

BIOSENSORS INTERNATIONAL AND CHINA (A)

In early 2010, Yoh-Chie Lu, the chairman and single largest shareholder in Biosensors International Group (BIG), mulled over options for his company in China. His decision would have a major impact on the Singapore-listed medical device maker's future. Biosensors was a small, innovative maker of drug-eluting stents (DES) used in the treatment of heart disease. Unlike the firm's foreign competitors, which exported stents to China, Biosensors had a joint venture with China's leading medical device company, Shandong Weigao Group Polymer Company, to manufacture DES in that country. The venture, JW Medical Systems (JWMS), enjoyed the third largest share of China's promising DES market, making Biosensors the strongest foreign player, ahead of Medtronic, Boston Scientific, and other multinational rivals.

JWMS, however, was at a crossroads. Although Biosensors and its Chinese partner had worked hard to develop a good relationship over the years, they had reached a stalemate over how to spend the 50:50 venture's profits. Unless they overcame the impasse, JWMS would never reach its potential and would likely start losing ground. Was there a solution that would simultaneously advance BIG's China market strategy and add value for shareholders? If so, could Biosensors convince Shandong Weigao to embrace it?

INDUSTRY BACKGROUND AND MARKET OVERVIEW

China's Medical Device Market

China's market for medical devices grew exponentially over the preceding decade. Valued at US\$780 million in 2000,¹ the market ballooned to more than US\$12 billion in 2010. It expanded at a compound annual rate (CAGR) of 22.4 percent from 2006 to 2010 to become the world's fourth largest medical device market after the United States, Japan, and Germany (see Exhibit 1). On a per capita basis, however, the market's size was tiny compared to these countries, just

¹Ames Gross, "China Medical Device Market 2000," Pacific Bridge Medical, 2000, http://www.pacificbridgemedical.com/publications/china/2000_china_medical_device_market (May 22, 2012).

Case writer Pamela Yatsko prepared this case for use in Stanford University's Program in Biodesign as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

US\$10 per person in China in 2010 compared to US\$348 in the United States, indicating plenty of room for growth. Analysts forecast the device market's size to reach US\$25 billion by 2016.²

A number of factors came together to power the Chinese device market's take-off, such as increasing urbanization, disposable income, and consumer purchasing power, as well as a rapidly graying population (see Exhibit 2). Other drivers included the expansion of government-subsidized medical insurance coverage and medical service beyond China's major cities. Although out-of-pocket patient payments still accounted for some 49 percent of China's healthcare expenditures in 2008, the number of uninsured obtaining some kind of coverage grew at a CAGR of 42 percent between 2004 and 2009 and was slated to reach 100 percent by 2020.³

Rising government expenditure under China's 2009 Healthcare Reforms and Twelfth Fifth Year Plan (2011-2015) also contributed to the device market's brisk growth. Healthcare expenditures in China overall doubled between 2007 and 2010 to reach more than US\$300 billion and were forecast to surge at CAGR of 14 percent between 2007 and 2020. The five-year plan sought to modernize China's healthcare infrastructure, treat growing health problems such as cardiovascular disease and diabetes, and to increase investment in R&D for innovative products. (Besides R&D by domestic companies, multinationals were also setting up research centers to develop products tailored to local markets).⁴

The quality, availability, and expenditure on healthcare varied greatly in China depending on location. First tier cities, such as Beijing, Shanghai, Guangzhou, and Shenzhen, offered relatively high per capita incomes, huge populations, and sophisticated hospitals with highly trained physicians and strong purchasing power. Multinational medical technology companies normally focused their premium products on this tier. They left second tier cities, such as Tianjin, south of Beijing, and more rural third tier areas, where roughly half of China's 1.4 billion-strong population resided, to domestic players able to compete on price.

Despite the Chinese device market's rapid growth and potential, device makers could find the market challenging to navigate. The Chinese government, like other governments, subjected the industry to rules, regulations, and technical requirements, and had been tightening its regulatory grip. For instance, stent manufacturers, such as Biosensors, had to seek approval for their devices from China's State Food and Drug Administration (SFDA), which in recent years had increased the requirements for clinical trials, thereby lengthening the regulatory approval process and making it more costly to gain SFDA approval. Obtaining SFDA approval took roughly three years, with foreign stent makers generally experiencing more difficulty than local entities.⁵

In its ongoing effort to contain healthcare costs, the central government announced in 2009 its intention to restrict profit margins and play a more forceful role in the pricing of high value medical supplies, including coronary stents. Besides imposing mandatory price ceilings, the

² Chris Shen, Global Design Lecture Slide Presentation, Biodesign in a Global Context, Biodesign Program, Stanford University, April 25, 2012, pp. 6 and 7.

³ Ibid., pp. 5, 8 and 11.

⁴ Ibid., pp. 5 and 9.

⁵ "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," Morgan Stanley Research, December 13, 2011, p. 89.

government kept prices in check by requiring state-run hospitals to procure high-value devices from manufacturers or their distributors at prices set through competitive tenders, normally held every two to three years. Expert panels, composed of hospital officials and doctors, selected bids based on price, sales network, brand reputation, doctor preference, and safety record. China's Ministry of Health oversaw a centralized bidding process starting in 2007, but announced in 2010 that provinces and municipalities could conduct their own tenders. The change spelled additional costs for device makers seeking to sell into multiple provinces. It also contributed to downward pressure on prices, which favored local manufacturers.⁶ Average prices for drug-eluting stents had dropped year-on-year since at least 2007 (see Exhibit 3).⁷

Reimbursement policies and amounts differed by region and often favored domestic producers, whose devices were much less expensive, often selling at a 50 percent or more discount to imports. Shanghai health insurers, for instance, reimbursed 70 percent of the cost of an imported drug-eluting stent compared to 80 percent for a domestic one.⁸

Protecting intellectual property (IP) and trade secrets was an ongoing concern for device manufacturers. Not only did they have to contend with domestic competitors stealing their IP, they also had to worry about the intentions of their Chinese partners. Chinese companies were notorious for stealing their foreign partner's IP and then using it in their own operations to compete with and ultimately undercut the foreign partner in China and potentially elsewhere over time. Traditionally multinationals found it very difficult to seek redress for rampant IP infringement by domestic companies in China. However, some Chinese companies in recent years had begun to focus more on R&D rather than simply competing on price. As a result, they were starting to sue infringing rivals in Chinese courts, which awarded damages in some cases.⁹

Device makers also often found themselves operating in an environment rife with unethical business practices including pay-offs in exchange for doing business. Companies that did not want to partake in these practices had to differentiate themselves and their products in some other fashion to compete. Foreign companies in some cases had a "don't ask, don't tell" policy with Chinese partners who then dealt with these matters as they saw fit.

