs are meeting our high standards.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question is from the line of Jeff Holford with Jefferies.

Jeff Holford - Jefferies

Just wanted to get a little bit more of an update on the diabetes care businesses where you have been progressing to in terms of market share versus your key competitors and just what you think outside of reimbursement changes what the underlying growth rate here just for expectations going forward? Thank you.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Jeff, are you referring to which of our businesses? Our MD&D diabetes business or Invokana?

Jeff Holford - Jefferies

Sorry, MD&D diabetes.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Okay. We believe that we have been relatively flat in share this last quarter. We think that there may have been a slight downtick based upon some of the pricing changes that are being made and particularly intrusion of store brands and other offerings. Obviously it's something that we are watching very closely.

Dominic Caruso - Chief Financial Officer, Vice President

Jeff, I want to add, our estimation is that the overall market is declining there. So overall market trends are negative in the diabetes test strips. The market volumes are declining overall.

Louise Mehrotra - Vice President, Investor Relations

Next question, please.

Operator

Your next question is from the line of Bob Hopkins, Bank of America.

Bob Hopkins - Bank of America Merrill Lynch

I know its getting late. So two very quick ones. Thanks for taking the call. First, there hasn't been a lot of commentary on your general surgery franchises within medical technology. So I am wondering if you can just comment a little bit more specifically on of those businesses and what you are seeing there because the growth rate in general surgery and especially surgery did look like it was a little better than last quarter. So just a little bit of a commentary there on what you are seeing in those markets and what you are seeing competitively? Is the uptick more of a little better market or is it a little bit more little better market or is it little bit more or less share loss more you can think?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure. Look, there's a number of things driving our performance over there. I think, first of all, we saw modest growth overall in the specialty surgery category for the quarter. Our biosurgicals platform had solid growth, particularly outside the United States. We also saw good growth in the U.S. in our ENT business. And while the worldwide energy business continues to grow driven by the continued expansion in new emerging markets and new product launches, we were challenged in the U.S. with our energy business with low cost competitors, as well as some competitive pressures. So, that's the way I would described specialty surgery. In general surgery, of course, our business was impacted by what has taken place and women's health and our decision to exit some of those businesses, so that had negative. We look at suture and some of those basic platforms we are seeing very consistent growth with the overall market that we think it is basically up about 1% or 2%.

Bob Hopkins - Bank of America Merrill Lynch

Okay. Then just one quick follow up on an earlier question on emerging markets. I know you talked a lot about how well position you think change is, but just in terms of the outlook for growth of the markets in emerging markets, especially as relates to MD&D, how confident are you that the current growth trends in the market can continue as we

look forward over the couple of years. So, again, it's really question of gauging confidence in light of some of the things that have gone on in these economies, in your confidence and abilities of these market, specifically medical devices to continued growth, nice pace we've seen over the last year or so.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Sure. Look, I think there is a couple of forces and dynamics that will be impacting it. You know, first of all, you've got a significant increase in the middle-class populations in those countries. So, for example in China, I think most of the recent statistics would suggest you have about 150 million people in the middle-class. That could go as high as north of 500 million, close to 800 million people over the next 10 years. And, what we also know is that these people move up the economic ladder, they generally consume more health care. And, so we think that the urbanization trend, the trend towards an increasing middle-class does offer a significant growth opportunity.

Now, of course, offsetting that will be pressure put on governments on how they are going to control overall healthcare spending. But if you look at the healthcare spending levels in places like Brazil, Russia, India and China, it's very low single digits. We think that it's an opportunity for them to invest in their society even have a more stable society as well as a more productive society, so we think that the growth opportunities there will continue. We recognize that it's going to take perhaps a different portfolio of products that are really targeted towards specific disease states areas of unmet medical need for those markets. It will take time for different commercial approaches, but overall we do think that emerging markets will be a major source of growth for the next several years.

Louise Mehrotra - Vice President, Investor Relations

With respect to everybody's time, we will take one more question and then we'll have some closing remarks by Alex.

Operator

Your next question is from the line of David Lewis, Morgan Stanley.

David Lewis - Morgan Stanley

Good morning. Maybe two quick ones here, Louise, to keep on the time schedule here. First, Dominic, on the cash flow, free cash specifically got better in 2012 versus 2011, I believe. How do you feel about first half free cash generation. I know you don't give specific guidance, but if you just think about free cash versus net income, how do you expect back half '13 and '13 general to shape up relative to '12. And then I had a quick follow-up maybe for Louise, just on ibrutinib any timing expectations can could we see that approval for year end. Thank you.

Dominic Caruso - Chief Financial Officer, Vice President

David, we are pleased with our cash flow generation. And, for the first half of the year, free cash flow is little over $6 billion, so we expect to be well north of $12 billion, which is where we ended last year's free cash flow, so I think we will see '13 overall free cash flow generation better than we saw in '12, and that we are off to a good start already.

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Yes. And, regarding ibrutinib, look the NDA, the new drug application for ibrutinib was submitted June 2013, which was announced recently and this was announced by the FDA. We do have the Breakthrough Therapy designation, which we are very excited about for the treatment of patients with chronic lymphocytic leukemia CLL, SLL, and we have received at least one prior therapy in patients also with mantle cell lymphoma MCL who have received at least one prior therapy. We got to two pivotal trials that we think are both the very strong and the FDA has not communicated the PDUFA date and the review period is not dictated in the existing breakthrough therapy guidelines from the FDA. Now that being said, we have requested a priority review designation which has an FDA goal for completion of six months after a two-month validation period but we really cannot comment beyond that at this time. All that being said, we think this is going to really offer a great option for patients and for physicians in a very difficult to treat area and be a tremendous extension of our emerging oncology portfolio and franchise.

Louise Mehrotra - Vice President, Investor Relations

So some final remarks, Alex?

Alex Gorsky - Chairman of the Board, Chief Executive Officer

Okay. So thanks for your time everybody. On behalf of Dominic, Sandi, Louise and myself and even more importantly from the 128,000 employees of Johnson & Johnson around the world, I would like to close today's conference call by thanking you for participating in the meeting. Your engagement in our business is much appreciated. We look forward to discussing our future results as we move through the rest of the year. So enjoy the rest of summer and thank you very much.

Operator

Thank you. This concludes today's Johnson & Johnson second quarter earnings conference call. You may now disconnect.