In 2011, estimated revenues generated by sales of orthopaedic products reached $43.1 billion worldwide, an increase of just under 5% from 2010. As in 2010, sales in the U.S. accounted for 60% of total revenues, and the top three companies ranked by overall orthopaedic revenue were Stryker, Johnson & Johnson/DePuy and Zimmer.

Joint replacement represented just under one-third of global orthopaedic revenues in 2011, with the U.S. claiming slightly more than 50% of the segment. Growth in procedure volumes remained at low- to mid-single digit levels during the year as people and companies alike faced lingering economic uncertainty.

Still, nearly 2.9 million joint replacement procedures take place worldwide, annually – including more than 1.4 million hip, 1.1 million knee and more than 100,000 shoulder replacements. Over 231,000 hip replacements occur annually in the U.S. alone.

Estimated 2011 global sales of joint replacement products (that is, hips, knees, shoulders, elbows, ankles, wrists, digits) exceeded $13.8 billion, with knees taking the largest piece of the recon pie, as illustrated in Exhibit 1.

Estimated year over year growth for the three segments shown below came in at hips +2%, knees flat and extremities +7%.

The world’s eight largest joint replacement companies – Zimmer, Johnson & Johnson, Stryker, Biomet, Smith & Nephew, Wright Medical, Aesculap and Tornier– generated 95%
Focus on Joint Replacement...

of hip, knee, shoulder and other joint product sales in 2011. Very little share shift has occurred in the segment in the past ten years. Exhibit 2 illustrates estimated market share for these top companies.

Hundreds more companies also occupy the joint replacement space. During 2011, a number of strategic alliances occurred among the group, such as Apax France’s acquisition of Amplitude, Arthrex’s acquisition of Cardo Medical’s joint arthroplasty assets and China Kanghui’s majority stake in Wei Rui. (Reports alleged that Smith & Nephew was the subject of potential takeover bids from Biomet and Stryker, but such a transaction did not come to pass.)

China Kanghui and Consensus Orthopedics entered into an exclusive partnership to market joint replacement products in China and select ex-U.S. markets. Bonovo Orthopedics formed Bonovo Recon, kicking off with a full line of hip and knee products for sale in China, while Zimmer established a new research and development center in China to support development of products and technologies to meet the unique needs of patients there.

Some separations occurred, as well. During 2011, Corin and Stryker agreed to terminate their distribution agreement for the Cormet Hip Resurfacing product. Corin now distributes the product in the U.S.

Activities from “generic implant” companies continued in 2011. For instance, ANOVA Orthopaedic Solutions filed a non-provisional patent application providing methods to result in reduced costs, increased surgeon alignment and improved efficiencies across the orthopaedic supply chain.

Last year marked a heightened interest in small joint initiatives, and in how devices are implanted: via customized/personalized instrumentation, robotic assistance, minimally invasive surgical (MIS) approaches and so on.

During 2011, for instance, MAKO Surgical commenced launch of the MAKOplasty Total Hip application, including the RESTORIS Meta-Fix femoral stem and RESTORIS Trinity acetabular cup. More MAKO systems for use with hip applications are slated for launch in 2012.

Exhibit 2
ESTIMATED JOINT REPLACEMENT COMPANY MARKET SHARES

DePuy/Inj 23%
Wright Medical 3%
Aesculap 2%
Stryker 18%
Smith & Nephew 12%
Tornier 2%
Biomet 11%
Zimmer 24%
Focus on Joint Replacement...

A key trend in knee replacement to emerge over recent years has been the use of customized instrumentation. OtisMed, acquired by Stryker, began the trend with TRIOS, a custom disposable alignment cutting guide tailored to the anatomy of individual knee replacement surgery patients.

Taking pre-op CT or magnetic resonance imaging scans, the technology applies proprietary pre-op planning software and rapid manufacturing technology to create a template and cutting “jig” that accurately fits the unique anatomy of each patient. In 2011, Stryker received clearance for ShapeMatch cutting guides for use with the Triathlon total knee.