Coronary Stent Industry Background

BIG's primary product, coronary stents, were small, tubular, cage-like medical devices used during coronary balloon angioplasty to treat coronary artery disease (CAD). The build up of plaque in the arteries causes CAD and could ultimately lead to chest pain and heart attack. During balloon angioplasty, doctors expand the coronary artery to improve blood flow by inflating a balloon in the artery via a balloon dilation catheter. Coronary procedures performed with a catheter are known as percutaneous coronary interventions, PCI. (See Exhibit 4 for a

⁶ Ibid., pp. 49, 60, 89.

⁷ Ibid., pp. 49, 60, 83, 89, and Jay Briggs, "Overview of China Medical Device Registration," U.S. Department of Commerce, Office of Health and Consumer Goods, July 28, 2009 <http://www.gotocmp.com/reference/00452706.html> (May 17, 2012).

⁸ "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., pp. 92-93.

⁹ Chris Shen, op. cit., p.17.

glossary of common terms.) Doctors then deposit the stent in the enlarged portion of the artery in an effort to prop it open permanently.

Without the insertion of a stent, the treated artery narrows and becomes blocked again (known as restenosis) at a 30 percent to 40 percent rate. With stenting, the rate of restenosis drops considerably — albeit not completely.¹⁰ The first balloon angioplasty occurred in 1977 and the first coronary stent implantation during PCI took place in 1986. Other treatments for coronary heart disease included drug therapies and coronary artery bypass surgery, first performed in the 1960s. The later was more invasive and costly than PCI procedures, but was considered more effective in some cases.¹¹

There are two categories of coronary stents: Bare metal stents (BMS), which are small, thin, expandable tubes made from surgical-grade stainless steel wire mesh, and drug-eluting stents (DES). Med-tech innovators developed DES in an effort to reduce restenosis rates of more than 20 percent for bare metal stents -- usually six months following the PCI procedure. Restenosis in these cases was not caused by a reoccurrence of coronary artery disease, but rather from the thickening of the vessel wall due to the proliferation of smooth muscle cells in reaction to the angioplasty procedure itself. To inhibit this response, scientists tried coating BMS stents with drugs, to create the first drug-device combination medical product. During clinical trials, drug-eluting stents trimmed restenosis rates to below 10 percent.¹² DES systems generally consist of the stent, a stent delivery catheter, the drug, and often a thin polymer coating, which acted as the drug's carrier for timed release into the artery.¹³

The first drug-eluting stent, developed by Johnson & Johnson's Cordis subsidiary, received regulatory approval in 2002 in Europe and in 2003 in the United States.¹⁴ The DES market subsequently took off. Doctors in 2003 implanted stents in roughly three-quarters of the 2.1 million angioplasty procedures performed worldwide that year.¹⁵ Boston Scientific, Guidant, Medtronic, Abbot, Terumo, and Biosensors were some of the other interventional cardiology companies that were doing R&D and pursuing clinical trials for drug-eluting stents.

Controversy, however, erupted in 2006 when some studies showed that drug-eluting stents resulted in more late stage thrombosis (clotting a year or more after implantation) than bare metal stents in certain circumstances, temporarily damping the market.¹⁶ Later generations of stents (offering biodegradable polymers or polymer-free forms) were shown in clinical trials to be more effective and safer than bare metal stents in many ways,¹⁷ reinvigorating sales.

¹⁰ "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., pp. 76-77. "Drug-Eluting Stents," Orbiclinic, <http://www.orbiclinic.com/news/drug-eluting-stents> (May 24, 2012) and "Drug-Eluting Stent Overview," Angioplasty.Org, September 2011, <http://www.ptca.org/des.html> (May 25, 2012).

¹¹ "Drug-Eluting Stent," Wikipedia, http://en.wikipedia.org/wiki/Drug-eluting_stent (May 24, 2012).

¹² Prospectus, Biosensors International Group, April 22, 2005, p.3. <http://biosensors.listedcompany.com/misc/ipo.pdf> (May 31, 2012).

¹³ Ibid., p.1 and "Drug-Eluting Stent Overview," loc. cit.

¹⁴ "Drug-Eluting Stent," loc. cit.

¹⁵ Prospectus, Biosensors International Group, loc. cit.

¹⁶ "Problems Resurface with Drug-Eluting Stents" Angioplasty.Org, September 9, 2006, <http://www.ptca.org/news/2006/0904.html> (May 25,2012).

¹⁷ "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., p. 77; and "Drug-Eluting Stent," loc. cit.

Worldwide DES sales by 2010 accounted for a larger share of the global coronary stent market than bare metal stents (some 55 percent). Still, the problem of late-stage thrombosis persisted.¹⁸ Scientists theorized that a completely biodegradable stent i.e., one that fully dissolved in the body, might resolve the problem.

In 2011, the value of the market for coronary stents worldwide was estimated at roughly US\$6 billion, and was forecast to expand at a 2010-2016 CAGR of 6.6 percent, according to Transparency Market Research.¹⁹ Drug-eluting stent sales were expected to grow even faster, at a roughly nine percent clip (CAGR) over the same period.²⁰ Besides advances in stent technology, the growing incidence of coronary heart disease due to aging populations and rising obesity was spurring this growth. The United States, Europe, and the Asia-Pacific respectively were the most important markets for coronary stents, with Boston Scientific, Abbott Laboratories, and Medtronic enjoying the largest market share. J&J (Cordis) had also held a leading position until it decided to abandon the coronary stent market in early 2011 to focus on other types of cardiovascular devices.²¹

China's Stent Market

Compared to the United States and other developed regions, stent makers had barely penetrated China's coronary stent market. Whereas more than one million patients in the United States underwent PCI procedures in 2010, only 300,000 patients in China did the same, even though some 40 million patients suffered from coronary artery disease.²² Still, the number of cardiac surgery procedures in China had grown considerably, from 90,000 in 2004 to 150,000 in 2010.²³ Similar to the medical device market generally, industry analysts expected the growth of China's coronary stent market to far outpace global demand going forward. Market research firm Frost & Sullivan, which valued the market in China at 3.8 billion yuan (US\$1:Rmb6.8) in 2007, predicted China's coronary stent market to expand at a 24 percent CAGR to reach 16.9 billion yuan in 2014.²⁴ Drug-eluting stents, which doctors in China used instead of bare metal stents in 95 percent of cases,²⁵ were slated to dominate sales.

