Canaccord Genuity Musculoskeletal Conference and AAOS 2011 Highlights

Conference takeaways – Ortho is back!

- Overall, we felt a strong sentiment that a bottom has likely been reached in orthopedics as far as procedure volumes and semi-elective procedures go.
- With strong balance sheets in a stabilized macro-environment, we expect a high level of M&A activity in 2011.
- We continue to see large joint customization as the only novel technology in large joint reconstruction, especially as it expands outside of uni’s.
- BioMimetic Therapeutics’ Augment Bone Graft is another disruptive technology with FDA approval for foot and ankle fusion likely in 2011.
- The trend of surgeons turning to hospital employment seems to have only accelerated, with little to no near-term catalysts to reverse the momentum.
AAOS & MUSCULOSKELETAL CONFERENCE TAKEAWAYS

We recently attended the American Academy of Orthopaedic Surgeons 2011 meeting and hosted the sixth annual Canaccord Genuity Musculoskeletal Conference in San Diego, CA. Our overall feeling after speaking with a number of management teams, surgeons, sales reps, product managers, and investors was very positive. Below we have outlined our general takeaways, our estimates for market sizes and growth, and specific takeaways from the companies that presented at our conference and the booths we visited on the conference floor.

Ortho is back – GARPY names likely to catch rising multiples tide

As noted above, following our Musculoskeletal Conference and through our channel checks, we came back from San Diego very upbeat about the space, large joint reconstruction and sports medicine in particular. The consensus was overwhelming that that a bottom has likely been reached for semi-elective procedure volumes. (Note that spine remains under a bit more pressure than large joint reconstruction and sports medicine as it is dealing with payer pushbacks.) In particular, for hip and knee reconstruction, which experienced another dip in volumes in Q2/10 and Q3/10, it seems as though the tier-2 and tier-3 surgeons’ surgical queues are filling back up again. We see this as a positive indicator as during the recent difficult times, the lower volumes had relatively a smaller impact to the top-tier, high-volume surgeons, while the lower-volume surgeons experienced a big drop-off in their case loads. We believe that a robust surgical queue could mean pent up demand could be working its way through, as the economy gradually rebounds and consumer confidence builds. The charts below show the recent historical volume and mix growth, and reported hip and knees growth from some of the large joint reconstruction players. While pricing is expected to stay in the (1%)-(2%) range, we believe volume could get back to the high-single digits in the next 12 months (but have not baked this into our estimates for individual companies). Even if reported growth is only back to the mid-single digits, with multiples as low as they are, we see room for significant appreciation between now and next year’s Academy meeting in San Francisco.
Figure 1: Orthopedic volume & mix growth 2007-2010

![Graph showing orthopedic volume & mix growth from Q1/07 to Q4/10 for SYK, ZMH, JNJ, BMET, and WMGI.]

Source: Company reports

Figure 2: US hip and knee growth 2005-2010

![Graph showing YoY growth in US hip and knee from 2005 to 2010 for SYK and ZMH.]

Source: Company reports and Canaccord Genuity estimates

Musculoskeletal M&A – high demand but low supply (at attractive valuations)

Speaking with management and business development teams during the week, it was obvious that companies are out on the prowl for acquisitions. Like other spaces in medtech, the musculoskeletal industry is ripe for increased M&A activity. During the Great Recession and credit crunch, the lower revenue growth and cash generation, combined with limited access to capital, spawned an 18-24 month period of cash...
hoarding. Stock buybacks, distributed dividends, and acquisitions were put on hold for the most part.

Fast forward to Academy 2011, companies are sitting on piles of cash, experiencing improved results and outlooks, expecting cash generation to improve, and dealing with impatient investors asking how cash will be used. Considering the need to bolster growth in the space, management teams of musculoskeletal companies are actively evaluating both larger and tuck-in acquisitions. More interestingly, while demand has improved, we are also hearing that valuation expectations for companies looking to sell are becoming more realistic as well. However, we note that CEO’s of smaller companies with highly differentiated products, who have struggled through one of the most difficult macro-environments, are not likely to sell the company cheaply now that the worst is behind them. We believe this emotional aspect of it will prevent many “good deals” for acquirers from occurring anytime soon. Purchasers will likely have to pay a premium for novel technology/IP or strong data in this space, which we believe means multiples of at least 5-6x 2012 revenues. Having said that, given the increasing stock prices in the space, we believe stock buybacks could make a comeback. Below, we have highlighted the cash balances of some of the players in the space that we believe will be looking to put their cash to good use in 2011.

<table>
<thead>
<tr>
<th>Ticker</th>
<th>Enterprise Value</th>
<th>Cash Balance</th>
<th>FCF^</th>
<th>% Sales</th>
<th>FCF Yield (EV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYK</td>
<td>$21,932</td>
<td>$4,380</td>
<td>$1,426</td>
<td>19.5%</td>
<td>6.5%</td>
</tr>
<tr>
<td>MDT</td>
<td>$49,075</td>
<td>$3,467</td>
<td>$4,629</td>
<td>29.2%</td>
<td>9.4%</td>
</tr>
<tr>
<td>ZMH</td>
<td>$12,062</td>
<td>$934</td>
<td>$877</td>
<td>20.8%</td>
<td>7.3%</td>
</tr>
<tr>
<td>NA</td>
<td>$229</td>
<td>$135</td>
<td></td>
<td>5.0%</td>
<td>NA</td>
</tr>
<tr>
<td>SNN</td>
<td>$11,077</td>
<td>$207</td>
<td>$544</td>
<td>13.7%</td>
<td>4.9%</td>
</tr>
<tr>
<td>MDT</td>
<td>$1,277</td>
<td>$179</td>
<td>$20</td>
<td>4.2%</td>
<td>1.6%</td>
</tr>
<tr>
<td>WMGI</td>
<td>$699</td>
<td>$172</td>
<td>$26</td>
<td>4.7%</td>
<td>3.9%</td>
</tr>
<tr>
<td>ARTC</td>
<td>$1,036</td>
<td>$133</td>
<td>$70</td>
<td>19.8%</td>
<td>6.8%</td>
</tr>
<tr>
<td>IART</td>
<td>$1,774</td>
<td>$129</td>
<td>$68</td>
<td>9.3%</td>
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</tr>
<tr>
<td>OFIX</td>
<td>$758</td>
<td>$37</td>
<td>$16</td>
<td>2.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td>EXAC</td>
<td>$128</td>
<td>$4</td>
<td>$10</td>
<td>-5.3%</td>
<td>-3.6%</td>
</tr>
<tr>
<td>Average</td>
<td>$10,785</td>
<td>$220</td>
<td>$588</td>
<td>11.3%</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

Source: Company reports and Thomson Reuters

**Figure 3: Musculoskeletal cash positions**

Large joint customization is still turning our head – expanding from just uni’s

At this year’s AAOS, we searched high and low for any novel, game changing technology to come to market in orthopedics. Outside of extremities, we continue to believe it is not a matter of IF implant customization will become the gold standard in large joint reconstruction but a matter of WHEN it will become the gold standard. Currently, MAKO Surgical and ConforMIS (private) have the game changing technology, in our view, but unfortunately do not have the sales and marketing power to change the current practices in orthopedics overnight. We see the bone preservation, natural joint kinematics restoration and recovery time reduction providing the trifecta of benefits. Also, we would like to mention that both ConforMIS’ and MAKO’s technology reduces the large number of instruments usually needing to be sterilized to a small box of instruments that are
disposed of following the procedure. However, MAKO requires the purchase of a ~$800,000 robot, while ConforMIS does not.

While the large ortho players have long downplayed this technology, it is important to note that almost all now offer patient specific cutting guides/jigs. In our opinion, the real reason there has not been an acquisition of the two companies is because: 1) a very high multiple would need to be paid (we believe 8x – 10x a few years forward projected revenues); 2) the transition of patients to partial knees from total knees (at a lower price) could negatively impact the business model temporarily for a large player; and 3) the resulting re-characterization of instrument inventory and depreciation could cause significant one-time charges. However, we do note in the case of ConforMIS, that a total knee is on the way, which would eliminate the partial knee pricing issue, but not the instrument and inventory write-down problem. Despite the long-term growth opportunities, we believe this ‘no pain no gain’ decision is too difficult for CEO’s in this environment, and it will not be made until it is crystal clear that these technologies are here to stay and will continue to take market share. Thus despite the immense opportunities, we would not expect a trigger to be pulled until significant data and market share is accumulated over the next few years. Both companies were launching new systems at AAOS, which we believe will aid in the continued adoption of patient specific joint arthroplasty.

- **Hip MAKOplasty application**: MAKO unveiled its hip application at AAOs this year. The product is currently under limited launch with full commercialization expected in H2/11 or early 2012.

- **iTotal**: January 2011, ConforMIS received FDA clearance for its iTotal CR Knee Replacement System. The iTotal CR is made to fit an individual patient precisely without the under-sizing and overhang common with standard systems. The iTotal will be released through a limited launch in 2011 with full commercialization projected for 2012.

**Biologics 2.0 – BioMimetic has the lead horse in a field of weak ponies**

Another disruptive technology that could likely be on the market this time next year is BioMimetic Therapeutics’ Augment Bone Graft. The product’s pivotal trial demonstrating non-inferiority to autograft for foot and ankle fusion met its primary endpoint. The FDA advisory panel is scheduled to meet on May 12, and we expect a favorable outcome given the published data. If approved, we believe the orthopedics landscape will be permanently changed, as surgeons will now have another potent tool to achieve fusion in the foot and ankle as well as other future applications.

During the company’s investor event, additional details regarding its Injectable trial and soft tissue application pilot study were highlighted. The FDA has given approval to commence enrollment of the Augment Injectable US pivotal trial. The trial is expected to enroll 201 patients at 25 institutions with 2:1 randomization to autograft. The PMA filing will include 6-month effectiveness and 12-month safety data. The Augment Rotator Cuff Graft Pilot trial is expected to enroll 30 patients by the end of Q3/11, with interim data to be released in H1/12.

We would note that stem cells have been the only bright spot in the cloudy skies of orthobiologics. Specifically, by our estimate, stem cells for orthopedic applications generated $106 million in revenue in 2010, up 64% YoY with NuVasive, Orthofix and
Alphatec as the only players. However, the roughly 1.9 billion orthobiologics market, which grew only 1% YoY in 2010, has scant data for the products that make up this segment. In fact, Medtronic’s Infuse is the only PMA approved product in the space with Level I data, while the balance of products have minimal to no data. Stem cell products have been sold into the spine market for over three years now, but data has not been forthcoming. We believe the lack of available data, given the length of time that stem cell products have been on the market, may indicate that these products are not as efficacious as believed. As a result, we expect the growth rate for the stem cell segment could slow significantly should unflattering data surface.

**Surgeon hospital employment – a trend that continues to gain momentum**

We see another trend continuing to proliferate in orthopedics, with more and more surgeons leaving their private practices to join hospitals. We spoke with a number of surgeons and sat in on a symposium session on the topic and believe the trend is accelerating with no foreseeable catalyst to reverse it. We have outlined the drivers versus the barriers below:

**Pros**

During these uncertain times, orthopedic surgeons are seeing the benefits of working for the man, including: a guaranteed salary, no start up costs, leveraged insurance negotiations, no “buy in” or “partner,” and access to an in-house legal team. For the hospital, it sees the opportunity to: gain market share, eliminate competition, reduce operating costs (supply chain), rationalize large investments and reduce exposure to healthcare reform (i.e. bundled payments).

**Cons**

On the downside some of the negatives for surgeons can be the long-term contract, having a ‘boss’, heavy Medicare oversight, local non-compete agreements, minimal pre-tax deductions, and having no equity in an individual practice. For the hospital, there are risks of decreased productivity, fewer checks and balances, legal exposure and reduced efficiencies.

Despite these negative aspects, we believe the fear of the current uncertainty will continue to drive surgeons into the hospital. Furthermore, once the doctor has made this move, the transition out to private practice, and starting from scratch, will be too difficult in the new world of healthcare. It is expected that sometime soon we will switch to a fee-for-value system, where the patient actively shops for value for each healthcare dollar spent. We believe the downward pressure on reimbursement will make the risk/return profile of starting an orthopedic private practice highly unattractive and expect most surgeons to work for hospitals in the next five years. Again, this trend will continue to put pricing pressure on commoditized orthopedic implants going forward, with premium prices only being justified with strong comparative effectiveness or cost/QALY data.
2010 MARKET SIZE AND GROWTH RATES

We have outlined our estimates for 2010 market sizes and growth rates below. Given the slowdown in procedure volumes, lower pricing, and unfavorable foreign exchange conversion rates through most of 2010, growth rates decelerated in most segments of the market orthopedic market from 2009.

2010 ORTHOPEDIC MARKETS

In 2010, we estimate that overall worldwide revenues from orthopedic implants, stimulators, bracing, and biologics grew 5% to $33.4 billion. There was a continued market slowdown from 6% growth in 2009 and 11% in 2008. The sluggish year was due primarily to the recession’s impact on procedure volumes and pricing pressure. Sales of extremity products led the way in 2010, growing 18% in 2010. Sales of global spinal implants cooled to 3% growth, with US at only 1%, which was impacted by pricing pressures and procedural slowdowns. Total joint revenues comprised of approximately 39% of the total market, with spinal implants coming in second at 21% but gaining.