Stryker is not alone in its ability to provide customized instrumentation for knee replacement procedures. Customized instrumentation systems are also available from:

- **Biomet** – Signature Personalized Patient Care System that uses 3D MRI to create personalized positioning guides that don’t require instrumentation of the bone canal, thus allowing for a potentially less invasive procedure; Oxford Microplasty Instrumentation
- **ConforMIS** – iUni-G2 with implants, iView patient-specific imaging data and iJig patient-specific instrumentation; iTotal CR Knee Replacement, iDuo G2 next-generation bi-compartmental knee resurfacing system
- **DePuy** – TruMatch Personalized Solutions with software customized to the patient’s anatomy and the surgeon’s surgical preferences along with integrated metal saw and pin captures for improving accuracy and minimizing osteolytic debris (received 510(k) clearance in 2011 for use with SIGMA Fixed Bearing Knee)
- **Medacta** – MyKnee cutting blocks that use MRI and x-ray images to create customized instruments for use with the company’s GMK Total Knee System
- **Smith & Nephew** – Visionaire Patient Matched instrumentation system that uses MRI and x-rays to create custom instrumentation for use with the company’s knee implants
- **Wright** – Prophecy Pre-Operative Navigation Guides that work with MRI or CT’s cans to provide more accurate implant positioning
- **Zimmer** – Zimmer Patient Specific instruments that use MRI imaging and pre-operative software planning to create disposable, patient matched, femur and tibia pin placement guides

During 2011, Biomet received U.S. regulatory clearance for the Signature application to create guides for use with Oxford Partial Knee.

In small joint initiatives, companies like DePuy, Integra, Tornier and Wright market total ankle systems in the U.S. Memometal Technologies, acquired by Stryker in 2011, had previously acquired Advanced Bio-Surfaces’ OrthoGlide Ankle, akin to a unicompartmental knee in its more conservative approach vs. total ankle replacement or ankle fusion.

Ex-U.S., Baumer, Corin, Euros, FH, Implantcast, Integra, JMM, Link, Protetim, Sovereign Medical and Tornier sell ankle systems. Of note, outside the U.S., mobile bearing ankle designs prevail, with Corin, Dedienne Sante, Integra, Tornier and Van Straten all marketing mobile bearing ankles.

In 2011, Arthrosurface launched its HemiCAP Talus Resurfacing system in Europe and certain ex-U.S. markets. Results from 4-year clinical evaluation of >100 implantations of the device indicate a very high level of patient satisfaction.

Integra acquired Ascension Orthopedics in 2011. The company’s products include FDA cleared and CE Mark approved silicone and pyrocarbon digit implants, the first pyrocarbon trapeziometacarpal implant, resurfacing hemiarthroplasty for Great toe, a hemi-arthroplasty device for treatment of thumb-based arthritis and an implant for treatment of arthritis in the fourth and fifth tarsometatarsal joints of the foot. Integra reportedly plans to introduce a 2-piece (and eventually 3-piece) total ankle in the U.S., noting that the 3-piece device would require a multi-year premarket approval trial.

### Segment growth estimates, 2011 vs. 2010:

- **Hips** $5.8 billion, +2%
- **Knees** $6.9 billion, flat
- **Extremities** $1.1 billion, +7%
Focus on Joint Replacement...

In 2011, Extremity Medical performed the first KinematX Midcarpal Joint Hemiarthroplasty procedure. The company will continue limited evaluation of the product, and plans future commercialization of a Total Modular Kinematic Wrist. Further, Extremity Medical received FDA 510(k) clearance and approval under the CE Mark for its IOFix Intraosseous Fixation System for use in the foot/ankle. Limited product launch occurred in the U.S. and Europe during 2010, opening to broader ex-U.S. markets in 2011.

Long a leader in digit implants, Wright Medical also offers elbow, radial head, ulnar head, wrist, trapézium, lunate, scaphoid, finger, thumb, ceramic interpositional implants, Great Toe, hinge toe and hammertoe implants. During 2011, the company received FDA approval to conduct an IDE clinical study on use of the INBONE Total Ankle for treatment of end-stage ankle arthritis or revision of a failed ankle replacement with subtalar joint insufficiency. The company has also commenced full commercial launch of a next generation INBONE II device.

