Executive Summary

China Kanghui has emerged as one of the leaders in China's orthopedics industry, building a business first on trauma and, more recently, spine. Now, with a pending move into reconstruction, the company is looking to other emerging markets, and eventually the US and Europe.

"This company has the opportunity to become one of the largest medical device companies in China over the next three to five years. It's just a massive opportunity. If we do our job right, this should be a multibillion-dollar company."

- Chen Yu, China Kanghui

Orthopedics

China Kanghui Holdings has emerged as one of the leaders in China's orthopedics industry, building a business first on trauma and, more recently, spine. Now, with a pending move into reconstruction, the company is looking to other emerging markets, and eventually the US and Europe.

By Tom Salemi

Six years ago, Kanghui's founder made an unusual move for a Chinese company. He handed control of the company to a CEO with experience at a multinational, DePuy Orthopedics.

Kanghui reached outward further, raising $34.5 million from Chinese entities of US venture firms, establishing a network outside of China.

Kanghui left some money on the table by going public in the US instead of in the Hong Kong market, but the IPO gave the company the validation it needed to complete its next step onto the global...
stage - a licensing deal with a US orthopedics company.

With a line of FDA-approved hip and knee implants queued up for release in the next two years, Kanghui feels it’s in position to not only dominate China and other emerging markets, but also to someday beat US-based multinationals on their home turf.

In emerging markets like China and India, the chronically ill, if frustrated with Western medicine, sometimes find a certain level of relief in so-called traditional treatments that have been used for centuries in Asia. Used by an estimated 80% of the population in some Asian and African countries, according to the World Health Organization, these traditional medicines and treatments might on occasion be a last resort for those suffering from intractable diseases or conditions that simply don’t respond to remedies accepted in the West.

One might wonder if medtech investors - particularly those investing in orthopedics - might be open to new alternatives as well. The US market is stagnant. Michael Matson, senior analyst at Mizuho Securities USA Inc., puts his 2012 growth forecast for joint reconstruction and spine to be 1% and 0%, respectively. Even his 6% growth projection for trauma is down a percentage point from last year’s growth. "We are reducing our orthopedic market forecasts due to slow economic growth, stubbornly high unemployment, and poor consumer confidence," Matson writes. "We no longer expect a significant rebound in orthopedic procedure growth in 2012."

Contrast those projections with the market in China, where the number of orthopedics procedures is expected to see 18.2% in compound annual growth in coming years (2009-2015) and the number of spine procedures is predicted to follow behind with 17.6%, according to "China Surgical Procedure Volumes 2010" by Clearstate Pte. Ltd., a report distributed by Medtech Insight, a division of Elsevier Business Intelligence. (See Exhibit 1.) This growing orthopedic pie has presented a tempting target for multinational companies for years. But the opportunity comes with unique challenges and stiff competition from foreign and domestic suppliers. "Much like any company here today, we face not only the globally competitive large orthopedic manufacturers, but also up to 20 to 30 local competitors," explains Sean O’Hara, managing director of emerging markets, Asia Pacific, for Zimmer Holdings Inc. "This makes China a far different market compared with the US or other established markets."