Figure 4: 2010E worldwide orthopedic market

Source: Company reports and Canaccord Genuity estimates

2010 spinal implant market overview

In 2010, we estimate that the worldwide spinal implant market grew 3% to $7.5B. There was a major deceleration from 2009, when it grew 9%. The US spinal implant market alone grew only 1% to $4.9 billion, according to our calculations. Growth in this market came to almost a complete halt in 2010, decelerating significantly from 2009 when it grew 9%. Procedure volumes declined in 2010 as private payers began to push back and increase the requirements for pre-authorization. Specifically, patients being treated for
degenerative disc disease with back pain only as the primary symptom are finding it increasingly difficult to gain pre-approval. Additionally, pricing pressures began to have a huge impact on the industry. We estimate a steady price decline in the low- to mid-single digits, as hospitals continue to tightly manage expenses. Medtronic continues to dominate the spine market but is losing share to smaller players like NuVasive, Globus, Orthofix and Alphatec. We believe that the large players in spine are having a more difficult time maintaining growth and market share, as the small- and mid-tier players are commercializing innovative products while expanding distribution channels. For example, both NuVasive and Globus increased market share in US spinal implants during the difficult year. NuVasive now has approximately 7.7% share compared to 6.5% in 2009. Globus, as well, increased its share to 5.7% from 5.3% in 2009.

In regard to overall market growth, we would be surprised to see spine return to historic growth rates in the double digits anytime soon. With a macro-economic environment still in recovery mode, the looming healthcare reform likely to hit hospitals in the next few years and the extraordinary amount of competition in the spine market, we believe pricing pressures will likely continue into 2011 and beyond. Furthermore, a spine company’s major defense in protecting its ASPs in this market is developing high-quality products that benefit the surgeon, patient and hospital, with the clinical data to prove it. We have highlighted 510(k) clearances for 2009 and 2010 below and note the slowdown.

<table>
<thead>
<tr>
<th>510k Clearances in Spine</th>
<th>2009</th>
<th>2010</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDT</td>
<td>18</td>
<td>15</td>
<td>33</td>
</tr>
<tr>
<td>SYK</td>
<td>12</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td>JNJ</td>
<td>7</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>NUVA</td>
<td>9</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Globus</td>
<td>11</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Synthes</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>ATEC</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>OFIX</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>67</strong></td>
<td><strong>55</strong></td>
<td><strong>122</strong></td>
</tr>
</tbody>
</table>

* Source: Spine Market

With a challenging regulatory environment, we find this defense tactic neutralized. As a result, we continue to believe that the mid-tier players are best positioned. Specifically, new business is incrementally positive and therefore does not impact margins. In addition, open geographies for distribution expansion leave lots of room for future growth. As an example, Globus could increase its sales force approximately 4x before matching the number of sales reps Medtronic has in its spine unit. Therefore, with the hefty cash positions established by many of the mid- to large-tier players, we expect to see an increase in strategic decisions to increase market share and believe acquisitions of small, under-capitalized spine companies with differentiated products makes sense in this environment. However, we note that our overarching thesis is that companies with small market share and broad product lines are best positioned going forward.
We estimate the worldwide 2010 reconstructive implant market generated sales of $13.1 billion, growing only 4% annually. The growth rate was flat compared to 2009. Within the reconstructive segment, we believe knees were $6.6 billion, growing 4%; hips totaled $5.6 billion, growing at 3%; and extremities (shoulder, elbows, ankles, small extremities) were $855 million, growing at 18%.

Worldwide knee implants in 2010 generated estimated revenues of $6.6 billion, growing 4%. The growth rate in 2010 was in line with that in 2009. The knee implant market continued to be impacted by procedural volume slowdowns and pricing pressures.

Johnson & Johnson, Zimmer Holdings and Stryker remained the leaders in the segment,
collectively controlling an estimated 71% of the knee market. Continued advancements in the space revolve around the need for patient-specific cutting blocks and implants. We continue to believe that the knee market is poised to see expansion for custom solutions from companies such as MAKO Surgical and ConforMIS considering the MIS nature and reproducibility afforded by these procedures.

**Figure 8: 2010E worldwide knee market**

![2010 WW Knee Market](image.png)

**2010 WW Knee Market**

*Est. Value of $6.6B, Growing 4%*

Source: Company reports and Canaccord Genuity estimates

For 2010, we estimate worldwide hip implants generated revenues of $5.6 billion, growing 3%. Hips experienced a slight increase in growth compared with the 2% growth experienced in 2009. The hip implant market was again impacted by procedure volume slowdown and pricing pressures. Johnson & Johnson, Zimmer and Stryker remain the leaders in the segment, collectively controlling an estimated 74% of the hip market. We continue to see modularity in hip stems and necks as an attribute that is of increasing importance to surgeons. Companies offering strong modularity platforms can provide a benefit to surgeons who want to personalize the implants to each patient’s anatomy and biomechanical needs. Considering the data and reports showing complications from hypersensitivity from metal-on-metal (MoM) bearings and the squeaking/wear issues with ceramic-on-ceramic (CoC) bearings, we believe that stratification will continue to occur in the hip market as surgeons continue abandoning alternate bearing surfaces, like MoM and CoC, and shift back towards metal-on-polyethylene. In 2010 we saw companies that focused on traditional bearing surfaces benefitted from this shift while those who focused on alternate bearing surfaces suffered. Alternative bearing materials are believed to garner 15-20% of the hip unit volume in the US.
We estimate worldwide extremity sales in 2010 were $855 million, growing 18%. There was strong growth throughout the extremity segment, with Zimmer, Johnson & Johnson, Wright Medical and Biomet holding 58% of the market. Shoulder procedures continue to make up the largest portion of the market, accounting for nearly 50% of the market. Technology continues to advance at a rapid pace, allowing companies to maintain high ASPs. Additionally nearly every major player in the space is now offering a complete product portfolio (partial, total and reverse). Furthermore, the success of these shoulder replacement products has allowed smaller players like Tornier and Exactech to pull through business in other areas like fracture and trauma plating.

Source: Company reports and Canaccord Genuity estimates
2010 orthobiologics market overview

We estimate the 2010 worldwide orthobiologics market generated revenues of $1.9 billion, growing 1%. This was a sharp deceleration from 2009, when the market grew at 7%. We note that the slowdown in growth was due to the slowdown in spine procedures (where most orthobiologics products are sold) and also to the contraction of sales of INFUSE, which garners ~38% of the orthobiologics market. Sales for orthobiologics products were dominated once again by Medtronic and its INFUSE product. While INFUSE has grown from a $400 million product in 2004 to $708 million in 2010, it is down 9% YoY due to pricing pressures, reduction in off sales usage and usage of smaller kit sizes, as well as the increasing use of stem cell-based products. Orthovita and DePuy continue to lead the $328 million bone graft substitutes market, and Synthes/MTF is dominating the $420 million machined bone allograft market. We have designated the orthobiologics products into five distinct buckets; growth in these sub-segments is as follows:

- Machined bone products generated sales of $420 million, growing 4%.
- Demineralized bone matrix products generated sales of $283 million, growing 2%.
- Bone morphogenic protein (BMP) products generated sales of $748 million, declining 8%.
- Bone graft substitute (synthetic) products generated sales of $328 million, growing 5%.
- Stem cell-based products generated sales of $106 million, growing 64%.

We believe that the segment likely to experience the most growth in 2011 will be stem cell-based products and synthetics. During 2010, NuVasive started selling Osteocel Plus, and Orthofix launched Trinity Evolution. More recently, Alphatec launched its PureGen stem cell product in Q4/10, while RTI biologics announced it was developing a product as well (expected 2012). Both NuVasive and Orthofix are conducting efficacy studies with these stem cell products to support utilization in the spine. Finally, given the significant difference in price point between INFUSE ($5,000+ per case) versus the competition (ranging from $1,000 to 3,000 per case) and continued mix shift toward lower cost alternatives to INFUSE, we would expect the orthobiologics market to realize YoY deceleration in overall revenues in 2011 versus 2010. That being said, we expect procedure volumes to continue to increase at a mid- to high-single digit rate, which is well above lumbar and cervical procedural growth rates in the mid-single digits as surgeons continue to transition from autograft to orthobiologics.
Figure 11: 2010E worldwide orthobiologics market

2010 WW Biologics Market
Est. Value of $1.9B, Growing 1%

Source: Company reports and Canaccord Genuity estimates

Figure 12: 2010E worldwide machined bone allograft market

2010 Machined Bone & Allograft Market
Est. Value of $420M, Growing 4%

Source: Company reports and Canaccord Genuity estimates
Figure 13: 2010E worldwide demineralized bone matrix market

2010 WW DBM Market
Est. Value of $283M, Growing 2%

Source: Company reports and Canaccord Genuity estimates

Figure 14: 2010E worldwide bone morphogenic protein market

2010 WW BMP Market
Est. Value of $748M, Declining 8%

Source: Company reports and Canaccord Genuity estimates
2010 trauma market overview

For 2010, we estimate the worldwide trauma market grew 9% to $4.3 billion. Synthes remained the leader in the trauma market, generating 48.8% of worldwide sales. Stryker and Smith & Nephew were a distant second and third, respectively. We believe the trauma market is ripe for new product development with companies profiling expanding IM nails, and anatomically (MRI based) designed fracture plating systems.
2010 arthroscopy market overview

The estimated $4.4 billion worldwide arthroscopy market is growing at 8% and continues to be an area of novel product integration. Companies continue to study the most effective method of soft tissue sculpting and ablation; video- and image-guided surgical products continue to improve surgeon control and reproducibility; and implants continue to be developed to enhance ease of repair and/or fixation as well as reproducibility. Of note are the move toward better fixation of soft to hard tissue and a push toward “knotless” sutures and anchors. On the capital equipment front, 2010 offered signs of a rebound as we saw YoY growth from many manufacturers, with management commenting that big-ticket purchases were due more to hospitals replacing older equipment than buying the latest and greatest technology. While the competitiveness of hospital spending has yet to return, we expect the macro-economic environment’s impact on hospital spending to continue to improve YoY in 2011. Due to the semi-discretionary nature of many arthroscopy procedures, the macro issues caused by the job market and the expiration of unemployment benefits could start to lift as the economy improves.
**2010 bone stimulation market overview**

We estimate the bone stimulation market generated sales of $574 million in 2010 and is growing at 7%. There are four major players in the space, with Orthofix holding the largest share of the market with the only product approved for use in the cervical spine. Of note is that this sector is under intense scrutiny by the Department of Justice (DoJ). The DoJ is looking into sales practices (specifically sale vs. rental), and as a result has disrupted distribution for at least one of the major players (Orthofix). We believe the DoJ investigation could continue to negatively impact the industry with further slowing in growth rates possible. There are two sub-sectors in bone stimulation:

- spinal stimulation sales were an estimated $289 million, growing 9%, and
- long bone stimulation sales were an estimated $285 million, growing 5%.

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*Source: Company reports and Canaccord Genuity estimates*
Figure 19: 2010E worldwide bone stimulation market

2010 WW Bone Growth Stimulation Market
Est. Value of $574M, Growing 7%

Source: Company reports and Canaccord Genuity estimates

Figure 20: 2010E worldwide spinal stimulation market

2010 WW Spinal Stim Market
Est. Value of $289M, Growing 9%

Source: Company reports and Canaccord Genuity estimates
**2010 WW Long Bone Stim Market**  
*Est. Value of $285M, Growing 5%*

![Pie chart showing market share of different companies in the 2010 WW Long Bone Stim Market.]

**Source:** Company reports and Canaccord Genuity estimates

**2010 Bracing Market Overview**

In 2010, we estimate bracing products produced revenues of $1.5 billion, growing 7% compared to 2009. Bracing products consist of soft and rigid bracing solutions as well as cold therapy products. DJO continues to be the market leader for the full spectrum of bracing products and makes up roughly 50% of the market, with Biomet and Orthofix’s Breg unit far behind but close to each other.

**2010 WW Bracing**  
*Est. Value of $1.5B, Growing 7%*

![Pie chart showing market share of different companies in the 2010 WW Bracing Market.]

**Source:** Company reports and Canaccord Genuity estimates
PUBLIC COMPANIES

Alphatec (ATEC : NASDAQ : $2.74 : Mkt Cap $241M | BUY)
Price target: $3.50

Alphatec Holdings is a medical technology company focused on the design, development, manufacturing and marketing of products for the surgical treatment of spine disorders. Alphatec’s broad product portfolio and pipeline includes a variety of spinal disorder products and systems focused on solutions addressing the following segments of the market: cervical, thoracolumbar, intervertebral, minimally invasive, motion preservation, vertebral compression fracture, osteoporotic bone, and allograft.

Growth drivers

PureGen: Alphatech launched its PureGen Osteoprogenitor Cell Allograft for spinal fusion. The product is a highly concentrated, pure population of adult stem cells that originates in bone marrow and is collected from live, healthy donors. The company is conducting three post-release clinical studies for the product: ACDF, posterolateral fusion and lumbar interbody fusion. PureGen began market introduction in Q4/10.

OsseoFix: Alphatec gained FDA approval of the IDE to begin the 510(k) clinical study, and the protocol was recently revised, which should accelerate enrollment. The study will be a 1:1 randomized study head-to-head with kyphoplasty, with non-inferiority as the primary endpoint, and will include 200 subjects at 15 sites with 12-month follow-up. OsseoFix is an expandable metal cage that is implanted into a vertebral body using a minimally invasive technique. The product is successfully commercialized in Europe with over 1,900 cases by year-end 2010, tracking at 200-300 per quarter.

ARC Portal & Guided lumbar interbody fusion (GLIF) system: The product, launched in Q2/09 on a limited basis with a handful of surgeons skilled in using the system, is now being rolled out more aggressively with full introduction expected in H1/11. The GLIF system (licensed September 13, 2007) is a unique product that gives surgeons the ability to perform a 360-degree procedure using a minimally invasive technique. The procedure only requires one incision and does not necessitate any repositioning of the patient during surgery. Management expects sales to ramp up in the H2/11 as more instrumentation systems are introduced, with plans for over 50 full sets in the field by the end of 2011.

OsseoScrew: The 510(K) for the OsseoScrew was originally submitted in Q2/09, but clearance was delayed because of an issue with the instrumentation and retrievability of the implant. Management noted that it has worked out the instrumentation and retrievability issues and is planning to resubmit to the FDA H1/11.