Whereas foreign companies accounted for the lion's share of China's coronary stent market prior to 2004, domestic manufacturers by 2009 had captured more than 77 percent of DES sales by volume and 66 percent by value. Lower manufacturing costs, ability to offer lower prices, and better distribution networks than multinational corporations allowed domestic DES makers to compete in second tier markets, the fastest growing market segment.²⁶ MicroPort Scientific in Shanghai, Lepu Medical Technology in Beijing, and BIG's JWMS were the leading players,

¹⁸ "Global Drug Eluting (DES), Bare Metal (BMS) And Other Coronary Stents Market (2011 - 2016)," Transparency Market Research, PRLog Press Release Distribution, February 9, 2012, <http://www.prlog.org/11794794-coronary-stents-market-and-bare-metal-stent-market-2011-to-2016.html> (May 25, 2012).

¹⁹ Ibid.

²⁰ Ibid.

²¹ Ibid., and "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., pp. 44 and 84.

²² Ibid., pp. 43 and 81.

²³ Emil Salazar, "China Healthcare Reform and Its impact in IVD, Pharma, and Device Markets," October 2011, Kalorama Information, p.114.

²⁴ "China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., p. 81.

²⁵ Ibid.

²⁶ Ibid., p. 43.

claiming 25.1 percent, 20.5 percent, and 18.5 percent of the market by value that year respectively. Prior to quitting the stent market altogether, J&J had been the fourth most successful stent maker in China. Its imported stents had grabbed an 18 percent slice value-wise compared to Medtronic's 11 percent and Boston Scientific's 4 percent (see Exhibit 5).²⁷

Market leader Microport, which went public in Hong Kong in 2010, was the first domestic company to develop and launch a drug-eluting stent in China. CEO Chang Zhaohua founded the company in Shanghai in 1998 after working as a vice-president of R&D in the industry in the United States. Although Microport was working to expand its product portfolio, DES products accounted for some 90 percent of total 2010 sales revenue. Its sales were mostly domestic, but it planned to enter the European market in 2013. The company invested considerably more than domestic rivals in research and development, spending roughly 15 percent of sales on R&D, three times more than Lepu for example. Among other things, it benefited from strong domestic brand recognition, established hospital contacts in Tier 2 markets, and experience navigating China's regulatory approval process.²⁸

Founded in 1999 and listed in Shenzhen in 2009, Beijing-based Lepu was also strong in Tier 2 markets. After winning SFDA approval, Lepu launched a polymer-free DES in 2011, which it could sell for a higher price than its second generation DES with a durable polymer. Some analysts predicted that Lepu would eventually overtake Microport as the leading market player, while others expected its new DES to compete with JWMS's stent and MNC imports. New local players entering the market were expected to put additional pressure on prices in second and third tier markets.²⁹

BIOSENSORS HISTORY

Founder Yoh-Chie Lu

Biosensor founder You-Chie Lu was born in Taiwan in 1951, but grew up in Japan. Through schooling and conversations with his ethnically Chinese parents, he mastered Japanese, Mandarin, and Shanghainese. When he was 17 years old, he left home to attend college in the United States at the University of California, Berkeley, where he learned English and studied engineering. After visa complications precluded him from taking a job upon graduation with a Fortune 500 engineering firm in San Francisco, he sought a graduate degree in business at Thunderbird School of Global Management in Arizona to take advantage of his language abilities and ease in a number of different cultures. Although he wanted work that involved Asia, his first priority was to make a living, which led him to take a job in finance with packaging products maker Owens-Illinois. While there, he accepted his first foreign post: Puerto Rico. These experiences, he said, taught him the importance of flexibility in life and of accounting and budgeting in business.

²⁷ Ibid., pp. 44, 83, 84, and "China Interventional Cardiovascular Device Industry Report, 2010: Summary," ResearchInChina, January 2011, <http://www.reportlinker.com/p0370585-summary/China-Interventional-Cardiovascular-Device-Industry-Report.html>, May 18, 2012.

²⁸ China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., pp. 40, 44, 46, 49.

²⁹ Ibid., pp. 42, 45, 49, 78, 84.

Lu's first professional forays into the med-tech industry, entrepreneurship, and Asia came serendipitously in 1977. While at Owens-Illinois he realized he did not have a stomach for office politics and was relieved to receive a call from an executive search firm that introduced him to Gould Electronics, which was looking for a controller to work in Puerto Rico. The executive who interviewed him, however, determined that Lu could do more than finance for the company. He offered Lu a job building from scratch the company's medical division in Asia using Tokyo as a base. "Somehow he saw something in me that I did not see myself," Lu said.³⁰ Gould gave Lu freedom to build his business and, with Asia booming, it did not take long for Lu's Asia operation to become the medical division's top performer. During his tenure there, he built a factory in Singapore and formed a joint venture with a Japanese partner, experiences that came in handy when he later set out to build his own business.

Through a leveraged buyout in 1986, Lu and partners acquired the division from Gould to form SpectraMed, which was listed on NASDAQ in 1986. In 1988, they sold the company to British Oxygen. After meeting his commitment to work for British Oxygen for two years—an experience that confirmed he did not like working for large corporations—the then 38-year-old Lu determined it was time to strike out on his own.

BIG's Early Days

With his own money and a loan from a friend in Japan, Lu in 1990 founded three companies that eventually became part of Biosensors International Group. The first company, Biosensors, did contract manufacturing of critical care catheter systems and related accessories used during heart surgery and intensive care treatment and monitoring. Lu chose to locate the factory in Singapore based on his past manufacturing experience there. He also established Sun Instruments in Japan to handle sales and distribution and Sunscope International as BIG's purchasing arm, which he based in California where he chose to live and raise his young family. He had 12 employees in 1992.

Lu soon noticed that although he could make ends meet contract manufacturing, his profits were constantly being squeezed. It was a godsend, then, when Progressive Angioplasty in 1994 approached Biosensors and Sun Instruments to distribute their bare metal stent and percutaneous transluminal coronary angioplasty (PTCA) catheters in Asia, especially Japan. Lu discovered he could in a short time make much more money doing product distribution than by contract manufacturing thanks to high margins and explosive growth in the PTCA/BMS business.

However, the good times did not last. Within two years, J&J bought Progressive Angioplasty, incorporating it into its coronary business and terminating Biosensors distribution agreement. This crisis forced Lu to think hard about his business and its poor profit prospects if he continued simply to make and distribute products for other people. He determined he had to develop a proprietary technology in-house, despite the prospect of lengthy and costly research and development periods, which characterize the industry.

³⁰ Interview with Yoh-Chie Lu, founder and chairman, Biosensors International Group, May 1, 2012. Subsequent quotations are from the author's interviews unless otherwise noted.