### Exhibit 1

**Growth In Number Of Orthopedic And Spine Procedures In China (2009-2015)**

<table>
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<tbody>
<tr>
<td>Fracture Management and Repair</td>
<td>261,186</td>
<td>327,315</td>
<td>409,672</td>
<td>513,253</td>
<td>642,709</td>
<td>804,817</td>
<td>1,007,814</td>
<td>25.2%</td>
</tr>
<tr>
<td>Joint Replacement</td>
<td>173,117</td>
<td>202,736</td>
<td>237,523</td>
<td>278,718</td>
<td>327,571</td>
<td>385,588</td>
<td>454,581</td>
<td>17.4%</td>
</tr>
<tr>
<td>Tendon Repair</td>
<td>209,310</td>
<td>239,347</td>
<td>273,695</td>
<td>312,972</td>
<td>357,885</td>
<td>409,244</td>
<td>467,974</td>
<td>14.4%</td>
</tr>
<tr>
<td>Amputation</td>
<td>149,070</td>
<td>160,996</td>
<td>173,876</td>
<td>187,786</td>
<td>202,809</td>
<td>219,033</td>
<td>236,556</td>
<td>8%</td>
</tr>
<tr>
<td>Ortho Total</td>
<td>793,083</td>
<td>930,394</td>
<td>1,094,956</td>
<td>1,292,729</td>
<td>1,530,974</td>
<td>1,818,682</td>
<td>2,166,925</td>
<td>18.2%</td>
</tr>
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</thead>
<tbody>
<tr>
<td>Total Disc Replacement</td>
<td>96,485</td>
<td>111,923</td>
<td>129,831</td>
<td>150,604</td>
<td>174,700</td>
<td>202,652</td>
<td>235,077</td>
<td>16%</td>
</tr>
<tr>
<td>Disc and Bone Removal</td>
<td>32,893</td>
<td>40,037</td>
<td>48,733</td>
<td>59,317</td>
<td>72,200</td>
<td>87,881</td>
<td>106,968</td>
<td>21.7%</td>
</tr>
<tr>
<td>Spinal Fusion</td>
<td>72,299</td>
<td>86,065</td>
<td>100,677</td>
<td>118,415</td>
<td>139,293</td>
<td>163,871</td>
<td>192,810</td>
<td>17.6%</td>
</tr>
</tbody>
</table>
Zimmer and its competitors, Medtronic Inc., Stryker Corp., Biomet Inc., and DePuy Orthopaedics Inc., a division of Johnson & Johnson’s DePuy Inc., don’t reveal details about sales in China, lumping the numbers into larger “emerging markets” portfolios. The companies clearly are making headway in the market, but not enough to lift their moribund orthopedics franchises. But one domestic player in the Chinese market - China Kanghui Holdings - is looking to ride this surge in orthopedics in China and other so-called emerging markets onto an international stage. And over the past several years, the company has taken important steps to position itself as a global player, partly by courting investors and partners outside of China.

A Perfect Union

Kanghui's global pursuits require a unique global perspective, something the company has been compiling steadily over the past five years. Like other Chinese orthopedics companies, Kanghui began in 1997 as a trauma company. The company emerged among the dozens of competitors along with Trauson Medical Instrument Co. Ltd. and Shandong Weigao Group Medical Polymer Co. Ltd. as leaders in the country's orthopedics industry. In 2005, Kanghui's founder Yikang Jiang, now chairman, took the step of installing a professional manager as CEO, unusual for a Chinese company. Libo Yang had spent four years at DePuy Orthopedics as business unit head of DePuy China from 2000 to 2004, and thus brought insights not only of the Chinese market, but also of the global orthopedics market as seen from one of the world's leaders. Chen Yu, managing partner at Vivo Ventures, an investor in Kanghui, says Yang brought a new level of experience to Kanghui and he gives Kanghui's founder Jiang "a ton of credit" for giving up operational oversight to a manager with experience in the global device field. "I've just never seen it," Yu says. "Almost all the time the founder just won't let go."

A year after Yang's arrival, Kanghui raised its first round of international capital, a $5 million Series A round from IDG-Accel Growth Fund and TDF Capital China, two Asian-based entities with ties to US venture firms. Kanghui went on to raise a $27.5 million Series B round in 2008, followed by a $4 million Series B-1 extension round, bringing in SIG China Investments One Ltd., and Vivo Ventures as new investors. The relationship between Yu and Yang begin in 2007 when Vivo first approached the company for investment but was not formalized until the Series B-1 extension round in 2009. The company and Vivo Ventures had traveled on parallel tracks. Both were founded in 1997. Vivo Ventures, then called BioAsia Investments, represented one of the first US-based efforts to span the Pacific as an investor of Asian, US and European capital into US life sciences companies. Kanghui clearly had been seeking such a bridge. "The honest truth is when [Kanghui] did the financing, the company didn't need our money," Yu says. "The investors were generous to let us in. But among the management team, I think, some advocated for us to come in because we could help them on a broad set of issues." In an e-mail, Libo Yang, Kanghui's CEO, says he spoke with other US-based VCs, but felt Vivo Ventures fit best. He credits Yu and Vivo with identifying strategic partners in the US including those willing to license products to Kanghui or have the company distribute them in China. But ultimately, he sees the ties between Kanghui and its US partners as helping his company sell orthopedic devices in the US and Europe in coming years as Kanghui demonstrates its ability to manufacture quality orthopedic implants and Western markets become increasingly concerned about price. "Kanghui will become a very competitive full-line ortho player, especially in the emerging markets," Yang explains. "We will sell in
Europe, step-by-step. Then last, but not least, we will be in the US market."
Having products that are "high quality at a reasonable price will enable us to compete."