Other small joint implants can be found in the portfolios of Aptis Medical (CE Mark approved and FDA cleared distal radioulnar joint), ESKA (proximal interphalangeal/PIP, MCP, ankle, and Great toe), Memometal (hammertoe fixation system), Merete Medical (FDA-cleared ToeMobile Anatomical Great Toe Resurfacin System), Mathys (finger), Metasurg (subtalar implant), Nextraity Solutions (NEXTRA Hammertoe Correction), Tecres (MCP implant), Vilex (Hemi and Mini Hemi Toe Implant), etc.

MIS techniques in joint replacement typically center on the refinement of instruments and modification of surgical techniques such that they can be used with standard hip and knee implant components with minimal or no compromise to surrounding structures. MIS techniques allow for smaller incisions, minimal disruption of key soft tissue integrity and reportedly more rapid rehabilitation and less pain.

MIS approaches are intended to reduce surgical trauma, blood loss, scarring and length of hospital stay, while improving overall recovery. MIS procedures can be performed with standard implants, although implant makers have developed implants specially designed for small incision procedures. Most joint replacement companies have MIS instruments and techniques in their product portfolios.

Moving forward, joint replacement technologies likely will not change dramatically. Nor will the overall market or the competitive standing of companies. Dynamics expected to positively affect the market include an aging, obese and active population, while mitigators to growth will include more price conscious environments, rationing of care and an increased pursuit of evidence-based medicine that challenges joint replacement as an option to treat arthritis.

Exhibit 3 provides a summary of key dynamics in the joint replacement market.

**EXHIBIT 3**

**THE JOINT REPLACEMENT MARKET: KEY MARKET DYNAMICS**

- Market estimates: Hips $5.8 billion, +2%; Knees $6.9 billion, flat; Extremities $1.1 billion, +7% from 2010 to 2011
- More than 2.9 million procedures annually
- Highly competitive - 95% controlled by top 8 players; very little share shift in 10+ years
- Highly price sensitive and expected to become increasingly so
- Technologies driving growth: MIS, customized/personalized instruments, small joint initiatives; lowered interest in materials

Excerpted from THE ORTHOPAEDIC INDUSTRY ANNUAL REPORT®, updated May 2012.

**QUARTERLY REVIEW**

Final 1Q12 Results

ORTHOWORLD’s estimates place overall 1Q12 market growth at 4% over 1Q11, as shown in Exhibit 1. Performance highlights follow and pertain to 1Q12, unless noted otherwise.