Bottom line

We believe the company’s business is beginning to stabilize following a very difficult period post the Scient’x acquisition, with integration issues being compounded by macro headwinds within the general spine market. Both Q3/10 and Q4/10 illustrated QoQ growth in the US. With a broad product line and minimal market share, we believe Alphatec is well positioned to be a share taker in the current environment. Lastly, we would expect differentiated products like OsseoScrew, PureGen, OsseoFix and ARC Portal to drive both domestic and international growth in 2011 and beyond.
Arthrocare (ARTC : NASDAQ : $35.25 : Mkt Cap $1.2B | BUY)
Price target: $41.50

ArthroCare is a platform technology company that designs, develops, manufactures and markets medical devices based on its Coblation technology, which precisely removes, cuts, coagulates and thermally modifies or sculpts soft tissue through the body. The company is segmented into three major business units: Sports Medicine, Spine, and ENT. ArthroCare’s distribution model utilizes both direct reps and independent distributors.

Growth drivers
Sports Medicine business: ArthroCare’s Sports Medicine business continues to outpace the overall market, growing 10.6% in 2010 to $232M.

- Ambient: Launched mid-2010, Ambient is a platform technology for sports medicine that allows the surgeon performing the arthroscopic procedure to know the real-time temperature of the fluids in the joint.

- Soft tissue product launches: the company launched four soft tissue products in 2010 with plans to launch an additional two over the course of 2011, refreshing its Opus product line.

ENT: ArthroCare continues to have one of the largest ENT sales forces in the US with over 100 sales reps and has a leading position in the tonsillectomy market. Management announced plans to launch the CI-Q controller, which is totally digital and offers more flexibility in design for future products. We note that while the CI-Q controller has been 510k cleared, ArthroCare is submitting a new 510(k) with additional data to the FDA in Q1/11 for the associated disposable wands

Outstanding liabilities being resolved:
- SEC investigation: The company recently announced it has settled with the SEC, resolving the litigation against the company. No monetary penalty or fine was imposed.

- DoJ investigation: There has been little to no progress made, according to management, but with the resolution of the SEC investigation we believe management now has the time to focus on being more proactive with the DoJ.

- Class action shareholder lawsuit: The lawsuit is ongoing; however, management’s comments on the Q3/10 call concerning the settlement with the auto insurers as well as the settlement with the SEC indicate that a resolution may be seen in the near term.

Bottom line
We believe the company has turned the corner on a challenging year operationally and has moved toward removing its legal overhang. The Q4/10 results were strong, as procedure volumes have likely bottomed, new products are starting to hit the market, and the removal of the SEC investigation provides momentum to remove the other two legal overhangs as well. We believe the company continues to get closer to a take-out by a larger player, which we believe is being somewhat reflected in the stock at these levels.
BioMimetic Therapeutics (BMTI : NASDAQ : $13.40 : Mkt Cap $356M | BUY)
Price target: $17.50

BioMimetic Therapeutics is developing and commercializing its bio-active drug-device combination products for the healing of musculoskeletal injuries and disease, including orthopedic, spine and sports injury applications. BioMimetic received marketing approval for periodontal regeneration following completion of human clinical trials, which demonstrated the safety and efficacy of its platform technology in this indication. Additionally, the company has clinical trials ongoing worldwide for orthopedic bone healing indications. The company’s products and product candidates all combine recombinant protein therapeutics (platelet derived growth factor) with tissue-specific scaffolds to actively stimulate tissue healing and regeneration.

Clinical trial update

**Augment US foot & ankle indication**: The company completed its 100-day meeting with the FDA in Q3/10 with no unexpected questions that would have potentially impacted the regulatory timeline. Additionally, BioMimetic recently announced that the FDA has tentatively scheduled a meeting with the Orthopedic and Rehabilitation Devices Panel to review the PMA application on May 12, 2011. We continue to expect a favorable decision from the panel given the strong data.

**New updates post analyst day at AAOS**

**Augment Injectable Bone Graft (AIBG)**: The FDA has given approval to commence enrollment of the Augment Injectable US pivotal trial. The trial is expected to enroll 201 patients at 25 institutions with 2:1 randomization to autograft. The PMA filing will include six-month effectiveness and 12-month safety data.

**Sports medicine trials**: The company has outlined its plans for the sports medicine market, including clinical trials for rotator cuff repair, osteochondral defects and tendinosis. It was announced that the Augment Rotator Cuff Graft Pilot Trial is expected to enroll 30 patients by the end of the Q3/11, with interim data to be released in H1/12.

**Bottom line**

We continue to believe that Augment has a solid market opportunity in the foot and ankle market alone and that the data from its pivotal trial is strong. We would expect a favorable decision to come from the FDA panel in late spring and an FDA approval by year-end 2011, given the strong safety data and successful meeting of trial endpoints.
CONMED (CNMD : NASDAQ : $26.50 : Mkt Cap $750M | Not rated)

CONMED Corporation is a medical technology company with an emphasis on instruments and equipment for minimally-invasive surgical procedures such as arthroscopy and endoscopy. The company’s products are used by surgeons and physicians in a variety of specialties, including orthopedics, general surgery, gynecology, neurosurgery and gastroenterology. Patient care products, including vital sign monitoring devices, are used in various clinical settings.

Growth drivers

**Linvatec Shoulder Restorative System** (SRS): A complete system for rotator cuff repair supporting multiple surgical techniques with one instrument set and multiple PEEK and titanium anchor options.

**Endotracheal Cardiac Output Monitor, ECOM**: The ECOM system is a minimally invasive method for measuring the volume of blood pumped by the heart. Traditional monitoring requires a surgery and implantation of a catheter, while this product is easily inserted down the patient’s airwave. Management noted that the potential market for the system is ~$900M

**Altrus Thermal Tissue Fusion System**: Was approved in Q4/10 and expected to launch in 2011. The system utilizes thermal energy to seal, cut, grasp and dissect vessels up to 7mm. The system has models for both open and minimally invasive procedures.

**Rebound in hospital capital equipment demand**: During 2010 we saw a slight rebound in the capital equipment market, with management teams commenting that hospitals were beginning to strategically replace older systems. While the capx market has not regained its peak of a few years ago, we believe that as the global economy recovers, we expect capital equipment businesses to benefit.

**Bottom line**

We believe the company will continue to benefit from the improving capital equipment market in 2011.
Exactech (EXAC : NASDAQ : $18.53 : Mkt Cap $243M | BUY)  
Price target: $26.50

Exactech is a profitable orthopedic company that is gaining market share in the rapidly expanding global orthopedic industry. The company’s products are used in the restoration of bones and joints that have deteriorated as a result of injury or disease such as arthritis. Exactech’s strategy is to provide superior mechanical and biological technologies for bone and joint restoration. Exactech develops and markets its orthopedic implant devices and unique biologic materials to hospitals and physician in more than 30 countries around the world. Founded and led by an orthopedic surgeon and biomedical engineer, the company has built its success on its customer-centric culture. The company has four major revenue reporting segments: knees, hips, extremities (shoulders) and biologics.

**Growth drivers**

**Knees: Optatrack PS Logic & Logic CR instrument sets** continue to be introduced to the distribution channel. Exactech has also introduced a proximal tibial spacer and the FIT Tray Set.

**Hips: BIOLOX delta ceramic femoral head:** Launched at the AAOS meeting, the Biolox Delta ceramic femoral head will be used in conjunction with the company’s existing Connexion GXL crosslinked polyethylene liners.

**Shoulders: Product line extensions in various stages of introduction:** Exactech has several product line extensions, including the Reverse Fracture Stem, a Proximal Humerus Fracture Plate, Anterior Augment Glenoid and Cage Glenoid (which is in front of the FDA right now).

**Biologics: OpteCure line expansion:** Exactech expanded the Optecure product line to include 2cc and 20cc sizes to accommodate a broader range of surgical procedures. The 20cc size is specifically designed for spinal applications.

**Distribution expansion:** The company continues to invest in its sales force, increasing to 257 agents/reps in 2010 from 243 in 2009. Furthermore, productivity per rep also continues to increase.

**Bottom line**

Exactech is a small player in the enormous orthopedics industry. That being said, new products are accelerating revenue growth rates to above-industry averages, and we would note that Exactech is in the early stages of several new product introductions as highlighted above. It is also important to note that Exactech’s shoulder product offering continues to be one of the best on the market with the company garnering almost 10% market share in the US in 2010.

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**EARNINGS SUMMARY:**

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All amounts in US$ unless otherwise noted.
Source: Canaccord Genuity estimates
Integra LifeSciences Holdings Corporation, a world leader in regenerative medicine, is dedicated to improving the quality of life for patients through the development, manufacturing, and marketing of cost-effective surgical implants and medical instruments. Its products – used primarily in neurosurgery, extremity reconstruction, orthopedics and general surgery – are used to treat millions of patients every year. Integra’s headquarters are in Plainsboro, New Jersey, and the company has research and manufacturing facilities throughout the world. Integra is the market leader in neurosurgery and has a growing presence in the spine and extremities segments of orthopedics.

Growth drivers
Sales force expansion and system breadth drives extremities: The company has a comprehensive product offering for this rapidly growing market, leveraging both the wound and hardware-based markets. Additionally, Integra is one of two companies with an extremity-focused sales team, employing 120 direct reps in the US with plans to add 15-20 more over the next 12 months. Integra employs an additional 50 direct reps OUS. We believe continued execution of product launches and sales force expansion positions Integra to drive robust sales growth in the extremities market.

Spine: Integra has a three-pronged approach to expanding the spine franchise: 1) Expand the US distribution footprint, which is currently at ~65 agents, with ~200 reps, 2) increase the international presence, which is minimal at this point, and 3) add new products to the bag, and six new products are slated for introduction in 2011. For the nine months ended 2010, spine and biologics contributed $90M, up from $90M for all of 2009.

Rebound in hospital capital equipment demand: Demand for capital equipment significantly rebounded in H2/10 after a sluggish year in 2009. We note that the disposable components of the capital goods markets have continued to grow, while the box components continue to experience replacement when necessary. As the global economy recovers, we expect the capital equipment businesses to continue to benefit.

Bottom line
We believe Integra is well positioned to maintain above-market growth rates in orthopedics given new product launches and expanding sales force. In addition, we believe its unique product offering in extremities for both orthopedics and skin and its designated direct sales force differentiates it from the other competitors in the market.
Johnson & Johnson (JNJ : NYSE : $61.06 : Mkt Cap $167B | Not rated)

Johnson & Johnson and its subsidiaries have approximately 118,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field.

The Medical Devices and Diagnostics segment includes a broad range of products, including Cordis’ circulatory disease management products; DePuy’s orthopedic joint reconstruction, spinal care and sports medicine products; Ethicon Endo-Surgery’s minimally invasive surgical products; and Ortho-Clinical Diagnostics’ professional diagnostic products. Distribution to these health care professional markets is done both directly and through surgical supply and other dealers.

Growth drivers:

RECLAIM revision hip: DePuy received FDA clearance for the system its RECLAIM revision hip system just prior to the AAOS meeting. The modular system, which can be used with the PINNACLE acetabular system, offers improved instrumentation and more options for challenging cases.

Mitek product launches: On the sports medicine side, the company launched two new products: the HEALIS TRANSTEND implant system, a minimally invasive solution for partially torn rotator cuffs, and the VAPR VUE, a new radiofrequency device.

Bottom line

DePuy is dealing with a number of headwinds in both its large joint reconstruction and spine businesses. Specifically, being such a large player with an undifferentiated product offering provides opportunities for competitors to take share. We expect a difficult year for DePuy in 2011 and note that David Floyd, worldwide President of DePuy Orthopaedics, announced his resignation effective at the end of March.

EARNINGS SUMMARY:

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All amounts in US$ unless otherwise noted. Source: Reuters estimates
China Kanghui Holdings (KH : NYSE : $17.05 : Mkt Cap $320M | BUY)
Price target: $19.50

Kanghui is a leading Chinese developer, manufacturer and marketer of orthopedic implants in China. The company offers a wide array of proprietary orthopedic implant products in trauma and spine and is the #2 market share company in China for both of those market segments. Kanghui has an extensive network of distributors for its products in China. In addition, Kanghui’s products are distributed in 24 countries. Kanghui has strong research and development capabilities and is focused on developing new proprietary products, including new product lines, extensions of existing product lines and enhancements of existing products.

Growth drivers

Partnership with Consensus: China Kanghui announced an exclusive partnership with US based Consensus Orthopedics in Q1/11 to manufacture and market its hip and knee products. The agreement significantly broadens Kanghui’s product portfolio and enables the company to enter the $250M large joint replacement market in China that is currently growing at a rate of ~20%. The Consensus products and complementary total joint products are expected to be introduced in China in 2013/2014.

Strong product pipeline: The company has launched five of eight previously announced products (five in spine, three in trauma), with expectations to commercialize the remaining three in 2011, building upon the eight new products (four spine, four trauma) launched in 2008 and 2009. We believe this robust R&D pipeline combined with the company’s strong brands will help it further penetrate the top-tier hospital base in China.

Bottom line

We believe the company is well positioned to capitalize on the emerging Chinese orthopedics industry. Specifically, Kanghui continues to launch new products and add to its distribution channel. Furthermore, we expect domestic Chinese manufacturers are well positioned to capture increasing market share from multi-national corporations as product quality improves.
Kensey Nash (KNSY : NASDAQ : $26.49 : Mkt Cap $226M | Not rated)

Kensey Nash Corporation is a leading medical technology company that provides a number of innovative products into multiple medical markets, primarily in the endovascular, sports medicine and spine markets. Many of the products are based on the company’s significant expertise in the design, development, manufacture and processing of absorbable biomaterials, which has led to partnerships to commercialize technologies. The company is known as a pioneer in the field of arterial puncture closure as the inventor and developer of the Angio-Seal Vascular Closure Device, which is licensed to St. Jude Medical.

Growth drivers

Extracellular Matrices (ECMs): Management again showcased its development of this regenerative medicine product, which is porcine-derived. Potential markets include hernia repair, breast reconstruction, and pelvic floor reconstruction. The company is currently assessing its distribution strategy for incremental market segments.