Lu heard about a new technology: drug-eluting stents. Investing the last portion of his savings, roughly US\$1.2 million, into R&D in Newport Beach, CA, he convinced some scientists he knew from his days at Gould to work part-time to explore possibilities. Although the scientists did not have stent experience, they offered know-how in pharmacology, chemistry, and medical devices generally. They were also willing to take a chance on a start-up company: Scientists with stent expertise at the time normally preferred to work for established stent makers, such as J&J (Cordis) or Guidant. Lu hoped that his scientists' lack of history in the stent field would free them from stifling preconceptions of what was or was not possible.

Technology Innovation Success

BIG's first minor success developing a proprietary technology came in 2000 when the company launched the S-stent, the first bare metal stent developed for Asians outside of Japan. Although it offered larger surface area for drug delivery and worked especially well for treating small, tortuous coronary vessels,³¹ it was largely a me-too product. "It was good, but nobody respected us," said Lu. BIG's scientists then hit on a novel idea to reduce restenosis and thrombosis risk: What if the polymer controlling release of the drug dissolved in the body rather than remaining? "Everybody thought we were crazy," Lu recalled, "They said, 'You are releasing your polymer into the vessel, and it's so dangerous. You don't know what you're doing.'"

At a major cardiac trade conference in 2002, just as Lu was running out of money to fund further R&D, the show's organizers decided to spotlight the company's biodegradable polymer, which Biosensors had shown to be safe in lab tests on animals. This first-of-its-kind drug carrier technology, which dissolved six to nine months following the PCI procedure, reduced some of the risks associated with durable polymers (see Exhibit 6). Around that time, Biosensors R&D director Jack Wang introduced Lu to an executive at Guidant to discuss the possibility of Biosensors licensing its biodegradable polymer to the California-based company. The conversation led to an initial US\$20 million licensing deal that eventually brought in US\$95 million as Biosensors later met specific milestones. Biosensors also concluded licensing deals with Terumo of Japan, California-based Xtent, and California-based start-up Devax (which Biosensors later acquired).

Biosensors scientists around this time were working on a number of other advances, including a proprietary anti-restenotic DES drug Biolimus A9, whose novelty lay in its superior binding properties to coronary artery tissue.³² With the licensing money from Guidant, they were able to develop their proprietary pharmaceutical agent in-house. Biosensors, unlike many other players at the time, would not have to pay royalties to use another company's drug and could out-license the drug, which it did to Terumo in Japan. Together, the S stent (and accompanying "Senso" stent delivery balloon catheter), the biodegradable polymer, and the Biolimus A9 drug comprised BIG's BioMatrix DES system. Biosensors filed for patent protection for BioMatrix in Europe in 2006, which it received in 2008.³³ A four-year clinical trial underscored the system's better efficacy and safety profile compared to J&J's durable-polymer DES. Morgan Stanley analysts

³¹ Prospectus, Biosensors International Group, April 22, 2005, pp. 1-2, <http://biosensors.listedcompany.com/misc/ipo.pdf> (May 31, 2012).

³² Ibid., p. 2.

³³ China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., p.10.

described Biosensors as “the only emerging stent company with proprietary technology” and BioMatrix’s technology as “one step ahead of MNC players.”³⁴

BIG’s attempt to enter the U.S. market, which in 2010 made up 54 percent of the global DES market, was less successful. Armed with some US\$100 million from licensing deals, BIG began its efforts there in 2004, but its FDA submission for BioMatrix foundered and it pulled the plug in 2007, some US\$55 million poorer. “People kept telling us that we needed a presence in America to succeed,” Lu recalled. The foray coincided with tightening U.S. regulatory restrictions, ballooning regulatory approval costs, and a decline in the value of the U.S. DES market (see Exhibit 8). It also coincided with a rapid growth in BIG’s personnel, which had ballooned to almost 500 people in 2007 from around 250 in 2004.” As we brought in more people from a big company environment, they had many reasons to spend money,” Lu said. Had the BioMatrix clinical trials not succeeded, Biosensors would have been in financial trouble.

Biosensors underwent a leadership change in 2008 to bring new blood into Biosensors at the executive level. Lu continued as the company’s chairman, but stepped down as CEO. Biosensors appointed the former CEO of U.S. medical device company MicroVention, Robert Michael Kleine, as BIG’s new president and CEO.³⁵ In BIG’s annual report for 2007/2008, Kleine wrote:

Appropriately, the company’s historical focus has been development of its drug-eluting stent products and building the infrastructure necessary to commercialize this technology platform. Today, our focus has shifted... our commercialization phase has begun and the single-most important focus for Biosensors is to deliver our technology to as many physicians and patients as possible. While growth is our primary driver, we are also taking the steps necessary to improve our operating performance and move towards sustainable profitability.³⁶

The firm’s financial results eventually began to reflect its technological success. In fiscal year 2004, Biosensors reported licensing revenue of just US\$30 million related to its proprietary DES technology and sold US\$20.7 million worth of critical care and traditional cardiology products, mainly to Europe and Asia.³⁷ Following BIG’s public share listing in Singapore in 2006 and BioMatrix’s approval in Europe in 2008, Biosensors achieved profitability for the first time in 2010, earning roughly US\$35 million (see Exhibit 7).

BIOSENSORS IN CHINA

Just as Lu knew Biosensors had to develop a proprietary technology to survive, he also knew the company had to reduce its ever-increasing manufacturing costs. In the late 1990s, he began looking into transferring some of the company’s labor-intensive manufacturing to China to take advantage of that country’s relatively inexpensive labor. At the time, foreign medical device

³⁴ Ibid., p.4.

³⁵ Melanie Lee, “Singapore’s Biosensors appoints new CEO,” Reuters, January 23, 2008, <http://www.reuters.com/article/2008/01/23/biosensors-idUSSGC00165820080123> (October 24, 2012).

³⁶ “Biosensors International Group, Ltd. Annual Report 07/08,” Biosensors International, 2008, <http://biosensors.listedcompany.com/misc/ar2008.pdf> (October 29, 2012).

³⁷ Prospectus, Biosensors International Group, op. cit. p.1.

companies, if involved with China at all, tended to export to it rather than manufacture there. Indeed, Biosensors had been selling its critical care products into China via distributors since 1998 with middling results.

China had been on Lu's radar for a while. Lu's younger brother, Hongliang Lu, who founded UTStarcom in 1991, had during the 1990s become a successful entrepreneur in China's fast-growing telecommunications industry. Lu had a vague sense that the medical device market would also eventually take off there, but the critical care product market at the time was very small and the coronary stent business did not yet exist.