**EXHIBIT 1**

**ORTHOPAEDIC SALES¹ INCREASES BY PRODUCT SEGMENT: 1Q12 VS. 1Q11**

<table>
<thead>
<tr>
<th>Company</th>
<th>Hips</th>
<th>Knees</th>
<th>Extremities</th>
<th>Fixation</th>
<th>SportsMed</th>
<th>Spine</th>
<th>Bone Stim</th>
<th>Biologics</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>aap</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>51%</td>
</tr>
<tr>
<td>Alphatec</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-3%</td>
</tr>
<tr>
<td>Anika</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>26%</td>
</tr>
<tr>
<td>ArthroCare</td>
<td></td>
<td></td>
<td></td>
<td>5%</td>
<td>-24%</td>
<td></td>
<td></td>
<td></td>
<td>3%</td>
</tr>
<tr>
<td>Artimplant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>27%</td>
</tr>
<tr>
<td>Bacterin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29%</td>
<td>29%</td>
</tr>
<tr>
<td>Biomet²</td>
<td>6%</td>
<td>4%</td>
<td>18%</td>
<td>1%</td>
<td>22%</td>
<td>-3%</td>
<td>-10%</td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>China Kanghui</td>
<td>23%</td>
<td></td>
<td></td>
<td>35%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>22%</td>
</tr>
<tr>
<td>ConMed</td>
<td></td>
<td></td>
<td></td>
<td>14%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10%</td>
</tr>
<tr>
<td>DJO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4%</td>
</tr>
<tr>
<td>Exactech</td>
<td>37%</td>
<td>1%</td>
<td>37%</td>
<td></td>
<td>-13%</td>
<td>-13%</td>
<td>10%</td>
<td></td>
<td>21%</td>
</tr>
<tr>
<td>Globus Medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19%</td>
</tr>
<tr>
<td>Integra</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>136%</td>
</tr>
<tr>
<td>Internal Fixation</td>
<td></td>
<td></td>
<td></td>
<td>136%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>136%</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>1%</td>
<td>2%</td>
<td></td>
<td></td>
<td>-3%</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
</tr>
<tr>
<td>MAKO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>51%</td>
</tr>
<tr>
<td>Mazor Robotics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45%</td>
</tr>
<tr>
<td>Medirea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20%</td>
</tr>
<tr>
<td>Medtronic³</td>
<td></td>
<td></td>
<td></td>
<td>-3%</td>
<td>-16%</td>
<td>-6%</td>
<td></td>
<td></td>
<td>22%</td>
</tr>
<tr>
<td>NuVasive</td>
<td></td>
<td></td>
<td></td>
<td>22%</td>
<td></td>
<td>19%</td>
<td>22%</td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>Orthofix</td>
<td></td>
<td></td>
<td></td>
<td>10%</td>
<td>3%²</td>
<td>2%³</td>
<td></td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>Ossur</td>
<td></td>
<td></td>
<td></td>
<td>2%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>RTI</td>
<td></td>
<td></td>
<td></td>
<td>1%</td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
<td>1%</td>
</tr>
<tr>
<td>Sanofi</td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
<td>9%</td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>Seikagaku⁴</td>
<td></td>
<td></td>
<td></td>
<td>-1%</td>
<td>-1%</td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>-2%</td>
<td>6%</td>
<td>-1%</td>
<td>7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3%</td>
</tr>
<tr>
<td>Stryker²</td>
<td>3%</td>
<td>5%</td>
<td>10%</td>
<td>10%</td>
<td>4%</td>
<td>12%</td>
<td></td>
<td></td>
<td>7%</td>
</tr>
<tr>
<td>Synthes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>TiGenix</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>123%</td>
<td>123%</td>
</tr>
<tr>
<td>Tornier</td>
<td></td>
<td></td>
<td></td>
<td>11%</td>
<td>8%</td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>TranS1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-26%</td>
<td></td>
<td></td>
<td></td>
<td>-26%</td>
</tr>
<tr>
<td>Wright</td>
<td>-10%</td>
<td>-5%</td>
<td>-6%</td>
<td></td>
<td>-21%</td>
<td>-6%</td>
<td></td>
<td></td>
<td>3%</td>
</tr>
<tr>
<td>Zimmer</td>
<td>2%</td>
<td>2%</td>
<td>5%</td>
<td>8%</td>
<td>-6%</td>
<td></td>
<td></td>
<td></td>
<td>3%</td>
</tr>
<tr>
<td><strong>Market Growth</strong>⁵</td>
<td>2%</td>
<td>3%</td>
<td>6%</td>
<td>3%</td>
<td>8%</td>
<td>3%</td>
<td>0%</td>
<td>-1%</td>
<td>4%</td>
</tr>
</tbody>
</table>

**NOTES TO EXHIBIT 1**

1. Orthopaedic products; constant currency, pro forma growth
2. Includes biologics
3. For the quarter ended 2/29/12; includes Dental. Spine includes Bone Stim and Biologics; Bone Stim reflects all Bone Healing sales.
4. For the quarter ended 4/27/12
5. Spine
6. For the quarter ended 3/31/12
7. Extremities: extremities + fixation combined; Endoscopy: endoscopic + communications, most of which is orthopaedic; Spine: neuro + spine. Total growth excludes Patient Handling.
8. ORTHOWORLD estimates
9. For the quarter ended 3/31/12

---

©1997-2012 ORTHOWORLD Inc. All rights reserved.
Quarterly Review...