Generic Interest
Vivo Ventures' interest in Kanghui actually stems from its success in the generic drug industry. Vivo already had made an investment in Sagent Pharmaceuticals Inc., a generic drug company that went public in April. [See Deal] Yu says Vivo felt it could find similar success in the medical device industry, except there were no generic device companies. Then it became clear to Vivo - Chinese companies are the generic device companies. "They've got a large domestic market from which they can get to manufacturing scale," Yu explains. "They have an input cost advantage on labor in particular. That's a generic device company." The orthopedics industry, meanwhile, has seen limited innovation, particularly in trauma and large joint reconstruction, creating the right conditions for cost-savings through low-cost manufacturing.

Vivo Ventures' investments options were limited somewhat. Three Chinese orthopedic companies had really grown large enough to warrant investment: Kanghui, Trauson, and Shandong Weigao. Weigao was "too big" Yu says, and ultimately would sign a joint venture with Medtronic. [See Deal] "So it was really down to Trauson or Kanghui," Yu says. "Trauson is a great company, but we just felt that the Kanghui team was unusual, made up of people who had international exposure. And we saw that when you think about the next phase of growth, where you need systems and processes, it's better to have folks who are professional managers than a family-owned business." Yu says due diligence in Kanghui was also simplified, given that the company already had undergone two rounds of VC investments. Vivo also has offices in Shanghai and Chengdu with staff capable of performing the necessary due diligence.

Above And Beyond
Venture capitalists routinely take on executive roles in their portfolio companies, but those companies typically are start-ups in need of an experienced hand at the rudder in their first year or two in existence. It's far rarer for a VC to assume an executive post in a company that's received the kind of growth equity investment that Kanghui took from Vivo Ventures, but Yu did precisely that, assuming the role of chief business officer for Kanghui following the investment. This wasn't part of Yu's initial investment thesis. "This started off as a pure venture investment," he says. "Then we started to realize how much we were going to need to do in the US both in terms of partnering and in terms of capital market activities." The company needed a point person to seek out and vet potential partners. Yu says the company's options were limited by compensation. "Think about the pay scale of a Chinese company. The CEO makes roughly what a senior product manager in the US makes," he says. "So how do you hire someone who is senior in the US without upsetting the entire compensation structure?" Yu stepped up, assuming the role at Kanghui. The job came with an equity package "that would be meaningful for me," he says, while keeping the cash compensation in line with the rest of the internal compensation structure. At the same time, he took a significant cut in his Vivo salary. "For me the calculation was, if it actually works out, it'll be fine and I'll probably be economically positive," Yu says. "That was the risk I ended up taking. But my partners are very flexible, and I give them a lot of credit for that."

The flexibility was rewarded almost immediately when Kanghui staged a $68 million IPO in the US in 2010. [See Deal] By this time, Kanghui executives aspired to build out the organization into a full orthopedics company. Kanghui began as a supplier of trauma products and expanded its spine portfolio with
the 2008 acquisition of Beijing Libeier Biology Engineering Research Institute Co. Ltd., another Chinese orthopedics company with a line of spinal implants. Spine sales now account for one-third of the company’s sales. Kanghui anticipates steady growth as it releases new products including a just launched kyphoplasty system. With trauma and spine businesses thriving, the company saw joint replacement as the next significant market for expansion. To do this, Kanghui executives knew they needed significant capital, the kind that comes with a public offering.