The First Joint Venture

In 1999, when Lu started developing a China strategy, the company's finances were tight: Sales were roughly US\$12 million annually and Lu was trying to kick start the company's DES program. Rather than tackling the country solo, Lu believed he needed a Chinese partner to help handle regulatory issues, deal with government agencies, understand local business practices, and establish distribution networks. For instance, a local partner with strong relationships at the local Customs bureau would likely have an easier time getting a piece of imported equipment through Customs in a timely fashion than an inexperienced foreign company. On its own, Biosensors might have more trouble collecting payment from local distributors than if it had a Chinese partner with local influence who could exert more pressure. "We really needed somebody for local knowhow," Lu said. Biosensors in turn would offer its greater manufacturing and technological expertise and knowledge of international markets.

A friend in the venture capital industry subsequently introduced Biosensors to Chinese medical device manufacturer Shandong Weigao Group Polymer Company, which was looking for technologies to manufacture. Known as Weihai State-Owned Medical Apparatus Factory First Branch when first founded in Weihai City, Shandong in 1988, it manufactured disposable medical devices such as sterile infusion sets, plastic blood bags, syringes, and needles. In 2000, China's State Science and Technology Commission chose it to participate in two of its key R&D programs for advancing China's competitiveness in science and technology.³⁸ After receiving coveted Chinese government approval to go public overseas, it listed shares on the Hong Kong Stock Exchange in February 2004. That year, China's highest-ranking leader, Communist Party Secretary HU Jintao, honored it with a visit. In another honor, Shandong Weigao's chairman CHEN Xueli, who was also the company's Communist Party Committee secretary, was named a delegate to the Seventeenth National Congress of the Communist Party of China (at which major policy and leadership changes for China are formally announced).³⁹ By 2011, Shandong Weigao

³⁸ Under the State Torch Program, the State Science and Technology Commission named Shandong Weigao a "Key High Technology & New Technological Enterprise." It also identified the company as a "Preferred Manufacturing Base for New Products" developed by the State High Technology Research Development (863) Program." See "About Weigao: Enterprise Introduction." Wego Holding Company Limited, <http://en.weigaoholding.com/h/jtgs/> (June 18, 2012) and "About Us: History," Weihai Wego Medical Systems Co, Ltd., <http://en.wego-medical.com/history/&columnId=1d1da7da-82ab-4721-8a99-afea6e286e16.html>, (June 18, 2012). For information about the Torch and 863 programs, see <http://www.china.org.cn/english/features/China2004/107131.htm> (June 18, 2012).

³⁹ "News Room: News Center," Wego Holding Company, Ltd., <http://en.weigaoholding.com/h/xwzx/topic-1309.htm> (June 18, 2012).

was China's leading single use medical consumables manufacturer, with revenues of US\$3.2 billion.⁴⁰ It had 9,000 employees and 18 subsidiaries. According to its website, its goal was to transform over time from a domestic manufacturer into an internationally competitive conglomerate and leader in Asia.⁴¹

At the time of its introduction to Biosensors, however, Shandong Weigao enjoyed sales of less than US\$50 million and had never partnered with a foreign company. It did, however, boast a fairly efficient manufacturing operation and an extensive domestic sales and distribution network. Not only would Biosensors be able to reduce manufacturing costs to increase its competitiveness in export markets, it could expand distribution in China. Moreover, Biosensors could count on Shandong Weigao to have solid local relationships and know-how.

In July 2003, Biosensors and Shandong Weigao established a 50:50 joint venture within Shandong Weigao's industrial compound to manufacture central venous catheters and other critical care items.⁴³ The venture, known as JW ICU Medical, never fulfilled expectations. For one, it could not bring manufacturing costs down fast or drastically enough to compete with rivals in the United States. Part of the problem was the 50:50 decision-making process that the two sides had negotiated for the venture. Apart from Danny Tan, the venture's general manager whom Biosensors had sent from Singapore, the rest of the management team came from Shandong Weigao. That team was reluctant to defer automatically to Tan's manufacturing and technological expertise. The parties ultimately could not agree on how to cut costs. Projects, such as building a piece of equipment used in catheter assembly, would end up taking longer than necessary to accomplish. Also, if the venture factory needed supplies, it would turn to Shandong Weigao for them whenever possible, but the Chinese parent was not always the cheapest manufacturer, stymieing JW ICU Medical's competitiveness. Moreover, Shandong Weigao was unable to help as much as hoped in distributing the joint venture's catheters. "It was very difficult for them to engage in something they had never sold before," Lu explained. Domestic sales accounted for only 10 percent of the venture's business in 2004.

Lu came to the conclusion that Biosensors needed to have daily control of the venture's operation. Shandong Weigao executives were against the move except for Chairman Chen, with whom Lu had developed a good rapport. The chairman's voice prevailed and in May 2008, Biosensors officially bought out Shandong Weigao's 50 percent stake. Unlike other decision-making at the joint venture, negotiating a price for Shandong Weigao's shares did not prove difficult. Since the company had not been very successful, Shandong Weigao agreed to sell its stake roughly for the book price of the venture's physical assets. Biosensors also asked that Shandong Weigao take back the employees it had contributed so that Biosensors could hire its own people in China. "I felt that he [Chen] made a sincere effort to make it work. I felt very good about working with him on other projects," Lu said.

The following year, JW ICU Medical saw costs fall 30 percent from the previous year and profits increase 20 percent. Domestic sales grew to 20 percent of total sales in 2009. Despite its lack of

⁴⁰"Shandong Weigai Gp Medical – H," BloombergBusinessweek, <http://investing.businessweek.com/research/stocks/earnings/earnings.asp?ticker=1066:HK> (June 18, 2012).

⁴¹"About Weigao: Enterprise Introduction," loc. cit.

⁴³ The dates attributed to JW ICU Medical in this case study may vary from other publicly available sources.

an ownership stake, Shandong Weigao continued to use its local know-how to help JW ICU Medical resolve local problems as it had done previously. Shandong Weigao even helped mediate a dispute with a disgruntled former Chinese employee who threatened Tan. “If you find the right partner, it’s almost like a family,” Lu commented.

The Second Joint Venture

Shandong Weigao also had bigger fish to fry with Biosensors than squabble or refuse to help JW ICU Medical. Chen wanted Biosensors to work with Shandong Weigao to manufacture drug-eluting stents in China. From the start of their relationship, Chen had been excited about the future for drug-eluting stents in China and encouraged Biosensors to carry forth with its R&D efforts, Lu said. Through his contacts in the central government, Chen understood that coronary disease would be a future government focus and that coronary stents would be big business in China one day.