ECM partnership with Arthrex: Kensey announced its second ECM partner (Synthes was the first) in Q2/10 to develop the technology for application in sports medicine tendon repair procedures and small joint surgeries. Initial launch is planned for Q1/11. The companies also launched a cartilage repair device at the AAOS meeting that is intended for the EU markets.

Orteq Sports Medicine agreement: Management discussed its recent partnership agreement with Orteq related to the Actifit Synthetic Meniscal Scaffold. The product received CE mark in 2008 and is expected to receive FDA approval to start US clinical trials in 2011. The Actifit product is a synthetic scaffold allowing vascular and cellular in growth for arthroscopic repair of irreparable partial meniscal tears. The agreement included a $5M investment in Orteq which includes exclusive worldwide manufacturing rights and a 10% ownership in the company.

Acquires medical adhesives technology: Kensey announced the acquisition of Nerites, a medical adhesive technology company, in Q1/11 for $20M. The technology includes surgical adhesive and sealants that will allow Kensey to improve its current products and also explore additional markets and partners.

Bottom line

The company has a top-class R&D team and product pipeline, but does not have distribution capabilities. Given the company’s strong war chest with over $40M in cash and investments, we would expect it to continue to add to its strengths and address its weaknesses over the next few years given the opportunities available in today’s market.
Kinetic Concepts (KCI: NYSE : $51.47 : Mkt Cap $3.7B | Not rated)

Kinetic Concepts is a leading global medical technology company devoted to the discovery, development, manufacture and marketing of innovative, high-technology therapies and products for the wound care, tissue regeneration and therapeutic support system markets. Headquartered in San Antonio, Texas, KCI’s success spans more than three decades and can be traced to a history deeply rooted in innovation and a passion for significantly improving the healing and the lives of patients around the world. The company employs 6,800 people and markets its products in more than 20 countries.

Growth drivers

**VAC Via:** The latest iteration of KCI’s wound VAC products was showcased and is slated for a full launch in Q1/11. The VAC Via is a palm sized device with a quieter pump powered by Vortis technology. The updated design offers the clinical effectiveness of the VAC products but has a more intuitive design and is easier to use. The VAC via is focused on lower severity wounds. Furthermore, Via changes the treatment setting as it is a low-cost, portable, single-use product.

**Surgical wound products:** KCI highlighted two new products intended for the surgical wound market. The Prevena system, launched Q3/10, is marketed to reduce post-surgical complications and improve closed incision healing. The ABThera system offers a better intervention or tool for open abdomen procedures and has been approved for use in over 60% of level 1 and 2 trauma centers.

**Bottom line**

The company has a dominant position in the growing wound care market and is innovating with disposable VAC and synthetic products for the wound care market.
MAKO Surgical (MAKO : NASDAQ : $20.05 : Mkt Cap $793M | Not rated)

MAKO Surgical is a medical device company that markets both its robotic arm interactive orthopedic surgical platform and its proprietary RESTORIS implants for minimally invasive orthopedic knee procedures. The MAKO RIO System (RIO) is a surgeon-interactive tactile platform that incorporates a robotic arm and patient-specific visualization technology and prepares the knee joint for the insertion and alignment of MAKO’s resurfacing implants through a minimal incision. The benefits of MAKOplasty are that it is tissue sparing, requires a minimal incision and provides a precise, reproducible procedure and results in a shorter recovery time.

Growth drivers

**Hip system:** The company showcased its first generation hip system at the AAOS. The system is currently in a controlled launch, and the company plans to fully commercialize the product in H2/11.

**Clinical data:** MAKO continues to invest in clinical studies to further promote the adoption of the RIO. With over 58 clinical studies in progress, the company continues to build clinical data and understands the long-term value of such information.

**Growing number of sites:** MAKO continues to further penetrate the large market opportunity; it increased the number of sites to 67 by the end of 2010, up from 36 at the end of 2009. In addition, cumulative procedures grew to 3,485 in 2010 from 2,284 in 2009, with utilization per box reaching an all-time high in the Q4/10.

**Bottom line**

We expect the company to continue expanding on its strategy of building clinical data and educating surgeons and hospitals on the value proposition of the system. We would expect adoption of MAKOplasty to accelerate as hospital budgets continue to loosen up. The RIO System is appealing to patients, surgeons, and hospitals, so gating factors will be the cost of the robot and sales force execution, in our opinion. Lastly, we note that the adoption tends to be clustered, and therefore expansion into a new geography tends to drive increased sales and utilization.
Medtronic (MDT: NYSE: $39.26 : Mkt Cap $42B | Not rated)

Medtronic is a global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world. Medtronic competes in the orthopedics segment through its market-leading spine division.

Growth drivers

**VERTEX SELECT**: During the NASS conference Medtronic announced the US launch of the VERTEX SELECT reconstruction system posted screw module. It includes headless posted screws and adjustable connectors for procedures requiring fixation in the upper-thoracic spine. The components allow for and enable connection from any direction, angle, and/or height.

**Continuing to focus on discs**: The company continues to expand its cervical disc offering. The Bryan Cervical Disc System is rolling out on a limited-basis as the company fine-tunes the instrumentation. As a reminder, the PMA has been submitted for the Prestige LP.

**Bottom line**

We continue to believe that the big players in spine such as Medtronic will have a difficult time maintaining historic growth rates considering the pricing pressures impacting the industry. In addition, with the large number of small companies being relatively nimble and developing highly innovative products that surgeons desire, we believe it will be difficult for the company to maintain its share. That said, the company is approaching easier comps and C2011 is shaping up to be much better than C2010 due to stabilizing in market procedure volumes and pricing.
NeuroMetrix (NURO : NYSE : $0.51 : Mkt Cap $11.8M | Not rated)

NeuroMetrix is a science-based company advancing patient care through the development and marketing of innovative medical devices and products that aid physicians in the assessment and treatment of diseases and injuries of peripheral nerves, and that provide regional anesthesia and pain control.

Growth drivers

Diabetic peripheral neuropathy (DPN) device: The company has shifted all of its R&D focus to commercializing a DPN testing device. The product is expected to be a low-cost version of the current NC-stat device. The company expects to validate the product clinically in the H1/11 with initial launch projected at the American Diabetes Association annual meeting in June 2011. NeuroMetrix plans on using a distributor network for this product.

ADVANCE re-launch: NeuroMetrix is currently discontinuing its NC-stat sales and transitioning only to ADVANCE. The company plans to transition customers throughout 2011.

Bottom line

The company seeks to stabilize its base neuromonitoring business and has now divulged its plans to enter a larger, broader market with a lower-price-point product.

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All amounts in US$ unless otherwise noted.
Source: Reuters estimates
NuVasive (NUVA : NASDAQ : $26.94 : Mkt Cap $1.3B | HOLD)
Price target: $24.00

NuVasive is focused on the design, development and marketing of products for the surgical treatment of spine disorders. The company’s product portfolio is focused on applications in the US spine fusion market. The company’s current principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, which includes the XLIF procedure, as well as a growing offering of biologics, cervical and motion preservation products.

Growth drivers

Dominating the stem cell market: NuVasive’s Osteocel product is the current market leader in the stem cell biologics market, which we estimate grew 64% in 2010. We believe physicians will continue to seek lower-cost solutions to BMPs, and stem cell products appear to be the most viable alternative despite the lack of strong data to support efficacy.

Motion preservation: Management highlighted the PMA process for its cervical disc (PCM), which is expected to gain FDA approval in Q1/12. The filing was originally submitted in H1/10, and management commented that it would not require a panel meeting and there have been no delays to date. Approval would make NuVasive the third or fourth US company with a cervical disc, as Spinal Motion submitted a PMA for its cervical disc, KineFlex-C, in Q1/10.

Reimbursement/coverage is no longer an issue: With all of the major payers shifting back to positive, we believe the removal of the reimbursement issue returns execution risk as the main challenge for NuVasive. We note that NuVasive has executed superbly thus far and there is no reason to expect a change.

Bottom line

NuVasive continues to battle headwinds in the US spine market. While the company has outperformed the overall market to date, its differentiated product offering is attracting more competition, with many players commercializing lateral access platforms. Considering NuVasive created this market and holds the dominant market share, we expect the company will continue to experience pricing and volume pressure in 2011.
Orthofix (OFIX : NASDAQ : $32.30 : Mkt Cap $579M | BUY)
Price target: $41.00

Orthofix International, N.V., a global medical device company, offers a broad line of surgical and non-surgical products for the spine, orthopedic, and sports medicine market sectors that address the lifelong bone-and-joint health needs of patients of all ages – helping them achieve a more active and mobile lifestyle. Orthofix’s products are widely distributed around the world to orthopedic surgeons and patients via Orthofix’s sales representatives and its subsidiaries, including BREG and Orthofix Spine, and via partnerships with other leading orthopedic product companies.

Growth drivers
Spinal implants and biologics on solid footing: Orthofix Spine continues to show positive momentum and is not being significantly impacted by the current pricing and volume pressures experienced throughout the industry. We believe the environment has created an opportunity for smaller players with minimal share and broad product lines to penetrate new accounts. We believe this is positive for Orthofix as it can gain market share at a faster rate than it was before.

Spine stimulation under pressure: The company is currently experiencing a number of headwinds with its stimulation business. First, Orthofix is continuously required to go to battle with private payers, who are increasingly turning off reimbursement of the therapy, especially for the cervical market. Second, the Department of Justice and whistle blower lawsuit provide a legal overhang as well as a disruption to its sales force.

Trinity Evolution: Orthofix continues to benefit from the fast-growing stem cell biologics market with its Trinity Evolution product. Unlike some its competitors, Orthofix has the ability to leverage its larger distribution footprint to sell in markets outside of spine. We believe this product will continue to be a growth driver for the company in 2011.

Bottom line
Orthofix is an established, diversified player and has executed its business plan to turn around the spine business. However, we remain concerned with the macro pressures impacting its spine stimulation business. Specifically, we believe the DOJ interviews that are disrupting the sales force could impact near-term results while required changes in the sales practices could impact mid- to long-term performance of the business.
Orthovita (VITA : NASDAQ : $2.38 : Mkt Cap $183M | HOLD)
Price target: $2.50

Orthovita is a spine and orthopedic biosurgery company with proprietary biomaterials and biologic technologies. The company develops and markets synthetic-based biomaterials products for use in spine surgery, the repair of fractures and a broad range of clinical needs in the trauma, joint reconstruction, revision and extremities markets.

Growth drivers
VITOSS Bioactive Foam-2x: The company’s newest iteration of the VITOSS product family gained FDA 510(k) clearance in Q4/10. The product was cleared for use as a non-structural bone void filler in spine, pelvis and extremities, and was introduced at AAOS.

Staying balanced with its hybrid sales force: Orthovita continues to invest in its distribution channel, with 80-85 direct and 60+ distributors and agents. In addition, the company is striving to maximize the productivity of each rep and leverage cross selling opportunities. The company also has new OUS sales leadership and is focusing on expanding its current network to high growth markets.

AAOS guidelines remain a threat: Orthovita’s CORTOSS business remains under pressure following last year’s release of the AAOS guidelines recommending strongly against the use of vertebroplasty in patients with vertebral compression fractures (VCFs). The recommendation cited the two NEJM articles published last year. However, channel checks during Academy lead us to believe that procedure volumes have stabilized and sequential improvement is expected going forward.

Bottom line
Orthovita’s base business remains solid, and we believe the hybrid sales force remains right-sized to continue to drive growth. Furthermore, with new iterations of VITOSS scheduled to launch over the next 12-18 months, we believe the company will be able to insulate itself from the strong price pressure headwinds facing this industry and resume growth starting in H1/11.
RTI Biologics (RTIX : NASDAQ : $2.58 : Mkt Cap $142M | BUY)
Price target: $3.25

RTI Biologics is the leading provider of sterile biological implants for surgeries around the world. RTI prepares human-donated tissue and bovine tissue for transplantation through extensive testing and screening, precision shaping, and proprietary, validated sterilization processes. These allograft and xenograft implants are used in dental, head and neck, ophthalmology, spine, sports medicine, urology and other specialty surgeries.

Growth drivers

Sports medicine: RTI’s sports medicine business continues to execute and exceed industry growth rates due to traction gained from the increasing experience of its direct sales force, combined with new product launches.

MAPC technology: Management announced in Q3/10 that it had entered into an exclusive, long-term licensing agreement with Athersys’ to develop and market its Multipotent Adult progenitor Cell (MAPC) technologies. This will be RTI’s first step into the fast growing stem cell biologics market. The first products are expected to be commercially available in H1/12.

Tuck-in acquisitions for Sports Medicine: Management noted that it is seeking tuck-in acquisitions for the Sports Medicine business, seeking to leverage its 100+ strong distribution network.

Bottom line

While the company has been facing significant macro challenges in its Dental and Spinal Constructs businesses, we believe that overall the company is well positioned for long-term growth with its expanding direct sales force in Sports Medicine and use of CR Bard as a distributor in Surgical Specialties. In addition, we believe operational changes begun in early 2010 should help drive 2011 results. With guidance for 2011 set very low and valuations remaining at a significant discount to its peers, we believe the stage is set for a strong year for the stock.
Smith and Nephew (SNN : NYSE : $58.12 : Mkt Cap $10.4B | Not rated)

Smith & Nephew is a global medical technology business specialising in orthopedics, including reconstruction, trauma, clinical therapies, endoscopy and advanced wound management. Smith & Nephew is a global leader in arthroscopy and advanced wound management and is one of the leading global orthopedics companies.

Growth drivers

**VERILAST technology:** Combines SNN’s OXINIUM metal alloy and highly cross-linked polyethylene to create improved wear characteristics and is validated out to 30 years. VERILAST drove knee growth in H2/10.

**Visionaire - Patient-matched instrumentation:** To date the company has completed 10,000 TKAs (mostly in the US) with the Visionaire. Visionaire utilizes an MRI to create patient-matched instrumentation and removes 20 steps from the surgical procedure. Visionaire was recently introduced in Europe and Asia Pacific.