Company executives debated whether Asian or US markets presented the best opportunity. The Hong Kong market offered the benefits of familiarity and proximity. In the long run, Yu says, it might have even allowed Kanghui to raise more capital. But the company decided a US listing would provide a level of comfort for potential partners in the US and help the company improve its brand worldwide. Just as the company had done in hiring a CEO and finding venture investors, Kanghui put an emphasis on international perception, both inside and outside of China. To execute fully on its plans to grow, Kanghui executives felt they needed something no other Chinese orthopedics company had - FDA-approved products. “One of the major challenges that a Chinese company has to overcome is, ‘Made in China,’” Yu says, that is, the perception that the products aren’t as high quality as products manufactured by Western companies. Kanghui would overcome that perception by acquiring implants developed, manufactured and sporting regulatory approval from outside of China, most notably the US. In doing so, Kanghui faced another potential concern of US companies - patent protection. (See "Device Companies Look West, East, Anyplace But US," IN VIVO, June 2011 "Device Companies Look West, East, Anyplace But US" - IN VIVO, June 2011.)

US companies in many device sectors are worried that a Chinese-based partner could turn around and manufacture an exact copy of a device. Yu says this hasn’t come up as a major issue for their partners in orthopedics where “there isn’t much IP that is meaningful anymore. That said, we honor the IP/design of all our OEM partners and that’s critical for our reputation and our long-term business interests.” Information can be difficult to come by for potential partners and investors. Kanghui executives knew a listing on the New York Stock Exchange would give interested parties all the information - and assurances - they might need. That was good news for Yu. His first task was telling Kanghui’s story to US investors.

Finding Investors
The global financial markets clearly were still struggling when Vivo first invested in 2009, just a few months removed from the economic collapse of 2008. The appetite for new device issues didn’t exist, but Kanghui did have a strong track record, selling trauma and spine products within China as well as in 24 markets worldwide. The company generated $27 million in revenue and $18.9 million in profits in 2009. It also had a hot address - China - and managed to go public on August 12, 2010, missing its $75 million target with a $68 million raise. “The people who participated in our IPO were investors interested in emerging markets,” Yu says. “We are not yet on the radar screen of medtech investors that historically invest in large cap medtech like Stryker and Smith & Nephew [Smith & Nephew PLC].” Yu speculates that Kanghui might have raised more money in a Hong Kong listing where competitors like Shandong Weigao are listed. “In the short-term I would say we paid a penalty for going public in the US,” he says. In the longer term value is higher as the company draws up plans to become an international player in orthopedics, Yu says.

The company is working to build a base of investors that includes US and
European firms, and today its institutional investor base is quite diversified. Yu is betting that the pace of Kanghui’s growth, coupled with the huge potential for organic growth in the Chinese market, will draw traditional medtech investors who can’t find growth in US-based multinationals. “We are on the cusp of companies like Kanghui getting attention from the broad medtech universe for the first time,” Yu says. “That’s part of my goal. Kanghui should really be thought of as an international business.” It’s making progress. In June, Fidelity Investments acquired nine million shares, or 6.6% of the company.

**Reaching A Consensus**

The public listing on the US markets might have helped Kanghui distinguish itself from competitors Shandong Weigao and Trauson Medical. But company executives saw that as only the first step to get ahead of the pack. The second step would be more difficult to pull off. Kanghui used the US listing to position itself as a potential partner for US orthopedics companies. Specifically, Kanghui sought out a company that would sell or license FDA-approved hip or knee implants. Kanghui clearly couldn’t partner with multinationals such as Zimmer, Stryker, Medtronic, or Biomet. They have the size and means to build a business themselves or to take a dominant position in a partnership with a Chinese company. Medtronic, for example, established a joint venture with Shandong Weigao in 2007. The company paid $221 million for 15% of Weigao and 51% of a joint venture to market its own spinal products and the orthopedic offerings of Weigao including its hip, shoulder, spine and trauma products. The pair announced last month the opening of a research and development center focused on developing new orthopedic technologies and devices.