Biosensors briefly entertained the idea of doing a second venture with a startup in Shenzhen, but ultimately saw Shandong Weigao as a more suitable partner, despite the first joint venture’s problems. Lu already had a good relationship with Chen, the Chinese company enjoyed good local connections, and it had a factory compound with sufficient space. It also was getting ready to list on the Hong Kong Stock Exchange, which meant it would have plenty of cash. Lu did not consider sole ownership for the second joint venture. “I always considered that you needed to have a partner to hold your hand,” Lu said. Nor did Lu consider simply exporting coronary stents to China like other foreign companies. He wanted Biosensors to be a local company with a local cost structure to command a significant market share and be a major player. Otherwise, the high value-added tax on imports would limit Biosensors to Tier 1 hospitals when, in his view, the greatest potential lay in mid and low tier markets.

Key hire: Jack Wang

Lu asked BIG’s R&D Director Jack Wang to help Tan negotiate and set up the new joint venture. Wang would then run that company, while Tan continued as general manager of the critical care operation. Lu had hired the Beijing-born Wang in 2001. Wang, who had received a Bachelor of Science from China’s prestigious Tsinghua University before doing graduate work in the United States and Europe, had worked at Guidant as a manufacturing and R&D engineer and then in J&J’s Cordis division, where he had headed up a special stent program. Similar to Lu’s life-changing interview with the executive at Gould who hired Lu for the Asia job early in his career, Lu recalled a conversation with Wang in which he tried to convince the scientist to join Biosensors:

I knew he was the right person to have. He didn’t want to commit. He said, “Your company is too small. I already have an offer in the Bay Area. Why should I work for you?” So I had to convince him to work for me and that’s when I said, “China is going to be the future. You will be the best person to be part of the China project.” He said, “I’m an engineer. I am not even a businessman.” So I said, “I will turn you into a businessman.”

With the China possibility somewhere in the back of his mind, Wang agreed to join the company and was charged with developing coating technologies for drug-eluting stents. He had a novel idea: Rather than applying a base coat on the bare metal stent before applying the polymer and drug as was the common practice, why not develop a drug/polymer coating method that skipped the costly base coat application? Unfortunately, Wang couldn't convince his American-born colleagues at Biosensors that his idea was safe and they resisted moving forward with it. But it was during this period that Lu asked the native Mandarin speaker to negotiate the DES joint venture with Shandong Weigao. Fortuitously, Wang's parents were originally from Shandong province. "Shandong Weigao knew they had someone they could communicate with," Lu said.

Interested in building his own business and testing and commercializing his coating theories, Wang agreed to run the DES joint venture, which began operations in 2004.⁴⁴ It was a momentous decision for the company. Not only did Wang develop a safe but less costly coating technique that was eventually incorporated into BIG's proprietary technology portfolio, he also built JWMS into one of China's top three DES manufacturing franchises. The joint venture reported US\$89 million in revenue in 2010, up 43 percent over the previous year.⁴⁵

While travelling between the United States and China to negotiate the DES venture, Wang did some things that would be very important for JWMS's future: He developed a strong relationship with Chairman Chen; he gained a good understanding of Shandong Weigao's strengths and weaknesses; and he saw first hand what was happening at the critical care joint venture. "He knew what not to repeat. That gave us a tremendous amount of leverage," Lu said.

Decision-Making Authority

First and foremost, although JWMS was structured as a 50:50 joint venture, Wang insisted that he have control of day-to-day management. "The biggest thing we had learned was that you need to make decisions yourself, instead of jointly with your partner, or you can't get anything done," Lu said. Despite objections from Shandong Weigao executives along the way, both Lu and Chen entrusted Wang to run the business as he saw fit, just as the Gould executive had entrusted Lu to build its medical device business in Asia. According to Lu, "One of the key things in running JWMS so smoothly has been allowing Jack freedom to operate." Since Shandong Weigao did not have experience in drug-eluting stents, Chen acquiesced on the issue of day-to-day management control. Chen, who Lu described as both a good businessman and an honorable person, understood that each side had to do what it did best to achieve the best results. "He just wanted to see the business take off," Lu commented. Shandong Weigao still had a say in the big decisions affecting the company under the venture's 50:50 ownership structure. The new company had an executive committee consisting of two executives from each partner (Lu and Wang; Chen and another Shandong Weigao executive). Chen and Lu would take turns every two years as the venture's chairman.

The partners also agreed that the new company would have authority over hiring personnel. Unlike in the first joint venture, JWMS would not hire anyone from Shandong Weigao's organization unless JWMS picked them, with two exceptions: the heads of accounting and

⁴⁴ The start date for the JWMS joint venture in this case study may vary from other publicly available sources.

⁴⁵ China Medical Devices: Stents that Sell: Opportunities in China and Beyond," op. cit., p. 47.

personnel. Although these two key appointments might have led to surreptitious meddling from Shandong Weigao, they did not, said Lu. Any allegiance to Shanghai Weigao over JWMS abated as JWMS started showing strong business momentum. “Quickly Jack was able to manage them and demonstrate that he was the leader,” Lu said. Wang did not try to instill loyalty by paying these and other JWMS employees more than at Shandong Weigao. JWMS was careful not to upset local payroll standards. Rather, JWMS employees identified themselves with the company’s success and began to see themselves as part of JWMS, Lu explained.

Jack also introduced a training system to help instill loyalty and discipline and create a corporate culture distinct from Shandong Weigao’s. He invited local military officers to drill workers on principals such as punctuality and honesty. To incentivize excellence, management would praise and reward workers for accomplishments in front of colleagues. Likewise, it would publicly shame, demote, or fire poor performers.

Wang learned from the first joint venture to make clear right away behaviors that the new joint venture would not tolerate. For instance, unexpected visits from Shandong Weigao engineers had been a problem at the first joint venture, so Wang made it policy that Shandong Weigao employees could not visit JWMS without his permission. When they insisted, Wang did not back down. He had a diplomatic way of standing his ground, Lu said. Wang also was not shy about making use of BIG’s solid relationship with Chairman Chen when necessary. Shandong Weigao engineers eventually got the message and followed proper procedures for visiting.

Protecting Intellectual Property

Biosensors knew from the first joint venture that Shandong Weigao wanted to extract management, manufacturing, and intellectual property knowledge. He and Wang also knew it would be very difficult to protect Biosensors intellectual property in China from copycat operations generally, even with patent protection, which it obtained in China for its biodegradable polymer in 2006. Its Excel stent was the first in China to use a biodegradable polymer. (However, like competitors Microport and Lepu, JWMS used J&J’s Sirolimus drug for its DES in China, which was not patent protected in that country. Biosensors was awaiting China’s SFDA approval of its BioMatrix system, which used its proprietary Biolimus A9 drug.) The expense, time, and energy involved in taking an entity to court in China for intellectual property infringement simply were not worth the trouble. “We’d rather apply the same amount of energy to growing the business,” Lu said.