**RENASYS:** SNN’s RENASYS negative pressure wound therapy systems are the only devices to offer both foam and gauze options for wound interfaces. The system offers two models, EZ and GO, depending on the type of wound and the portability needed.

**Bottom line**

We believe that 2011 is poised to be a solid year for the company given the rebounding procedure volumes and easier comps. Furthermore, we remain believers in the “where there’s smoke, there’s fire” adage in regards to takeout offers from other large ortho players, which we expect will provide significant support for the stock over the next 12-18 months.

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**EARNINGS SUMMARY:**

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All amounts in US$ unless otherwise noted.
Source: Reuters estimates
Stryker (SYK : NYSE : $63.67 : Mkt Cap $25.3B | BUY)
Price target: $66.50

Stryker Corporation is one of the world’s leading medical technology companies with the most broadly based range of products in orthopedics and a significant presence in other medical specialties. The company’s products include implants used in joint replacement, trauma, and spinal surgeries; surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling and emergency medical equipment; and other medical device products used in a variety of medical specialties.

Growth drivers
Total Joints:
MDM X3 Mobile Bearing Hip System: The system is a third generation dual mobility device, allowing surgeons to offer the benefits of dual points of articulation to a greater range of patients. The launch follows last year’s launch of the ADM X3, showing Stryker’s intention to lead the market in mobile bearing hip offerings.

Endoscopy:
Tissue-Preserving Hip Arthroscopy Platform: Stryker Endoscopy showcased its newest system of instrumentation and devices to treat femoroacetabular impingement through minimally invasive techniques. The new platform is a complete system, including new technology for visualization, access, ablation and repair.

Other:
Rebound in hospital capital equipment demand: During 2010 we saw a gradual yet consistent rebound in the capital equipment market, with management teams commenting that hospitals were beginning to strategically replace older systems. While this still is not the historical “keeping up with the Joneses” market of prior years, we believe that as the global economy recovers in 2011, capital equipment businesses should benefit.

Bottom line
With new products being launched in its Orthopedics business and the macro environment favoring its MedSurg business, we believe the company is poised for a strong year. This holds especially true if procedure volumes have truly bottomed and patients, who have been holding off, start to get back into the surgical queue. Finally, with the company’s strong cash balance and FCF generation, we would expect continued M&A activity out of Kalamazoo, MI.
Symmetry Medical (SMA : NYSE : $9.15 : Mkt Cap $328M | Not rated)

Symmetry Medical is a leading independent provider of implants and related instruments and cases to the orthopedic device industry. The company also designs, develops and produces these products for companies in other segments of the medical device market, including arthroscopy, dental, laparoscopy, osteobiologic and endoscopy sectors. It also provides limited specialized products and services to non-healthcare markets, such as the aerospace market.

Growth drivers

Industry growth: Both in orthopedics and other markets.

Outsourcing trends: Larger market participants are seeking ways to reduce costs and accelerate time to market for new products.

Expanding distribution: The company is focusing on expanding its international presence, specifically in Asia. Additionally, it is also launching global marketing and brand development initiatives.

Total solutions offering: Symmetry is focused on expanded the services offered to its customers, thereby capturing more revenues per customer.

Bottom line

Symmetry is well positioned to benefit from the improving procedure volumes in knees and hips as well as company-specific growth strategies.
Synthes (SYST : VX : $125.05 : Mkt Cap $14.9B | Not rated)

Synthes is a leading global medical device company that develops, manufactures and markets instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues. Synthes is one of the leading multinational orthopedics companies with a significant market presence in the trauma and reconstructive markets.

Growth drivers
Synthes is expanding its product set to include non-hot trauma products for the extremity markets. Specifically, the company was profiling a dual column volar and dorsal plate for wrist fracture and the EPOCA complete shoulder system and fracture stem.

For the spine market, the company was profiling a new 5.5 CoCr Thoracolumbar system with snap-on screw heads called MaAnix. The product was introduced in September 2010.

Bottom line
As the global leader in trauma, Synthes has a solid footprint from which to attack the extremity market. We note that the extremity market is unique in that it blends both trauma and reconstruction and includes both “hot” trauma and scheduled cases.

| EARNINGS SUMMARY: |
|-------------------|--------|--------|--------|
| **FY Dec Revenue** | **2010A** | **2011E** | **2012E** |
| Q1                | -      | -      | -      |
| Q2                | 1,803.9| -      | -      |
| Q3                | -      | -      | -      |
| Q4                | 1,883.1| -      | -      |
| **Total**         | 3,687.0| 4,015.8| 4,316.0|

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All amounts in US$ unless otherwise noted.
Source: Reuters estimates
TranS1 (TSON : NASDAQ : $3.40 : Mkt Cap $71.1M | Not rated)

TranS1 is a medical device company focused on designing, developing and marketing products that implement its proprietary approach to treat degenerative conditions of the spine affecting the lower lumbar region. TranS1 currently markets the AxiaLIF family of products for single and multilevel lumbar fusion and Vectre and Avatar posterior fixation systems.

**Growth drivers**

**Humana coverage gained:** In January, Humana announced it will begin covering AxiaLIF lumbar fusion procedures. Humana has over 10 million covered lives concentrated in the South, Southwest, and Midwest and aligns well with the company’s direct sales force footprint. Trans1 is currently working with the payer to ensure efficient processing of surgeon reimbursement.

**Strategy announced for Category I code:** The company recently announced that it will wait until the October AMA CPT meeting, as two of its publications remain in the peer review process. Trans1 plans to graduate to a Category I code January 1, 2013.

**Bottom line**

We believe the company’s AxiaLIF technology remains one of the only differentiated technologies left in the space. We believe that the Humana announcement is a big positive, as it shows the likelihood of other payers turning on. In addition, with a positive outcome from the October AMA CPT meeting, we believe the company suddenly becomes a very attractive take-out candidate that deserves a premium multiple.

**EARNINGS SUMMARY:**

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All amounts in US$ unless otherwise noted. Source: Reuters estimates
Wright Medical Group (WMGI : NASDAQ : $16.66 : Mkt Cap $737M | HOLD)
Price target: $15.50

Wright Medical Group is a global orthopedic medical device company specializing in the design, manufacture, and marketing of reconstructive joint devices and biologics. Wright’s product offerings include large joint implants for the hip and knee, extremity implants for the hand, elbow, shoulder, foot and ankle; and both synthetic and tissue-based bone graft substitute materials.

Growth drivers
Wright’s extremities and biologics business: The company continues to expand its product offering in this space. By year-end 2011, Wright expects to have over 100 products commercially available, up from 37 in 2006. Also it plans to continue to grow its sales force, which has expanded to over 175 reps (both direct and independent agents’ reps) from one rep in 2006.

Evolution PS knee: Wright was profiling its Evolution PS. This is the first PS knee offered by the company and allows for expansion into a previously untapped segment of the market.

PRO-TOE VO: Management showcased its PRO-TOE VO hammertoe fixation system that was recently launched and is indicated for patients requiring fusion of lesser toes for hammertoe deformity. It promotes a solid fixation on both sides of the joint and provides a favorable alternative to k-wires. We note that there are ~500,000 procedures per year for this product to penetrate, and it represents a new market opportunity for Wright Medical.

EVOLVE Elbow Plating System: The company was highlighting EVOLVE as an anatomic plating system designed to treat fractures of the distal humerus and proximal ulna. Composed of polished stainless steel, the plates incorporate Wright’s advanced ORTHOLOC Polyaxial Locking technology, which allows the surgeon to place screws in the best possible trajectory and then solidly lock the screw to the plate. The product adds to its EVOLVE elbow product offering of Modular Radial Head and Radial Head Plate.

Bottom line
Wright continues to become one of the strongest players in extremities (approximately 14% share of the WW market in 2010, according to our estimates). However, its large joint reconstruction business looks likely to experience the usual headwinds in 2011, with knee sales benefitting from a new product introduction but hips being impacted by the mix shift away from alternative bearing surface technologies. Lastly, with FCF generation expected to be only $15M, we believe the stock is fairly valued.
Zimmer Holdings (ZMH : NYSE : $65.22 : Mkt Cap $12.6B | BUY)
Price target: $71.75

Zimmer Holdings is a global leader in designing, developing, manufacturing and marketing reconstructive and spinal implants, trauma and related orthopedic surgical products. Zimmer has operations in more than 24 countries around the world, sells products in more than 100 countries, and maintains close to 7,000 employees worldwide.

Growth drivers
Continuum acetabular system: Zimmer is continuing to roll out its new Continuum acetabular cup system. Continuum Shells are made from Trabecular Metal and incorporate alternate bearing options. Management recently noted that it is having a positive impact on mix as it commands a higher ASP and is benefiting from a shift away from MoM implants. The system has become the company’s best selling hip construct.

Pathfinder NXT: Zimmer launched the PathFinder NXT pedicle screw system for the spine at the AAOS meeting, building on its already existing PathFinder system by streamlining the surgical technique and developing innovative instrumentation. The new system offers options for both mini-open and percutaneous approaches.

NexGen LPS-Flex: The mobile knee bearing with Prolong highly crosslink polyethylene was recently launched and provides an anteriorly positioned pivot near the end of the ACL to replicate the anatomic center of knee rotation.

TM-S System: The TM-S Trabecular Metal Cervical Interbody Fusion Device is the first cervical interbody device that incorporates porous metal into the structure of the implant. Zimmer spine announced the FDA clearance of the system in Q1/11.

Bottom line
We believe the company is well positioned to capitalize on a rebounding procedure volume environment, especially considering the launch of new products. In addition, given the strong cash flow generation and lower valuation relative to the group, we believe 2011 will likely be a strong year for the stock.
PRIVATE COMPANIES

Anulex Technologies

Company description

Anulex Technologies is a private company focused on improving surgical techniques and developing proprietary medical technology to preserve and repair the soft tissue of the spine for patients undergoing a surgical procedure to remove a herniated disc. Anulex’s Xclose Tissue Repair System is an implant that provides a unique method for treating the compromised anulus fibrosus subsequent to a discectomy. The company also markets its Inclose Surgical Mesh System, which is an implant designed to allow a fast, simple, and safe way to provide a barrier and scaffold for soft tissue repair.

Key takeaways

- Xclose has received FDA clearance for use in soft tissue approximation for procedures such as general and orthopedic surgery. It has been used to treat over 1,300 patients in the US. A second generation Xclose product, Xclose Plus, was commercialized in the Q1/10 and offers a knotless design which reduces the learning curve for new surgeons, a more robust tension band, and a COGS reduction for Anulex.

- A randomized study (n=750) comparing Xclose with no repair at all found a 50.2% reduction in the risk of reoperation due to re-herniation using the device (surgeons that enrolled more than five patients). The reduction was 40% for all surgeons in the study. All patients have completed one-year follow-up, and >50% have completed two-year follow-up.

Ascension Orthopedics

Company description

Ascension Orthopedics was founded in 1996 and is dedicated to transforming the extremities market through a unique pyrocarbon material for implants. The company’s pyrocarbon implants for the hand have garnered widespread international acclaim. With pyrocarbon expertise in orthopedics, the company is now building on its success by expanding from hands to the elbow, shoulder, and foot. Surgeons worldwide use Ascension’s implants, streamlined procedures, and complete kits to improve patients’ lives. We note that a change in management has resulted in a shift of focus from a pure play technology company to proliferation of products utilizing this core technology.

Key takeaways

- Ascension had several significant product launches in 2010, including its PyroTITAN Humeral Resurfacing Arthroplasty System, which is the first commercially available shoulder resurfacing prosthesis made of pyrocarbon. The company also launched the TITAN, a modular total shoulder system, as well as several extremity plating systems.

- The TITAN system launched globally in Q4/10 after receiving CE Mark and 510k approval in Q2/10 and Q3/10, respectively.
• The company is continuing its focus on the shoulder market with the development of its PYROHEMI PyroCarbon humeral head. Ascension plans to submit an IDE to the FDA in Q1/11 with a full OUS launch planned for Q4/11.

Baxano

Company description

Baxano is focused on developing minimally invasive tools to restore spine function and preserve healthy tissue. Baxano is a well funded, privately held company that was founded in 2005 by Jeffery Bleich, MD, who had the vision to create flexible tools to provide precision lumbar decompression from the “inside out.” Baxano’s mission is to develop innovative tools that restore spine function, preserve healthy tissue, and enable a better quality of life for the patients it serves.

Key takeaways

• Baxano has developed the iO-Flex System, which utilizes thin, flexible instruments to provide precision lumbar decompression while still preserving the facet joint.

• The iO-Flex system has been used in over 550 cases with no adverse affects. A feasibility study was published in the December 2010 edition of SPINE magazine, and the company is currently enrolling patients for several effectiveness trials to take place in 2011.

• The company currently has five US distributors (with plans to expand to 10 in 2011) and is exploring OUS distribution as well.

Benvenue Medical

Company description

Benvenue Medical is advancing spine repair through the development of proprietary, minimally invasive surgical and interventional solutions. Benvenue Medical has developed a proprietary, flexible spinal implant technology with two primary minimally invasive applications: the treatment of vertebral compression fractures (VCFs) due to osteoporosis, trauma, and cancer, and the treatment of degenerative disc disease.

Key takeaways

• Benvenue has three primary products: 1) the Blazer, a unique channeling device for cavity creation (FDA cleared, waiting on CE Mark, 2011 launch); 2) the Kiva VCF system (CE Mark, IDE study underway); and 3) an MIS fusion device (CE Mark).

• The Kiva VCF Treatment System is a flexible PEEK-Optima implant that utilizes a unipedicular approach through a 5mm cannula. PMMA is then introduced via the Kiva delivery system. The implant provides significantly reduced PMMA volume, significantly less extravasation, preservation of cancellous bone, and fewer subsequent fractures (data from 60 patient OUS study). It could also provide structural support for use with biologics.