**AAP IMPLANTATE**
€9.9MM (~US $12.7MM), +51%
- LOQTEQ update: presented to potential new distributors in Asia, Europe, Latin America and U.S.; expecting full FDA clearance in 3Q
- By year-end, LOQTEQ line should cover ~80% of all trauma indications
- Signed contract with Dutch Sanquin Bone and Tissue Bank to process human tissue
- 20 potential customers in U.S. evaluating cannulated screw system

**ALPHATEC SPINE**
$48.4MM, -3% (U.S. $32.5MM, -4%; Ex-U.S. $15.9MM, flat)
- Growth affected by pricing pressure in low single digits, lower procedure volumes; many stocking distributors reducing inventory
- Continued gains from growth in Latin America and Japan (claims #4 market position in latter); Europe and Middle East continue to struggle
- U.S. hospital sales +3% excluding Xenon pedicle screw, driven by biologics and MIS products (including Illico SE)
- Xenon returned to the market in 4/12
- Will take on in-house manufacturing of certain high-volume, high-cost products, 1st to be Trestle Luxe anterior cervical plate
- Entered into financing arrangement that will allow company, once strengthened, to become active on acquisition front
- Late in quarter, voluntarily recalled deployment instrument for Solus Anterior Lumbar Interbody Fusion device (in beta launch) to improve its performance in surgeries involving extremely hard or sclerotic bone (a problem not dissimilar from other standalone ALIF devices)
- Modifications to Solus instrumentation expected to require resubmission of 510(k); expects product back to market by year-end
- Physician-owned distributorships account for substantially <10% of U.S. business, and declining

**BIOMIMETIC THERAPEUTICS**
- Received comprehensive post-panel response from FDA regarding Premarket Approval Application for Augment Bone Graft; expects to submit an amendment to application in mid-2012
- In 4/12, shipped initial orders of Augmatrix Biocomposite bone graft to distributors
- Evaluating options regarding clinical trial of Augment in treatment of chronic tendinopathy; will decide after filing of PMA amendment

**CHINA KANGHUI**
RMB 82.7MM (~US $13.1MM), +22% (China ~$10.1MM, +29%; ex-China ~$2MM, +18%)
- Trauma ~$8.2MM, +23%
- Spine ~$4.1MM, +35%
- OEM ~$0.8MM, -24%
- Added >330 new hospitals domestically, total now ~3,000
- Released new cannulated pedicle screw, indicated for treatment of osteoporosis
- Product launches for remainder of year include 1 for spine (2Q), 2 trauma and 3 joint (2H12)
- Will price TGM Hip and Knee product at a 20-30% discount to JNJ and Zimmer offerings

**GLOBUS MEDICAL**
$94.7MM, +21%
- Fusion $61.5MM, +9%
- Disruptive Technologies $33.2MM, +51%
- Recent product launches, Coalition and Caliber, represented 11% and 10% of sales, respectively
- Will add 24 more direct and distributor sales reps in U.S., expand to 8 additional countries by year-end
- Hired 32-rep salesforce to sell interventional pain management products under trade name Algea Therapies

**INTERNAL FIXATION SYSTEMS**
$0.15MM, +136%
- Released additional sets of redesigned cannulated screw systems, limited release of modular locking small fragment system
- Current distribution in 16 states (up from 2 in 1Q11)
- Manufacturer of “value priced orthopaedic and spinal implants” focused on existing, commonly used products, selling for 40-60% less than competition
- Current customers include ASCs, hospitals, surgeons, GPOs
- FDA 510(k) clearance for 25 products, including mini to large cannulated screws, locking plates/screws for use in upper and lower extremities; K-wires, drill bits, etc.