What Biosensors worked very hard to protect, however, were its trade secrets. Control over hiring, prohibiting uninvited visits from Shandong Weigao engineers, and instilling military-style loyalty and discipline in employees were all ways in which Biosensors sought to protect its trade secrets and IP (to the extent that protecting IP was possible). JWMS’s location in Shandong Weigao’s industrial compound theoretically should have made protecting trade secrets more difficult. However, JWMS had its own security team and surveillance, which Lu referred to as a “compound within a compound.” Wang made sure Shandong Weigao and even JWMS employees did not have access to documents without his authorization. He also was the sole person at JWMS who could enter into the lab to mix the drug and polymer, Biosensor’s core trade secret. He would do this after midnight when nobody else was present and would make enough to last three months. Later, he shared this know-how in China only with Tan, whom he

trusted completely and was grooming to succeed him at JWMS (prior to Tan's tragic accidental death in 2011).

Recognizing that JWMS would soon need more space for its growing operations, Wang in late 2006 began looking for a separate piece of land in Weihai City, away from Shandong Weigao's compound, on which to build a factory.

Wholly Owned Again?

There was one lesson that the first joint venture could not teach, however: How to manage financial success. Because the first joint venture had not been financially successful, the two partners were unprepared for the issues that JWMS's success would create. The partners had not realized how difficult their different self-interests would make reaching consensus. "We didn't know how successful it was going to be," Lu said, "We just thought we could work out arrangements if there was a dispute...because of our good relationship."

For instance, Biosensors would have liked to consolidate 100 percent of JWMS's revenues on its income statements to look better financially and needed Shandong Weigao's approval under the venture's 50:50 ownership structure to do so. Biomatrix had not yet received regulatory approval in Europe and Biosensors was hungry for sales. Shandong Weigao had become a much bigger company than Biosensors by that time and did not need JWMS's sales to shore up its financial statements. Still, it would not acquiesce. Lu commented: "If you own 51 percent, then you don't even need to discuss this. You have the right to consolidate 100 percent of the sales and then 51 percent of the profit."

The partners could not agree on how to spend the venture's cash, roughly US\$100 million, which stood idle in the bank, benefitting neither partner. Biosensors, for instance, wanted JWMS to distribute a dividend to shareholders. It needed money for R&D investment and did not want to have to borrow money to do so. Shandong Weigao, which was not cash-strapped and had access to capital, preferred to use profits to grow the venture's business, perhaps by acquiring local companies. Lu commented:

You need to think about what's good for the joint venture, but you also need to think what's good for the investors and the original shareholders. You want to at least have a win-win, but if these things end up being in a standoff, [the partners don't] get anything from the joint venture. When you have many millions of dollars in profits, but if it's only on the paper versus really having access to use your money freely, that's a big difference.

The situation ultimately made each side hesitate to help JWMS in ways that they should have. Biosensors, for instance, did not provide JWMS its latest technologies. Shandong Weigao did not provide JWMS as much assistance as it might have to develop the venture's sales networks in second and third tier cities, preferring to earn some profit by selling JWMS's and competitor's products through its own networks. Realizing the stalemate was untenable in the long-term, the two sides started negotiations to buy each other out. "Both sides in the end came to realize they needed to have control in order to really do something with this success," Lu said.

To Buy or Be Bought Out

Lu ruminated long and hard over what was best for Biosensors in China, and generally as a company, as the two were closely intertwined. Regarding the potential purchase of Shandong Weigao's stake in JWMS, he asked himself: "Do we really know how to manage China one hundred percent? Will Weigao still help us?" Could he even convince Weigao that Biosensors had enough money to buy it out? "Being very shrewd, good businesspeople, Weigao knew whether what we proposed would be doable," Lu said. Should BIG instead sell Weigao its 50 percent stake? For the amount of money that Biosensors would have to spend to buy the rest of JWMS, could Biosensors buy another company, asset, or pursue other opportunities? If Biosensors were to walk away from its partnership with Shandong Weigao in China, would there be any unwelcome consequences?

Around this time, financial markets were increasingly unsure of BIG's growth outlook. There was a growing perception in the financial markets that Biosensors needed strong financial and strategic partners to get to the next stage, rather than rely on its founder as if in perpetual start-up mode. In adding value for shareholders, Lu wondered whether Biosensors would be better off with a Japanese or an American partner than with a Chinese partner. Biosensors in the future would likely expand beyond its DES focus. If Biosensors chose an American competitor as a strategic partner, it could more quickly become a medical device platform company. Alternatively, if Asia and China held the greatest potential for medical device markets globally, did a partnership with a Chinese player make more sense?

DISCUSSION QUESTIONS

What are the pros and cons of Biosensor International's strategy to this point?

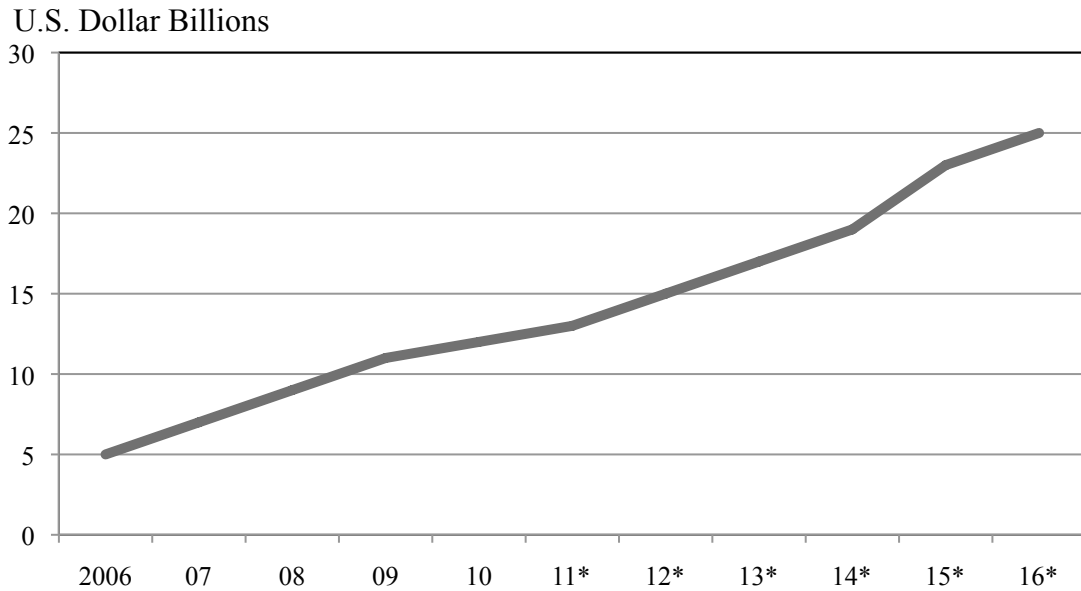
How did governance issues at JWMS impact the company's success in the China market? Would another governing structure work better?