• The company has an IDE approval from the FDA for its 510(k) randomized controlled trial comparing to balloon kyphoplasty (KAST trial). The primary endpoint is non-inferiority in terms of composite of pain, function, and safety. Enrollment is expected to be completed in Dec. 2011, with one-year follow-up completed 2012.
• MIS spinal fusion is another opportunity for the KIVA device, which received CE
Mark Q3/10.

Bonovo Orthopedics

Company Description

Bonovo is a leading provider of orthopedic products to the Chinese healthcare market. Bonovo distributes its own products and serves as a distribution partner for other leading international companies. The Bonovo team is committed to driving new standards of orthopedic care throughout China by bringing the best products to market that combine strong market demand and improve patient outcomes.

Key takeaways

• Bonovo experienced 54% sales growth in 2010 and currently has approximately 150 distributors in China.

• The company has distribution contracts with NuVasive, Pioneer Surgical Technologies, and Japan Medical Materials.

Carticept Medical

Company description

Carticept Medical has developed Cartiva, a synthetic implant to replace or repair damaged cartilage. Cartiva SCI is comprised of a proprietary polyvinyl alcohol (PVA) cryogen, which is a synthetic polymer prepared by the hydrolysis of polyvinyl acetate and has been used in medical device applications for over 20 years (think contact lenses). A patented manufacturing process enables Carticept to customize the PVA cryogel to meet defined functional requirements.

Key takeaways

• The Cartiva Synthetic Cartilage Implant is a synthetic biomaterial meant to mimic human cartilage. The target market is treatment of osteoarthritis in the MTP joint of the foot. The product is progressing through the PMA regulatory pathway.

• The company has also developed an all-in-one orthopedic injection system called the Navigator for steroid and/or more anesthetic injections that are most common to a practice. The Navigator received CE Mark in Q4/10 and is currently under review at the FDA. UK commercial launch is expected in the H1/11, and US launch, pending 510(k) clearance, is slated for Q4/11.

• SonoSite, the company’s hand-carried ultrasound device, offers physicians a portable high performance ultrasound system.

Cayenne Medical

Company description

Cayenne Medical is a multidisciplinary sports medicine company focused on leading the transformation of traditional ACL and meniscal repair procedures by applying advanced technology through minimally invasive techniques. The company has developed a complete set of solutions for the knee, including devices for soft-tissue ACL reconstruction, BTB ACL reconstruction, Meniscal repair and Soft Tissue PCL, MCL and
LCL reconstruction. To date, over 50,000 procedures have used Cayenne Medical’s AperFix, iFix and/or CrossFix devices.

**Key takeaways**

- In March 2009, the AperFix Femoral and Tibial Implants received 510k clearance for extended indications for use. While it is a superior solution for ACL reconstruction, it can also be used in a variety of tenodesis procedures (PCL, MCL, LCL, and MPFL reconstruction). The AperFix II, an updated version, launched at the 2011 AAOS meeting.

- The iFix device is a PEEK BTB ACL reconstruction solution that is a simple, reproducible technique that provides for strong fixation strength.

- The CrossFix system, a next generation meniscal repair system, is an all suture system that is fast and easy and provides a biomechanically strong repair.

**Consensus Orthopedics**

**Company description**

Consensus Orthopedics designs, manufactures, markets and sells high quality reconstructive total joint implants for the hip and knee that improve the lifestyles of patients. The company was founded in 1992 and is headquartered in El Dorado Hills, CA. Consensus offers a full line of hip and knee products and is a leader in modular hip stem technologies. The company’s strategic objectives include continued growth though the addition of new products and territories with the goal of improving patient outcomes. The company sells its products throughout North America, Western Europe, Turkey, Japan and Australia.

**Key takeaways**

- Consensus is currently selling its products in 11 countries, with 65% of sales coming from the US. Additionally, products are in the registration process in both Canada and Brazil.

- China Kanghui and Consensus entered into an exclusive agreement to distribute Consensus products and technologies in China. The companies are also exploring OEM opportunities.

- The company achieved $12M in sales in 2010 (up from $11.7M in 2009 and $4.9M in 2004) with plans to grow to $40M in total sales by 2015.

**ConforMIS**

**Company description**

ConforMIS develops and commercializes medical devices for the treatment of osteoarthritis and joint damage. The company’s *image-to-implant* process is made up of two technology platforms: iFit technology and iJig instrumentation. iFit utilizes MRI and CT scan data to create patient-specific resurfacing implants that are sized and shaped to match an individual patient’s anatomy. iJigs utilize the same data to create disposable, patient-specific cutting guides that simplify the surgical technique and eliminate costly instrumentation reprocessing.
Key takeaways

- The advantage of a ConforMIS custom implant is that the patient will benefit from less bone loss, better implant coverage and therefore less subsidence and a longer implant life.

- ConforMIS has multiple FDA-cleared implants for articular knee repair, including the iForma (Interpositional), iUni (Unicompartmental), iDuo (Bicompartmental), and iTotal (Tricompartmental).

- In January 2011, the company received FDA clearance for its iTotal CR Knee replacement System. The iTotal CR is made to fit an individual patient precisely without the under-sizing and overhang common with standard systems.

- The iTotal will be released through a limited launch in 2011, and broad commercial introduction is expected in 2012.

DFine

Company description

DFine is a privately held medical device company dedicated to improving patient quality of life through the development of innovative, minimally invasive therapeutic devices used to treat pathologies of the vertebrae. DFine, Inc. is the developer of Radio Frequency (RF) Kyphoplasty, a novel approach to stabilizing vertebral fractures, relieving pain and improving patient quality of life. Commercially available through the company’s flagship StabiliT Vertebral Augmentation System, RF Kyphoplasty provides physicians greater control in the treatment of vertebral compression fractures through site and size specific cavity creation, ultra high viscosity bone cement with extended working time, and its unique, remotely controlled cement delivery system.

Key takeaways

- DFine’s technology platform includes two treatment modalities for targeted MIS therapies: the StabiliT and Ablation systems.

- The StabiliT is a complete RF system for targeted vertebral augmentation; the system offers everything from access and cavity creation to delivery and fill of the cement.

- The StabiliT has treated over 7,500 fractures in 5,000 patients and is currently at a run rate of 100 additional cases per week.

- The Ablation system offers physicians a tool for targeted radiofrequency tumor ablation.

DGIMED Ortho

Company description

DGIMED Ortho developed and commercialized the DISTALOCK IM Nail and Drill System, which uses an innovative approach to facilitate the accurate placement of the distal locking screws used during intramedullary nailing procedures. The DGIMED DISTALOCK is easy to use and allows for consistent and accurate distal locking of the IM patient with each use.
Key takeaways

- Benefits of the DGIMED product include significant time savings and reduced exposure to x-rays for physician and patient.

- The DISTALOCK product does *not* alter the current procedure and will be developed to work with leading IM Nails on the market today.

- In Q4/10, DGIMED received CE clearance for its Drill and Intramedullary Nail System. The company plans to investigate OUS commercialization in Brazil and the EU in 2011.

- Q2/10 received regulatory clearance for the titanium femoral IM nail. Clearance for the tibial nail is expected Q4/11. Post clearance, US market introduction is expected to focus on key opinion leaders within the industry with 4-6 preliminary centers.

- Data was presented at the conference showing that 48 out of 50 cases achieved first attempt locking of both distal screws. The average time for distal locking was 14 minutes.

**DJO**

**Company description**

DJO is a global developer, manufacturer and distributor of medical devices that provide solutions for musculoskeletal health, vascular health and pain management. The company's products address the continuum of patient care from injury prevention to rehabilitation after surgery, injury or degenerative disease. DJO products are used by orthopedic specialists, spine surgeons, primary care physicians, pain management specialists, physical therapists, podiatrists, chiropractors, athletic trainers and other healthcare professionals.

Key takeaways

- Les Cross, an early employee of DonJoy and CEO of the company, will step down after a successful career to sail and play golf. He will be missed.

- DJO has leading market share across most addressable market segments with well-known, respected brands.

- The company has a broad distribution footprint that provides multiple market access and direct presence in key countries. Most recently, DJO acquired its South African distributor in Q4/10.

- Pro forma net sales for DJO in 2010 were $966.0M with pro forma EBITDA of $262.4M. In addition, DJO generated $64.4M in free cash flow during the year.

**Entellus Medical**

**Company description**

Entellus Medical is focused on the minimally invasive treatment of patients with chronic or recurrent rhinosinusitis through the development of innovative device technologies and treatments. Based in Maple Grove, Minn., Entellus Medical manufactures, markets, and distributes its products throughout the United States.
Key takeaways

- Entellus has two commercially available balloon dialation products for the narrowing of sinus pathways: FinESS and XprESS.

- The FinESS sinus treatment system is a minimally invasive office-based procedure that provides visualization and balloon dialation in a quick, minimally invasive procedure.

- The XprESS Multi-Sinus treatment system is a trans-nasal dilating FESS tool. The XprESS can be used in both office and OR settings and treats all sinuses.

**ENTrigue Surgical**

**Company description**

ENTrigue Surgical is committed to developing innovative products that improve patient care in Otolaryngology. ENTrigue has launched three product families (SerpENT articulating instruments, ENTact septal staplers and RegenerENT biologics) to date and is pursuing the formation of a comprehensive product portfolio. In addition to the current products offered by ENTrigue, the company has an R&D pipeline and intends to launch new products to the market on an aggressive schedule.

Key takeaways

- The ENTact septal staplers have FDA, Health Canada, and CE Marking regulatory clearances for use as a mucosal closure system for the soft tissue of the septum. The device offers an effective alternative for septal flap closure by using resorbable implants.

- A 510k clearance is pending on the MediENT Middle Turbinate Implant. If regulatory goals are attained, a commercial launch could begin immediately as the device has already been successfully commercialized OUS. The product has received CE Mark and Health Canada license.

- ENTrigue plans to expand its distribution model with direct sales reps, ENT-focused distributors, inside sales for uncovered territories, and OUS distributors and partners.

- The company has a robust pipeline and highlighted an expandable absorbable sinus stent as a future potential blockbuster product.

**Expanding Orthopedics**

**Company description**

Expanding Orthopedics is a medical device company dedicated to developing innovative products designed to address unmet needs for spinal surgery and orthopaedic trauma. EOI’s patent portfolio includes novel devices which allow for unique approaches to spinal surgery and orthopaedic fractures.

Key takeaways

- The XPED Pedicle Screw System is currently CE Marked, with studies demonstrating favorable toggle and pullout tests.

- Commercialization in the EU is expected mid-2011.
• FDA clearance is expected in H2/11, with US launch in early 2012.

**Flex Biomedical**  
**Company description**
Flex Biomedical was founded in 2007 and is focused on developing innovative treatments for orthopedic diseases. The company’s lead product, the Flex Polymer, is a synthetic polymer designed to treat osteoarthritis.

**Key takeaways**
• The Flex Polymer is a synthetic polymer intended to serve as a viscosupplement for joints damaged by arthritis. The company holds a worldwide exclusive license to the technology developed by Boston University.
• The Flex Polymer was shown to have statistically superior performance characteristics in protecting cartilage when tested against Synvisc-One in a lab setting.
• The company is currently completing preclinical tests, with a plan for an OUS clinical trial to begin H1/12.

**ISTO Technologies**  
**Company description**
ISTO Technologies is dedicated to improving patient quality of life through the development of products for spinal therapy, sports medicine and trauma. ISTO’s discrete cell-based and biomaterial platforms encompass a number of technological breakthroughs that are poised to advance the practice of medicine by offering solutions for unmet and/or largely unsatisfied clinical needs in the areas of cartilage and bone. The company’s cell-based cartilage technology is an off-the-shelf product derived from juvenile cartilage which offers economy of scale in manufacturing and can be leveraged into additional applications (spine, hip, and shoulder).

**Key takeaways**
• Clinical trials for DeNovo ET, an Engineered Tissue cartilage for knee injury, are being conducted with Zimmer, its strategic partner for the program. Phase III pivotal clinical trials are expected to begin in 2011.
• NuQu: The company completed a Phase I clinical study (the first cell-therapy human trial in the US for the treatment of degenerative disc disease) for NuQu, a cell-based injectable formulation for regeneration of disc nucleus. Six-month data collection is expected in H1/11 with the primary endpoint being patient safety. A Phase II trial is expected to begin in 2011.
• InQu: Isto’s synthetic bone graft extender for spinal fusion applications is commercially available and sold through an independent sales network primarily concentrated in the southeast/southwest. The product carries an 80%+ GM.
• ISTO’s commercialized products are currently generating a $10M+ annual run rate.
LDR

Company description
LDR provides innovative products for both fusion and non-fusion surgery worldwide through partnerships with surgeons and sales people to help ensure successful and reproducible clinical results. All the resources of the company are dedicated to the spine and neuro-surgical markets, which enables it to be a strong player in a rapidly changing high-tech field.

Key takeaways
- VerteBRIDGE, a minimal invasive stand alone interbody technology for anterior lumbar and cervical spine fusion, is the market-leading product for the company.
- The 24-month follow up for Mobi-C (artificial cervical disc) studies for both one level (n=260) and two levels (n=~335) were presented with very positive results. Of note, the one-level data showed an overall study success 8.3% better for Mobi-C, while two level data appears to support statistical SUPERIORITY versus ACDF. The one level PMA was submitted in January 2011, and the two level PMA for MOBI-C is expected to be submitted in the middle of March 2011.
- The company employs direct reps and exclusive and non exclusive distributors across US, China, France, Brazil, South Korea, Spain and Germany, and has an exclusive distributor network in 26 countries across the world.
- In 2010, LDR grew global revenues approximately 45% YoY to $60M, with 77% YoY growth in the US.