**MAKO SURGICAL**
$19.6MM, +51%
- Procedures $11.6MM, +79%
- RIO Systems $5.9MM, +9%
- Service/Other $2.2MM, +87%
- <10% penetrated in targeted domestic hospital market
- Reduced partial knee replacement procedures, pricing pressure, delays (not cancellations) in customer orders contributed to shortfall in system sales
Quarterly Review...

- 2,297 MAKOplasty procedures performed (Domestic: 2,008 knees, 211 hips), +76% from 1Q11
- 260 lateral and isolated patellofemoral procedures, ~13% of new procedure volume in 1Q
- 122 bicompartamental procedures, ~6% of knee volume
- Average selling price ~$5,000/procedure
- 6.6 average monthly utilization per domestic system
- Lower ASP for hip procedure ($4,800) attributed to slightly higher than expected utilization of non-MAKO femoral stem with MAKO acetabular cup, to be mitigated by expanded hip implant product offerings in 2012
- 6 RIO systems sold, 5 to domestic customers, 1 in Japan; now at 118 RIO systems installed
- 13 MAKOplasty THA applications sold, 9 as upgrades for current customers; now at 62 hip applications installed
- 53% of commercial domestic installed base have installed THA application
- Introducing next-generation hip application during 2012, will support a direct anterior approach
- Pipeline Biomedical’s Restoris tapered femoral stem and PST acetabular cup received 510(k) clearance, will be fully commercialized by year-end
- Restoris Z hip (manufactured by Total Joint Orthopedics) launched for use with MAKOplasty
- Competition from patient-specific instruments not perceived as a threat

**MAZOR ROBOTICS**

NIS 9.2MM (~US $2.4MM), +45% (U.S. ~$2.2MM, +100%)
- Sold 3 Renaissance surgical robotic systems; to date, 12 installed in U.S.
- Strong sales of disposable procedure kits (162 vs. 80 in 1Q11)
- Lease price $789,000/system
- To date, technology used in >3,000 spinal procedures worldwide in placement of ~20,000 implants
- In 5/12, commenced global launch of C-OnSite enhancement to enable fast, low-radiation, intra-operative 3D verification of implant placement using imagery from any standard 2D C-Arm
- List price for C-OnSite in range of $830,000

**MEDTRONIC** (for fiscal year 2012, ended 4/27/12)

- $3,267MM, -4% (U.S. $2,300MM, -10%; ex-U.S. $967MM, +12%)
  - Core Spinal $2,467MM, -2% (U.S. $1,596MM, -8%; ex-U.S. $871MM, +11%)
  - Biologics $800MM, -10% (U.S. $704MM, -13%; ex-U.S. $96MM, +28%)

**Fiscal Year 4Q12 revenue:** $818MM, -6% (~2% ex-Infuse; U.S. $557MM, -12%; ex-U.S. $261MM, +8%; Japan +20%)
- Core Spinal $629MM, -3% (U.S. $394MM, -8%; ex-U.S. $235MM, +7%; Core metal -3%)
- Biologics $189MM, -16% (U.S. $163MM, -19%; ex-U.S. $26MM, +4%; Infuse $126MM, -26%; Kyphoplasty flat, U.S. -26%; Bone morphogenetic protein -24%, U.S. -26%)

- Extensively reiterated growth strategy that focuses upon emerging market expansion, improving R&D productivity and enhancing execution, strong focus on demonstrating economic value to stakeholders
- Stated goals for spine: differentiate, protect price, enhance value
- Joint venture with Weigao in China delivering solid results; seeking to extend this past 2013
- Acquired AMT, German manufacturer with wide portfolio of interbody systems in new shapes, geometries, materials; aggressively increasing number of sets available
- Solera ~45% rolled out in U.S. (larger rod diameters used in more complex spine and deformity procedures rolled out less than that), represents ~20% of thoracolumbar revenue; launch should reach apex in FY13
- Atlantis Vision Elite cervical plate getting nice price uplift; ~100 sets in field
- MAST MIDLF pulling share, combines screws/rods, interbody devices, access instruments, biologics: 100 sets in field, trained ~200 surgeons, more than half of which are competitive; global rollout expected in 2Q FY13
- To bolster biologics, investing in localized product development around the globe, expanding into neuroscience, incorporating economic value into marketing messages
- ~60% of FY4Q decline driven by Infuse
- Not seeing smaller number of accounts using Infuse, just more selective use around indications and smaller kit sizes
- U.S. DOJ closed Infuse investigation
- Results from independent Yale Infuse study expected this autumn
- Continuing to invest in launch of Inductos in Europe, plus investing in new carrier and new indications for BMP-2 molecule
Quarterly Review...