**EXHIBIT 2**

**Kanghui’s Pipeline Products**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>TYPE</th>
<th>PRODUCT</th>
<th>LAUNCH</th>
</tr>
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<tbody>
<tr>
<td>Trauma</td>
<td>Internal Fixation</td>
<td>LISS System</td>
<td>2010</td>
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<tr>
<td></td>
<td></td>
<td>Ankle Plate System</td>
<td>2012</td>
</tr>
<tr>
<td></td>
<td>External Fixation</td>
<td>External Fixation System</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cable, Pin &amp; Wire System</td>
<td>2011</td>
</tr>
<tr>
<td>Spine</td>
<td>Thoracolumbar</td>
<td>GS General Spine System</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>U Spine II System</td>
<td>2011</td>
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<tr>
<td></td>
<td></td>
<td>MIS Pedicle Screw System</td>
<td>2012</td>
</tr>
<tr>
<td></td>
<td>Cervical</td>
<td>New ACP System</td>
<td>2011</td>
</tr>
<tr>
<td></td>
<td>Interbody</td>
<td>Kyphoplasty</td>
<td>2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cages &amp; Mesh</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEEK Cage</td>
<td>2012-2013</td>
</tr>
<tr>
<td>Large Joint</td>
<td>Consensus</td>
<td>Cementless Hip System</td>
<td>2013-2014 (China); 2012 (International)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knee System</td>
<td>2013-2014, (China); 2012 (International)</td>
</tr>
<tr>
<td></td>
<td>Wei Rui Li</td>
<td>Total Knee System</td>
<td>2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bipolar Hip System</td>
<td>2012</td>
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</tbody>
</table>

SOURCE: Canaccord Genuity

Kanghui instead signed an agreement early this year with a privately held US-based orthopedics company, **Consensus Orthopedics Inc.** (formerly Hayes Medical). The partnership gives Kanghui access to three lines of hip and knee implants designed and constructed by Consensus. In exchange, Consensus
secured a small equity investment, the promise of royalties from sales of its
designs in China (under Kanghui's brand name), and potential cost savings
through an OEM agreement that will see a portion of the company's
manufacturing done in Kanghui's Beijing plant. (Terms of the equity investment
weren't disclosed, but Kanghui officials told analysts it was less than $5 million
and gave Kanghui less than 20% ownership.) Kanghui doesn't expect to get
State Food and Drug Administration (SFDA) approval for the implants until
2012, but it's already laying the foundation for a recon practice through the
acquisition of a majority share in Beijing Wei Rui Li Medical Device Co. Ltd.,
a Chinese orthopedics company with a small line of hip and knee implants. [See
Deal]

Together, the products coming to Kanghui through the Consensus deal and the
Wei Rui acquisition give the company an immediate reconstruction pipeline. (See Exhibit 2) The latter deal will allow Kanghui to serve smaller, more rural
markets in China with less expensive implants. But the products acquired
through Consensus will put Kanghui up against the larger multinational
companies currently selling to China's top-tier hospitals. Kanghui will have
something no other major Chinese orthopedic manufacturer can claim, an FDA-
approved hip and knee implant, giving it an enviable edge against all comers,
both foreign and domestic.

Founded in 1992, Consensus Orthopedics sells hip and knee implants in the
US, Europe, Turkey, and so-called emerging markets. The company began
hitting its stride in recent years, but it's still quite small, bringing in roughly $15
million in revenue. The US accounts for 70% of its revenue. CEO Colleen Gray
says the company's growth has been aided somewhat by Department of Justice
investigations and charges into consulting agreements between major
orthopedic suppliers and influential orthopedic surgeons. "That just changed the
playing field tremendously now that loyalty isn't being driven through consulting
agreements," Gray says. "More surgeons are open to working with smaller
companies."

For a company as small as Consensus is, it has impressive international
ambitions but has yet to find a way to score significant sales outside the US.
The company pulls sales from European Union countries, Turkey and South
America. It previously had $1 million in sales in Greece before that country ran
into financial troubles. But the company hadn't found a way to China. Gray says
the company has a long history of selling in Japan, but "just had no clue how to
get into the Chinese market." Other US orthopedic companies have had a fairly
easy time with China's regulatory body, the SFDA, but the process was still
largely a mystery to Consensus executives. And even if the company could get
its hips and knees approved, it couldn't afford a direct sales force and "didn't
really feel comfortable getting into a completely arm's length distribution
agreement with a company we don't know." The company had decided a
strategic partner made sense when Kanghui came calling.