OmniGuide

Company description
OmniGuide is the worldwide leader in developing, manufacturing and marketing precision flexible CO2 laser fibers designed to help surgeons optimize their use of CO2 lasers in safely and effectively treating patients with a broad range of medical conditions. OmniGuide is committed to developing products that improve and expand surgical treatment options, improve clinical outcomes, and reduce treatment complexity and time. OmniGuide has several leading-edge flexible laser fibers for use in both hospital and office settings, sold as a part of the BeamPath brand.

Key takeaways
- The OmniGuide system is a precise surgical cutting and ablation tool utilizing CO2 laser energy. The system has been used in over 30,000 surgeries in the ENT, neurosurgery and gynecology fields.
- The company has 50 direct reps in the US and 10 distributors in OUS markets. The company also signed recent agreements in the UK, Italy, Spain and Netherlands.
- Capital equipment and disposable sale model driving sales from $2M in 2007 to $18.5M in 2010, with expected sustainable breakeven operational results at $30M. Disposables carry an ~80% gross margin.
Orthalign

Company description
Orthalign is committed to providing orthopedic surgeons with user-friendly, cost-effective, surgical navigation products for precise alignment. The company pioneered the KneeAlign system, a palm-sized, surgical navigation system for tibial alignment in total knee arthroplasty. The system is compatible with all total knee arthroplasty implant systems.

Key takeaways
- The latest generation of the KneeAlign system, 510(k)-cleared in Q1/10, is a disposable handheld device that simplifies the taking of anatomical landmarks and alignment of the implants for TKA. The product works with all TKA systems.
- The company expects to have completed 1,000 cases by the end of Q1/11.
- The next generation system, designed for femoral alignment, is expected to gain clearance in 2011.
- The company has four clinical studies underway, one of which was recently accepted for publication in the Journal of Arthroplasty.

OrthoHelix

Company description
OrthoHelix is a medical device company developing a comprehensive line of implants and instruments for use in hand and foot reconstructive surgery. OrthoHelix's initial product was the MaxLock Plate and Screw System, designed by a group of foot and ankle surgeons. The MaxLock system is a low profile, anatomically designed plate that offers multi-planar fixation. The MaxLock Plate and Screw System has since been improved into a second generation system, the MaxLock Extreme Innovative Plate and Screw System, which can be used in a variety of applications, including the foot/ankle and hand/wrist in both adult and pediatric patients.

Key takeaways
- The companies newest plating system, the MaxLock Extreme, is a comprehensive system offering anatomical plates, locking and non-locking, compression and polyaxial plating options.
- The EdgeLock incorporates a unique design to treat flat and calvus foot deformities with a plate/screw system rather than screws alone.
- The company achieved full-year positive EBITDA in 2010 and expects a positive net income for 2011.

OrthoScan

Company description
OrthoScan is a privately held medical device company providing state of the art imaging with a focus on orthopaedics. OrthoScan's Mini C-Arm is used for fluoroscopic imaging of the extremities in orthopaedic surgery and digital diagnostic imaging. The company’s
smaller and lighter weight Mini C-Arms provide superior adjustment-free image quality to healthcare professionals.

**Key takeaways**

- OrthoScan has developed a platform of Mini C-Arm products focusing on the extremity markets. The company is focusing on developing products for hospitals and surgery centers, extremity focus clinics and imaging clinics.
- Additionally, the company was displaying its new Mobile Digital Imaging product at this year’s Academy. This product is significantly different than competing products as it is much more compact and versatile.
- The company has almost 20 independent reps and stocking dealers serving over 12 countries.

**OrthoSensor**

*Company description*

OrthoSensor develops multiple accurate, low cost, easy to use, and versatile sensor systems for the multi-billion-dollar orthopedic market. OrthoSensor is developing and commercializing intelligent orthopedic implants and instrumentation that utilize advanced sensor and wireless communication technology to enhance orthopedic patient care. OrthoSensor’s proprietary technology is designed to improve surgical implantation and subsequent management of orthopedic implants for total joints, trauma and spine procedures. OrthoSensor’s sensors are designed to assist the surgeon via “smart” intra-operative instrumentation and allow post-op monitoring of the implant. The goal of intelligent implants and surgical procedures is to enable surgeons to obtain better clinical outcomes for their patients and allow remote monitoring of orthopedic implant function, as well as the patients overall musculoskeletal health.

**Key takeaways**

- Orthosensor is developing a platform of technologies intended to surround all aspects of arthroplasty, including planning, data collection/analysis and implants.
- Orthosensor’s three platforms are Surgical, encompassing balancing and alignment of implants; Intelligent Implants, products that are capable of monitoring for complications and communicating wirelessly with surgeon software; and Analytics, a data collection program that enables surgeons/hospitals to track and monitor all aspects outcomes of a case.
- The first product to be commercialized from the surgical platform is the OrthoSensor Knee Trial, a disposable, “smart trial” that incorporates sensors and electronics to analyze fit and joint load to determine the precise orientation and center of loading prior to implantation. The first knee trial has FDA clearance and is expected to launch for use with Stryker’s triathlon system in 2011.

**Paradigm Spine**

*Company description*

Paradigm Spine is a provider of non-fusion and fusion spinal implant solutions that serve to address the unmet clinical needs of spine surgeons and their patients. Starting with the coflex interspinous implant technology, Paradigm Spine develops a full non-fusion
product portfolio of motion preserving, tissue sparing technologies as well as fusion products.

**Key takeaways**

- The company has three product families that treat degenerative disc disease and spinal stenosis.

- Paradigm has three clinical studies underway, including a Level I study evaluating fusion vs. non-fusion for the treatment of stenosis. Enrollment in the study is complete, and the company expects to submit it to the FDA in 2011. The study includes a 97% patient follow-up out to two years.

- The company has over 600 customers worldwide, is growing at a rate of 37% and expects 2011 revenues of ~$20M.

**PEAK Surgical**

**Company description**

PEAK Surgical is a medical device company that is committed to providing physicians with surgical tools that have the precision of a scalpel and the bleeding control of traditional electrosurgery without the extensive collateral damage. Its flagship product, the PEAK Surgery System, consists of the PEAK PlasmaBlade, a family of disposable, low-temperature cutting devices, and the PULSAR Generator, which supplies pulsed plasma radiofrequency energy to the PlasmaBlade.

**Key takeaways**

- The PEAK Surgery System is cleared for use in general, plastic and reconstructive, ENT, gynecologic, orthopedic, arthroscopic, spinal and neurological surgical procedures in the United States and for use in general surgery in the EU.

- The benefits of the PEAK product include its precise cut, excellent coagulation and low thermal damage. The product is utilized for cutting skin and soft tissue like a scalpel but results in stronger, faster wound healing.

- The PEAK PlasmaBlade has been used in over 50,000 cases to date with no adverse events. Revenues in 2010 totaled over $16M, with YoY revenue growth exceeding 260%.

**ProChon Biotech**

**Company description**

ProChon Biotech is a privately owned biotechnology company focused on modulating the fibroblast growth factor (FGF) system to enable it to create more effective solutions for tissue regeneration. ProChon Biotech is pioneering new technologies that are redefining the focus of clinical orthopedics from traditional metal implants, plates, and screws to biology-based products for tissue regeneration, expanding treatment options, improving patients’ quality of life and reducing healthcare costs.

**Key takeaways**

- ProChon announced its intent to merge with Histogenics, becoming a wholly owned subsidiary of the company. The new company aims to combine ProChon’s cell therapies technology with Histogenics tissue engineering products into an industry
leading regenerative medicine company. The merger is in its final stages and is expected to be completed in the coming months.

- BioCart Cartilage is bio-scaffold technology that is composed of Fibrin & HA with Fibroblast Growth Factor to provide a biomimetic environment. Cells are delivered at a concentration of natural cartilage. It is non-mitogenic, biocompatible and immunogenic.

- ProChon is currently in the final stages of its Phase II clinical trial in the US for the BioCart Cartilage Regeneration System. Phase III is expected to commence in 2011 with a 245 patient superiority study at 20-25 sites with an expected endpoint of 12 months.

- Product pipeline includes CartiMate Scaffold for Cartilage Repair in microfracture procedures and One Step FGF2v plus Stem cell for Cartilage Regeneration.

- The new company plans to recapitalize post merger with a series A round of financing intended to raise $24M, which is expected to be the last financing until an exit through purchase in 24-36 months.

**Ranier Technology**

**Company description**

Ranier Technology is a medical device developer utilizing its proprietary Precision Polyurethane Manufacturing (PPM) technology to bring next generation, motion preservation spinal implants to clinical use. The PPM technology enables the design and production of load sharing, polyurethane implants with regions of graduated hardness which confer both programmable mechanical properties and high durability under load. Ranier’s lead products are Cadisc-L, a compliant lumbar total disc implant, and Cadisc-C, the company’s total replacement disc for the cervical spine.

**Key takeaways**

- The Cadisc-L received CE Mark in Q3/10 and is currently selling in Germany, Netherlands, Sweden and the UK. The company plans to submit an IDE in 2011.

- The company’s cervical disc, Cadisc-C, is expected to begin a European clinical trial H1/11.

- The PPM technology produces a single piece, variable density implant that is intended to better replicate the natural anatomy and prevent adjacent disc degeneration.

**Relievant Medsystems**

**Company description**

Relievant Medsystems is a private, clinical-stage medical device company that is developing a novel treatment for chronic low back pain. The company’s Intracept product, currently under development, is a minimally invasive system that allows a spine surgeon to target low back pain by ablating a nerve target within the vertebral body. The treatment takes one hour and is performed under real-time fluoroscopic guidance.
Key takeaways

- The company’s Intracept technology utilizes a small probe that is positioned in the vertebrae where it uses radiofrequency ablation to target one of the culprit nerves, rendering it unable to transmit.

- The 510(k) pivotal study is a 200-patient, prospective, randomized, controlled, double-blinded study designed to define pain reduction through ODI with an endpoint of six months. Simultaneous US/OUS trials received conditional FDA approval in Q4/10 with enrollment expected to begin soon. Data is expected H2/12, with full US product launch in 2013.

Replication Medical

Company description

Replication Medical is a developer of proprietary, hydrogel-based products for the spine, vascular and other surgical markets. The company designs and develops novel, biomimetic hydrogel implants which provide attractive alternatives to conventional surgical materials. Replication has just released its first product, the EnGuard Vessel Guard. The US FDA has approved the EnGuard device as a cover for spinal blood vessels following anterior vertebral spinal surgery.

Key takeaways

- EnGuard Vessel Guard can be easily inserted between the spinal column and the blood vessels after the major portion of the surgery has been concluded. There is no prep time associated with the product.

- The company recently received clearance in the EU for two new products, the Gelfix Interspinous Spacer and GelStix Nucleus Augmentation.

- The Gelstix is a shape memory device for use as a disc replacement for patients suffering from degenerative disc disease. The product is injected through an 18 gauge needle into the disc space to restore the natural anatomy. The product received CE Mark in 2010 and has been used in 20 patients. The company has a clinical trial underway in Europe with hopes to apply for an IDE in the US Q2/Q3-2011.

- The company is also developing the GelFix Interspinous Spacer, which is designed to provide a “soft solution” for spinal stabilization.

Salient Surgical Technologies

Company description

Salient Surgical Technologies develops and markets advanced energy devices for use in surgical procedures. The company’s proprietary TRANSCOLLATION technology allows surgeons to rapidly treat tissue at the surgical site by transforming specific types of collagen-based structures to improve patient outcomes. The net effect is reduced bleeding, which improves surgeon visibility, decreases surgery time and decreases pain and swelling and improves the rehabilitation process. Currently, Salient’s products are used most often in orthopedic reconstruction and trauma, spine surgery and in surgical oncology. To date, TRANSCOLLATION technology has been used in over 500,000 surgical procedures.
Key takeaways

• AQUAMANTYS 3, which was on display at the conference, is designed to be much more user friendly and could boost consumable revenues.

• The company continues to grow its feet on the street, as well as sales rep productivity, with 90 reps in 2010 averaging $833,000, which was up from $748,000 in 2009 on 75 reps.

• Salient has a robust commercialization plan for 2011 with nine product launches planned for 2011 in the ortho-trauma, spine and brain tumor, oncology and technology platforms.

• Revenues in 2010 increased approximately 37% to ~$80M. Additionally the company has been EBITDA positive since 2009.

SI-BONE

Company description

SI-BONE is a leading spinal medical device company dedicated to the development of tools and products for diagnosing and treating patients with low back issues related to sacroiliac (SI) joint pathology. The company has developed and is manufacturing and marketing less invasive approaches using implants for the treatment of SI joint pathology. SI-BONE has an experienced management team with extensive experience in orthopedic and spine medical devices.

Key takeaways

• The iFuse Implant System is a minimally invasive product for sacroiliac joint surgery and fusion. It uses a unique triangular-shaped implant rather than a standard screw for improved fusion of the sacroiliac joint.

• The iFuse is cleared for use through 510(k) and CE Mark. The company trained over 25 surgeons on the system in 2010 and aims to train an additional 400 in 2011.

Small Bone Innovations

Company description

Small Bone Innovations (SBI) is an orthopedics company that provides surgeon-designed and clinically proven total technology solutions around a joint for small bone and joint (SB&J) surgeons. Its efforts concentrate on improving the quality of life of patients by using SBI’s Precise Guidance Technology (PGT) allowing for consistent, repeatable, simple, minimally invasive techniques, resecting the least amount of bone tissue and leaving the greatest opportunity for future options open.

Key takeaways

• The company received PMA approval for its STAR system in May 2009. Reimbursement is being added by payers, most recently by Aetna and Cigna, and the product was introduced in Q4/09 with a controlled roll-out. There is only one other approved three-piece ankle replacement (approved via PMA) on the market today (marketed by JNJ/DePuy). Other companies, such as Wright Medical and Tornier, market a two-piece ankle (cleared via 510k in US).

• Approximately 90 articles have been published on the STAR system.
• SBI experienced Y/Y worldwide growth of 27% in 2010.