- Osteotech segment annualizing at >$100MM
- MagniFuse, Grafton driving double-digit growth in Other Biologics
- Introduced InflateFX, a balloon kyphoplasty-like product to repair tibial plateau fractures in extremities
- Believes that PODs will be ruled illegal in the face of anti-kickback laws

SEIKAGAKU (for fiscal year 2011, ended 3/31/12)
¥27.0BB (~US $339MM), -1% (Domestic ~$225.7MM, +0.1%, ex-Japan ~$43.9MM, +9%; U.S. +7%)
- Artz brand benefiting from introduction of plastic delivery syringe
- U.S. Supartz sales increased as sales reps focused on differentiation from competitors
- Exports to China, Italy continue to rise
- Commenced case registration for Phase III clinical trial in Japan to investigate SI-6603 condoliase enzyme in the treatment of lumbar disc herniation
- In 5/12, entered into exclusive agreement with Kaken Pharmaceutical for Japan marketing rights for SI-6603

TIGENIX
ChondroCelect €0.7MM (~US $0.8MM), +123%
- Leading private healthcare insurance company in the Netherlands has ruled treatment with ChondroCelect as compulsory for its insured

TORNIER
$74.5MM, +9% (U.S. $39.7MM, +7%; ex-U.S. $34.7MM, +11%)
- Total Extremities $58.1MM, +11% (Upper $47.0MM, +13%, Lower $7.0MM, +7%, Sports Med/Biologics $4.1MM, +8%)
- Large Joints/Other $16.2MM, +1%
- U.S. growth affected by changes in distribution: moved to direct selling in one market, replaced 2 underperforming territories
- Launched direct sales in Japan at very end of 1Q
- Extremities led by shoulder and elbow arthroplasty
- Expecting to launch 2 additional Ascend shoulder products in 3Q and 4Q
- Making progress on new pyrolytic carbon shoulder
- Lower extremities led by Salto total ankle, Stabilis ankle fusion system
- BioFiber synthetic scaffold performance helped mitigate declines in Conexa sales
- Expanding BioFiber with larger sizes, collagen coating, to launch 4Q
- Large joint offset by lower instrument sales
- On track to launch 14 new products in 2012 (6 in 2Q)
- Entering 5 additional countries in 2012: Argentina, Ecuador, Israel, Mexico, Taiwan

TRANS1
$3.8MM, -26% (U.S. $3.5MM, -24%; ex-U.S. $0.3MM, -50%)
- U.S. AxiaLIF revenue $3.1MM: 58% 1-level, 42% 2-level
- Non-AxiaLIF revenue ~$450,000, including ~$300,000 from VEO direct lateral cases
- 295 AxiaLIF procedures, 222 in U.S.; volume weak due to denials, limited physician reimbursement
- No update on OIG subpoena from 10/11
- Expecting announcement of value for Category I CPT code to be announced in 11/12 in Medicare final rule
- Positive early adoption of VEO; surgeons like 2-stage retraction
- In 2Q, will commence patient enrollment in RAMP trial comparing AxiaLIF to TLIF
- Planning an IDE clinical study to expand labeling for AxiaLIF to include use at base of fusion constructs of 3 or more levels (no current lumbar interbody fusion device offers this labeling)

Sources: Company press releases, earnings calls, filings with the Securities and Exchange Commission

Julie A. Vetalice is Editor, Information Products for ORTHOWORLD Inc. She can be reached at 440.543.2101 or julie@orthoworld.com.