Kanghui spoke with several companies before settling on Consensus as a
possible partner. At the time the partnership was announced, one analyst asked
why Kanghui would work with a company as small as Consensus, one that
might have difficulty competing in the global orthopedics market. Yu
acknowledges the orthopedics industry is challenging for smaller companies,
but Consensus' pipeline was "very strong." In addition, a company that size
would more likely treat the arrangement as an equal partnership. "This was very
additive to them," Yu says. "They really had no intention to go to China on their
own. And so our emerging market interest was almost like the mirror image of
their interest in North America and Europe. It was just a good fit.
geographically." Yu adds that Consensus’ Sacramento area office made it easy to visit from his base in Silicon Valley.

The negotiations took some time as both parties grew to know each other. Gray says Kanghui "is a little bit different than other Chinese companies we talked to," explaining that the other Chinese orthopedic companies were privately held and controlled by families. "There's nothing wrong with that," she says. "What we liked about Kanghui is they not only had a lot of US venture capital firms involved along with their Asian funds but they also were some of the largest and most well-known US VCs." Gray says the experience of the management also was appealing as was the company's public ticker. As for concerns about intellectual property protection, Gray says, "We feel there are enough benefits in working with Kanghui and entering the Chinese market to more than offset the risks associated with intellectual property concerns."

In exchange for an equity investment from Kanghui and the promise of royalties, Consensus agreed to let Kanghui license two of its four hip implants - the Consensus Hip System and the TaperSet Hip System. Both will be sold in China under the Kanghui name. Each already has FDA approval, but Kanghui must get a green light from the SFDA, something the company anticipates receiving in 2013. Kanghui also will distribute a third hip implant. Meanwhile, Kanghui licensed only one knee - Consensus' non-porous knee system - but obtained the rights to distribute others in areas where Consensus doesn’t currently sell.

Consensus also hopes to see a short-term reduction in costs from a new "shared supply chain" arrangement with Kanghui. The Chinese company will assume the responsibility for the early stage of manufacturing implants that it will sell under the Kanghui name. Raw materials for the implants will be sent to China for some machining and then over to the US where they'll be finished, polished, packed and sterilized, Gray says. "What we're going to do is to have them make some products for us - some of these products that go in this joint supply chain will actually be branded Consensus - and we will sell those products through our Turkish subsidiary, where they're less sensitive to a hundred percent of the work being done in the US," she says. All products sold in the US, Japan, Europe and Brazil will be made entirely in the US, Gray says. That may change over time as the cost of implants becomes a larger issue, and concerns over foreign-made materials a smaller concern. "At such time that the market in the US does evolve, we'll be able to evolve with it." For now, Kanghui's equity investment will fuel Consensus' more short-term growth. Consensus already has raised $38 million in venture capital from two primary investors, Zesiger Capital Group and Sycamore Ventures.

**Moving Down The Pyramid**

The implants acquired through the Consensus deal and the Wei Rui acquisition put Kanghui in position to pursue a large swath of China’s orthopedic market. According to Kanghui, the population of Chinese hospitals can be divided into three groups, with each group represented by a section of a pyramid. (See Exhibit 3.) At the top of the pyramid sits 100 top-tier hospitals based in China’s urban hubs. Multinational companies like DePuy Orthopedics and Stryker traditionally have targeted these pieces of low-hanging fruit as they're easy to access and the patients are more likely to be able to afford the premium prices established by distributors to these hospitals. This population has presented nice growth for multinational companies, but maintaining their current base will require US companies to hold their own against local Chinese competition, something they’ve been able to do by virtue of the superior reputation that Western companies have historically enjoyed over Chinese-made products. Here, too, Kanghui seems well positioned to battle US companies on their own
The addition of Consensus FDA-approved implants gives Kanghui the means to go head-to-head with companies such as Medtronic, Zimmer and others that have largely concentrated their sales on the country’s top-tier hospitals where patients can afford to - and insist on - paying for implants that have passed through the FDA.

In turn, Kanghui can expect increasingly to see US companies move downstream into hospital segments that have historically been served exclusively by Chinese companies. The top-tier hospitals represent a lucrative market, but only a small segment of China. Capitalizing on future growth of the Chinese market will require US companies to move down the pyramid to the 1,092 mid-tier hospitals or the 6,780 lower-tier hospitals, a trend that is just beginning. In December 2010, Zimmer reportedly paid $49 million to acquire orthopedics manufacturers Beijing Montagne Medical Device Co. Ltd., giving it broader access to the Chinese market. "The acquisition of Beijing Montagne allowed us to access smaller markets and different price categories in which Zimmer previously had no presence," explains Sean F. O'Hara, who oversees Zimmer's Asia Pacific business. "We already provided a significant portfolio of Zimmer products to the Chinese market, but our existing business served an end user and price segment that were different from Montagne's markets."