**Sonoma Orthopedic Products**

**Company description**

Sonoma Orthopedic Products (SOP) is a private company dedicated to developing products for the minimally invasive repair of problematic fractures. SOP has developed proprietary technology, known as Wavibody Technology, specifically to address fracture fixation. The company is targeting the treatment gap between casting and plating, starting with extremities and progressing toward weight-bearing long-bone. Sonoma’s first two FDA cleared products are for distal radius fractures and clavicle fractures.

**Key takeaways**

• Benefits of Wavibody Technology include a small incision for placement, which minimizes soft tissue trauma and provides three-dimensional support of the subchondral plate.

• Clinical data to date supports improved functional outcome and a lower rate of mal-union and non-union compared with non-operative treatment at one-year follow-up.

• Sonoma Orthopedic Products has received regulatory clearance for seven products and expects an additional clearance in 2011.

• The company is currently conducting a clinical study at the Mayo clinic to assess the efficacy of intramedullary fixation as compared to locked plates in wrist fractures.

• Sales and marketing infrastructure is being expanded to support US/OUS commercialization.

**Soteira**

**Company description**

Soteira has created and developed a cavity creation system for vertebral augmentation that provides superior and precise control of the instruments, implant and cement during the procedure. Over the past four years, the company has focused on development of easy-to-use and cost-effective designs, issuance of key patents for the products, building extensive laboratory and clinical data, completing regulatory approvals and preparing for manufacturing and commercialization.

**Key takeaways**

• The Soteira device treats VCF via an MIS implanted cage device that creates a cavity for cement placement. The implant has openings to allow for directional cement flow. A pilot study has been completed (n=20), with one-year follow-up showing no safety issues and comparable pain relief to vertebroplasty and kyphoplasty.

• Soteira has submitted the study results to the FDA for 510(k) clearance review.

• The product received CE Mark in 2009 and is commercially available in Germany, the UK, Italy, Spain, Belgium and Austria.
Spinal Kinetics

Company description

Spinal Kinetics is focused on partnering with spine surgeons to develop innovative and practical motion preservation systems for treating degenerative diseases of the spine. The company was founded in 2003 with the charter to develop a more physiologic performing artificial disc for the spine. Spinal Kinetics has developed the M6 series of artificial discs, which are designed to replicate the anatomic structure and biomechanical performance of a natural disc.

Key takeaways

- CE Mark has been received for both the Cervical (2006) and Lumbar (2009) discs. Over 8,300 cervical and 2200 lumbar M6 discs by Spinal Kinetics have been implanted to date.
- Spinal Kinetics is currently the number two player in the EU market with an estimated 23% share of the European cervical artificial disc market (#1 in Germany through a direct sales force). Distribution was expanded into 15 countries, including the UK, Switzerland, Spain, Portugal and Turkey.
- For the M6-C cervical disc, a 30-patient non-randomized pilot study was completed with one-year follow-up. All endpoints were met, and data was submitted to FDA.
- Conditional approval from the FDA is granted for the M6-C pivotal trial.

SpinalMotion

Company description

SpinalMotion is dedicated to preserving motion in the spine for patients with degenerative disc disease. The company combines the kinematics of a mobile bearing design with materials designed for low wear and improved longevity. Building upon international clinical experience since 2002, SpinalMotion completed enrollment in IDE clinical trials for lumbar and cervical artificial discs in the United States with approximately 900 patients. The Kineflex lumbar disc and Kineflex-C cervical disc are designed to mimic the motion of a normal spinal disc by using mobile bearing and metal-on-metal designs to minimize wear and improve longevity.

Key takeaways

- The Kineflex lumbar TDR pivotal trial two-year follow-up has completed. The 510-patient lumbar trial compared the Kineflex to J&J’s Charite lumbar TDR and was initiated in June of 2005. This was the first “disc vs. disc” study in the US. The results demonstrated a higher composite success than control. SpinalMotion submitted its PMA in Q4/09.
- The Kineflex-C cervical TDR trial (n=340, sites = 23 US) has also completed its two-year follow-up. The results demonstrated statistical superiority compared to fusion control. Lower narcotics usage was noted at six weeks vs. fusion, and patients returned to work in half the time. The PMA was submitted in Q1/10.
- Over 4,500 patients have been treated worldwide with the Kineflex lumbar and cervical discs.
• SpinalMotion is developing an MRI-compatible cervical disc (pilot study starting Q2/10) and a lateral lumbar disc (pilot started Q3/09, CE Mark expected H1/11).

**Spine View**

**Company description**

Spine View is committed to the development and commercialization of novel, minimally-invasive technologies aimed at improving spinal decompression and fusion with a collection of surgical and interventional products and procedures. Their enSpire Surgical Discectomy System is designed to cut, grind, and remove tissue to facilitate more complete discectomies and accelerate tissue removal in open and MIS lumbar interbody fusion procedures.

**Key takeaways**

• SpineView is developing a platform of endoscopic technologies for the treatment of spinal disorders

• The enSpire Interventional Discectomy system is a needle-based technology for discectomy removal. It is the size of a 16 guage needle that can expand within the vertebral space.

• The company is also developing a complete line of endoscopic products including a camera system, bone cutter and discectomy. The camera operated device is intended to bring a true MIS system to the field of spinal surgery.

**Spineart**

**Company description**

Spineart is focused on becoming a main actor in both fusion and motion preservation markets by combining the desires of leading surgeons with the creativity of its team, and by drastically simplifying the use of the set. Spineart has successfully marketed a full range of innovative fusion implants as well as the world’s first pre-assembled, MRI compatible, anatomical cervical disc designed to absorb shocks, the BAGUERA. the BAGUERA prosthesis has been successfully implanted over 4,000 times in 20 countries and on five continents.

**Key takeaways**

• Spineart opened its US office in 2009 and is focused primarily on MIS, motion preservation and fusion.

• Spineart’s products were used in over 17,000 procedures in 2011. The company is profitable and has grown over 107% in the past two years.

**Vertebral Technologies**

**Company description**

Vertebral has pioneered a straightforward intra-operative interbody spacer assembly technology. The company’s proprietary technology was designed to enable spine surgeons to achieve a large, customized and anatomical implant while utilizing a familiar, less-invasive posterior implant approach.
**Key takeaways**

- The company currently has its InterFuse interbody fusion product commercially available for posterior procedures. The transforaminal system began a limited launch in Q4/10, with a limited launch in Q1/11 planned for the anterior system and a Q4/11 launch projected for its lateral procedure device.

- The benefits of the InterFuse device are more complete endplate coverage, which reduces subsidence and migration, as well as loading on posterior stabilizing instrumentation, which reduces the risk of hardware loosening. The products are also customizable to allow for a range of patient anatomy.

- The company plans to have four spinal fusion products launched by the end of 2011.

- Since its 510(k) clearance in June 2008, InterFuse has been implanted in over 1,200 cases by 100 surgeons.

- The InterCushion Disc Nucleus Replacement utilizes the same proprietary intraoperative assembly technology as InterFuse, but is designed as a nucleus replacement. The InterCusion device is expected to be used in its first clinical cases in Q2/11.

**VertiFlex**

**Company description**

VertiFlex is a privately held medical device company dedicated to the advancement of minimally invasive and motion preserving technologies for disorders of the spine. The company currently markets products globally in addition to conducting a pivotal human IDE trial for a next generation interspinous spacer. The Superion interspinous spacer is a percutaneous titanium implant that fits between the spinous processes in the lumbar spine. Superion received CE Mark in 2007 and is currently undergoing a pivotal FDA clinical trial for the minimally invasive treatment of spinal stenosis.

**Key takeaways**

- The company’s Superion interspinous spacer IDE clinical trial is a 250-350 patient prospective, 1:1 randomized to X-STOP control. The trial is expected to finish enrollment in Q3/11 and includes traditional spine surgeons and spine interventionalists.

- The company plans to publish one-year, two-year and full trial results in 2011, 2012, 2013, respectively, with an expected PMA submission in 2013.

- The results of two international studies show less than a 1% device-related adverse event rate and a 3% combined explant rate. Furthermore, efficacy data shows ~50% improvement in pain and function, ~90% success at one year on Zurich Claudication Questionnaire (ZCQ) and ~80%-90% success rate on Oswestry Disability Index (ODI) at one year.

- The Superion ISS device addresses a $250M WW market that is growing at 15-20% per year.

- Predicate devices are currently reimbursed by medicare under a Category III code. Management expects a Category I designation by the end of 2012.
PRICE TARGETS AND INVESTMENT RISKS

Alphatec Holdings (ATEC : NASDAQ : $2.74 | BUY)

Price target

Our $3.50 price target is based on the average of a 1.6x EV/sales multiple applied to our 2012 revenue estimate of $217.0M. In our calculation, we assume cash of $23.2M, debt of $56.6M and shares outstanding of 88.1 million.

Investment risks

• New product delays could impact future expectations.
• The company operates in the highly competitive spine market
• Potential need for capital.

ArthroCare (ARTC : NASDAQ : $35.25 | BUY)

Price target

Our $41.50 price target is based on a 2.6x EV/sales multiple applied to our F2012 sales estimate of $406.8M. Our price target assumes cash of $132.5M, $0M in debt, and 33.2M shares outstanding.

Investment risks

• ArthroCare is currently undergoing a large amount of legal activity related to the alleged misconduct of previous management and the restatement.
• The SEC’s Division of Enforcement is currently conducting a formal investigation into the accounting matters related to the restatement.
• ArthroCare is being investigated by the Department of Justice for sales, accounting, and billing procedures related to its Spine business.

BioMimetic Therapeutics (BMTI : NASDAQ : $13.40 | BUY)

Price target

Our $17.50 price target is based on an increase in the average multiple to 2.9x and 28.3x applied to our C2013 revenue and EPS estimates, respectively, discounted back at 25% per year.

Investment risks

• BioMimetic Therapeutics is subject to the regulation of the FDA and international health organizations.
• The company’s products are dependant on specialty suppliers of raw materials.
• BioMimetic’s Augment products are closely related and adverse or unwanted results from any one product could have the potential to impact the entire portfolio.
• BioMimetic’s dependence on rhPDGF, which is supplied by Novartis (previously Chiron)
China Kanghui Holdings (KH : NYSE : $17.05 | BUY)

Price target
Our $19.50 PT based on a P/E multiple of 19.9x applied to our estimated 2012 EPS of $0.98

Investment risks
- Kanghui is vulnerable to adverse changes in political, economic and other policies of the Chinese government.
- Healthcare reform in China may adversely affect its business.
- Kanghui’s business is vulnerable to changes in coverage and reimbursement from the government, public insurers or third-party payers.

Exactech (EXAC : NASDAQ : $18.53 | BUY)

Price target
Our $26.50 price target is based on a 21.3x PE multiple applied to our C2012 GAAP EPS estimate of $1.25.

Investment risks
- New product delays could impact future expectations.
- Acquisitions may not perform to expectations

Integra LifeSciences (IART : NASDAQ : $50.10 | BUY)

Price target
Our $54.00 based on a P/E multiple of 17.0x applied to our estimated 2012 pro forma EPS of $3.20.

Investment risks
- Investors are unwilling to overlook acquisition expenses as hone-time in nature due to acquisitive nature of company
- The company makes a dilutive or non-performing acquisition
- Reduction in hospital spending could impact capital goods business.

NuVasive (NUVA : NASDAQ : $26.94 | HOLD)

Price target
Our $24.00 price target is based on our cash/non-GAAP EPS estimate of $1.44 applied to the 17.0x P/E multiple.

Investment risks
- Future acquisitions could impact corporate growth or be dilutive to shareholders.
- Department of Justice inquiries could impact the company.
- Patent litigation with Medtronic could impact the company.
Orthofix (OFIX : NASDAQ : $32.30 | BUY):
Price target
Our $41.00 price target is based on a 13.7x P/E multiple applied to our 2012E GAAP EPS estimate of $3.00.

Investment risks
- Department of justice is currently investigating the company’s spine and bone growth stimulator businesses.

Orthovita (VITA : NASDAQ : $2.38 | HOLD):
Price target
Our $2.50 price target is based on a 2.0x EV/sales multiple applied to our 2011 revenue estimate of $103.5M. We are also assuming $20.9M in cash, $34.3M in debt and 76.7 million shares outstanding.

Investment risks
- Recent studies published in the New England Journal of Medicine showed no clinical benefit for the use of vertebroplasty, which could impact future sales of CORTOSS.
- Pricing sensitivity in the spine market could also limit CORTOSS adoption.
- OrthoVita’s VITOSS product line is facing increased competition.

RTI Biologics (RTIX : NASDAQ : $2.58 | BUY):
Price target
Our $3.25 price target is based on the PE multiple of 19.2x applied to our 2012 GAAP EPS estimate of $0.17.

Investment risks
- RTI management must continue to execute on merging the Regeneration and Tutogen businesses.
- RTI relies on distribution partners (more than 70% of revenues) to market its spine, BGS, dental, general orthopedic, and surgical specialty products.
- Any discrepancies in product sterility would negatively impact the entire business.

Stryker (SYK : NYSE : $63.67 | BUY)
Price target
Our $66.50 price target is derived from a 18.0x multiple applied to our 2012 EPS estimate of $3.70.

Investment risks
- Company’s products are subject to FDA regulations.
- Weak US economy and impact on Capital goods purchases.
Wright Medical Group (WMGI : NASDAQ : $16.66 | HOLD)

Price target

Our $15.50 price target for Wright Medical is based on a multiple of 19.5x applied to our 2012 GAAP ESP estimate of $0.80.

Investment risks

• Delays in new product launches could impact financial projections.
• Wright was one of the first to market with its Ceramic-on-Ceramic device and also Big Femoral Head (BFH) metal-on-metal technology. Several competitors have been catching up with Wright, gaining FDA approval of competing products.

Zimmer Holdings (ZMH : NYSE : $62.75 | BUY)

Price target

Our $71.75 price target is based on a multiple to 14.0x, applied to our 2012E pro forma EPS projection of $5.13

Investment risks

• Product pipeline is subject to regulatory risk.

Gender specific products are not adopted.
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