Medtronic hopes to do the same through its agreement with Weigao. Stryker, meanwhile, is using a truck - equipped with a mobile training lab - to reach out to non-urban centers. Jim Cunniff, president, Stryker Emerging Markets, says Stryker is seeking to bring its technology "to people who cannot come to urban centers to see it. But it's also an opportunity for us to educate people about orthopedics through an interactive mobile training center. It's really going to be focused more on the tertiary cities rather than the primary cities on the East Coast." Cunniff says a "strong middle class" resides within many of those tertiary cities, making them an attractive place to expand sales. It's expected that multinationals will find China an increasingly difficult place to compete. A report by Frost & Sullivan suggests that Chinese-based companies last year accounted for 51% of all orthopedic revenues, up from 44% just three years earlier. By 2015, that stake should grow to 57%, according to the report.

Multinational orthopedic companies could someday find themselves in a predicament similar to that of US-based cardiology device firms that may be shut out of that country's drug-eluting stent market by strong China-based stent makers, as interventional cardiology continues to grow. (See "At PCR, Interventional Cardiology Looks East, Not West," IN VIVO, June 2011)
Kanghui's strategy positions the company to tackle the US-based multinationals head on. By acquiring Wei Rui's line of implants, Kanghui is building a business serving the low- to mid-tier hospitals. When the Consensus implants come on line in 2014 (2012 in international markets), the company will be able to sell to the same surgeons currently being courted by multinational players. No doubt, the competition will still be stiff. But Kanghui officials feel they have two advantages. First, Kanghui has built a broad network of distributors within China. At the end of the second quarter ending June 30, Kanghui reported having 283 domestic distributors (as well as 38 international sellers). Yu says roughly one-third of those Chinese distributors will sell hip and knee implants, so the company will need to add some new distributors.

The second advantage will be price. To sell in China, device companies must win a "tender" from a regional manager, giving them permission to sell in a specific region. Prices are set, and multinationals are allowed to charge more than local providers. This may have worked against Chinese companies in the past, but a company like Kanghui - with an FDA-approved product - could potentially swipe business away from a larger multinational if patients and hospitals feel they can obtain the same quality for less. Kanghui will still have to sell against the perception that products branded by and manufactured in the West are better products. But Consensus' FDA-approved devices should go some way to elevating Kanghui's brand. Just as importantly, Kanghui is counting on the fact that as China's health care system expands, bringing benefits to more and more people, cost will quickly become as important a selection criterion as brand. Chen Yu says orthopedic device manufacturers generally project that patients will pay roughly half their medical expenses, so prices matter. "If we're half the price, and you pay half the cost out of your own pocket, you care what you pay," he offers. "And as long as the perception on quality is close enough, then you're good to go."

China's ongoing efforts to reform its health care system may actually benefit smaller orthopedics even more. A three-year-old effort, RMB850B, by the Chinese government is providing the capital necessary to modernize smaller medical facilities and provide health care coverage for up to 90% of people in that country, "a dramatic rise from a mere 8% in 2002," according to the Clearstate report. In addition to committing capital to acquiring new equipment and expanding coverage, the Chinese government is experimenting with new methods of paying for health care. William Plovanic, managing director, at Canaccord Genuity, notes that the Chinese government is running several pilot programs to test the feasibility of diagnosis related groups (DRGs), similar to those used in the US. If China adopts DRGs, this could benefit smaller companies even further because hospitals would keep more money by purchasing cheaper implants.

**Bigger Fish**

Kanghui has guts. In what might be seen as an impossible scenario today, the company is suggesting that it can establish a dominant place in China and other emerging markets and, ultimately, compete for business in the world's largest markets - Europe and the United States. "To get to those markets you have to learn how to walk before you run," says Yu, acknowledging that Kanghui has a long walk ahead of itself before it's ready to enter those markets. The company's primary advantage is likely to be price - the company's lower manufacturing costs could be factored into pricing in the US and Europe - though convincing surgeons of the quality of its products will be critical as well, hence the importance of the Consensus relationship. Interestingly, Kanghui
could find itself battling the mirror impression that US companies face in China: if US companies have historically benefited from the perception that Western products are better, Chinese companies such as Kanghui will likely face early skepticism among Western doctors that Chinese products are of inferior quality - a concern exacerbated by the SFDA scandals of a couple of years ago - notwithstanding the OEM relationship with Consensus.

Bringing lower-cost implants to the US could prove not only highly beneficial to Kanghui, but also potentially disruptive of the US market, though Chen Yu says Kanghui would have to create an "innovative" sales structure that would enable it to compensate a sales team while charging steep discounts on implants. This might not allow sales reps to stand in every surgery, but he suggests surgeons may someday be comfortable enough with implants to operate without have a sales rep standing with them in the room. "We'd offer a significant discount," he says. "If you're a surgeon-owned center and you care about your bottom line, we'll be an attractive option."

But Kanghui is years away from making that happen. "We'll concentrate on the emerging markets well first, and then, when we're a bigger company, we'll be ready for the US," Yu says. "Unless we're a billion dollar company or more in capitalization, I don't see us being quite ready for the US."

Kanghui might be years away from selling in the US itself, but it's ready to partner with US companies. Yu sees Kanghui and other Chinese companies offering a clear alternative to traditional orthopedic firms for start-ups seeking strategic partners. "It's time that US companies started thinking about Chinese companies as potential strategic investors, just like we do with the big boys of the world," Yu says. Deals initially may center around the rights to selling in China, but eventually the deals could grow. In a few years, companies like Kanghui might even be in position to acquire US companies, giving them FDA-approved technology and a beachhead for a US sales push. "This company has the opportunity to become one of the largest medical device companies in China over the next three to five years," exclaims Yu. "It's just a massive opportunity. If we do our job right, this should be a multibillion-dollar company."

So Far, So Good

For now, outside of the largest multinationals, China remains a distant, distrusted opportunity for many US-based medical device companies who fear that, in going to China, they will find closed markets difficult to get into and will risk having their products and IP ripped off given lax intellectual property laws - all implying that Chinese companies are good at low-cost manufacturing but poor at innovation. How quickly Chinese companies like Kanghui deal with these issues and how long US companies can afford to take a standoff-ish stance toward China remains to be seen, particularly given the international ambitions of companies such as Kanghui and others.

So far, Kanghui is doing its job right. Canaccord Genuity's Plovanic says Kanghui has met or exceeded analyst projections in every quarter, thanks to the introduction of new products. The hip and knee implants will only increase those numbers if Kanghui can establish a reliable distribution network and, more importantly, secure one of the "tenders" necessary to sell in China. But the numbers won't move much initially. Plovanic's forecasts put Kanghui's total joint revenues at $1.8 million in the first year and $3.6 million in 2013, a fraction of the $70 million-plus the company will bring in from sales in trauma and spine. (See Exhibit 4.) This says more about the state of the Chinese total joint market than Kanghui. On a per citizen basis, "the US penetration rate for knees and hips is something like 20 times that of China," he says. "The Chinese
orthopedics industry is like the US orthopedics market in the 1960s and 1970s."
The report by Clearstate sees steady growth in the number of large joint procedures.

Kanghui's pan-Pacific ambitions may seem, well, overly ambitious, but it's almost a certainty that China-based companies someday will sell their implants in the US. Indeed, some China watchers argue that the country represents the same kind of threat to the US-dominated medical device industry that Japan did to the US electronics and automobile industries 25 years ago. It's just a question of how many years from now. But the company clearly can answer a more immediate question facing US-based orthopedic start-ups today: how can we get our products into China? It won't be easy. Chinese SFDA is raising, not lowering, the bar for approval, so smaller companies likely can't look to China as an easier path to market. But for those companies with products that have passed muster at the FDA and received the CE mark in Europe, Chinese medical companies present an opportunity to tap into a health care industry that's growing, not shrinking. That's a foreign concept to orthopedic companies in these difficult times, almost as foreign as an unfamiliar market like China.