Looking at the problems encountered in the second joint venture in China, could Biosensors have done anything differently to avoid those problems?

Regarding the questions posed on pages 1 and 15, what would you do if you were Lu and why?

If you were Lu and had to negotiate in 2010 a deal with Shandong Weigao over JWMS, what might that deal look like and how would you go about achieving it?

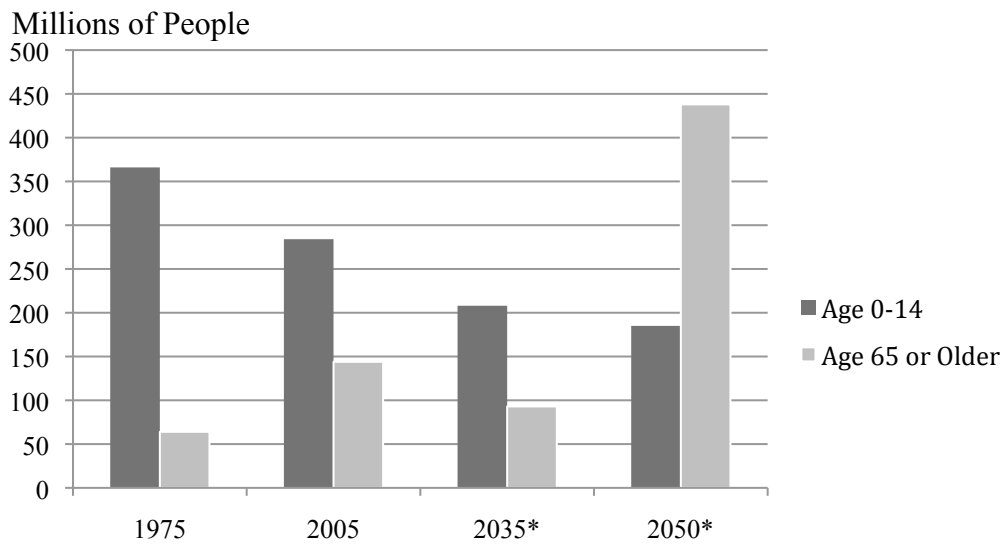
Exhibit 1
China Medical Device Market, 2006-2016



*Forecasted by Global Data.

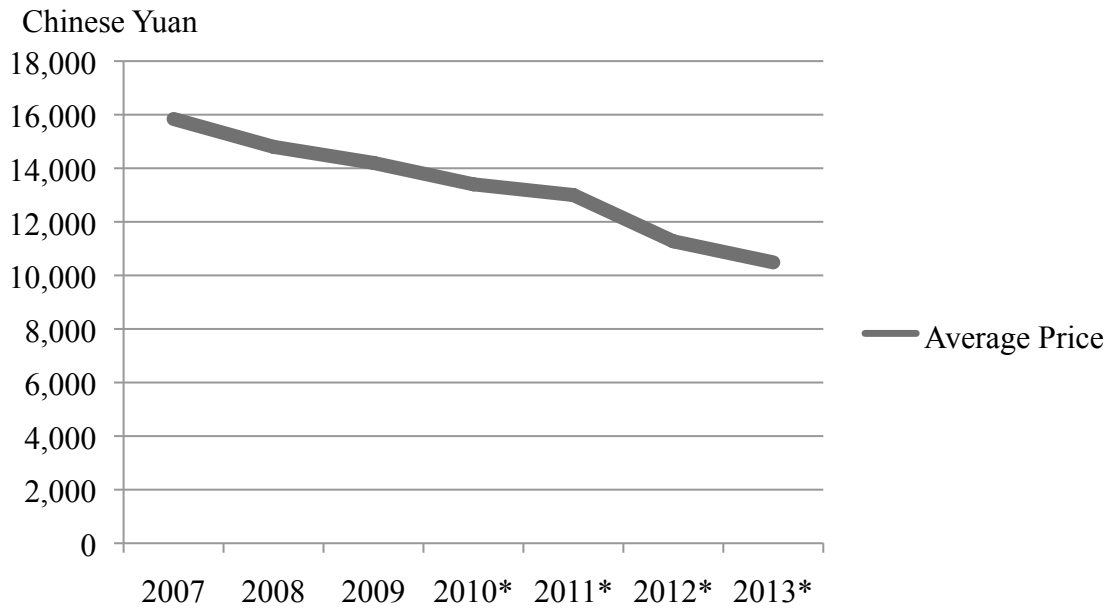
Source: Global Biodesign Lecture_ Shen2012.pdf, p.7, presented at Stanford University, April 25, 2012.

Exhibit 2
China's Population by Age, 1975-2050
Actual and Forecast



Source: Global Biodesign Lecture_ Shen2012.pdf, p. 8, presented at Stanford University, April 25, 2012.

Exhibit 3
Average Price of Drug-Eluting Stents in China, 2007-2013



* Estimated

Source: Chart compiled from data in “China Medical Devices: Stents that Sell: Opportunities in China and Beyond,” Morgan Stanley Research, December 13, 2011, p. 83.

Exhibit 4 Glossary of Relevant Terms

Angioplasty: Doctors expand narrowed coronary arteries to improve blood flow by inflating a balloon in the artery via a balloon dilation catheter.

Bare metal stents (BMS): Small, thin, expandable tubes made from surgical-grade stainless steel wire mesh.

Coronary Artery Bypass Surgery: Doctors perform this operation to circumvent blocked coronary arteries and re-channel blood to parts of the heart deprived of healthy blood flow.

Coronary Artery Disease (CAD): The build up of plaque and subsequent narrowing of the coronary arteries cause CAD and can ultimately lead to chest pain and heart attack. CAD is also referred to as coronary heart disease or ischemic heart disease.

Drug-Eluting Stents (DES): Stents that have been coated with an anti-restenotic drug. DES systems generally consist of the stent, a stent delivery catheter, the drug and often a thin polymer to carry the drug. Later generation DES came with biodegradable polymers or in polymer-free forms. Biodegradable DES fully dissolve in the body.

Percutaneous Coronary Interventions (PCI): Coronary procedures performed with a catheter.

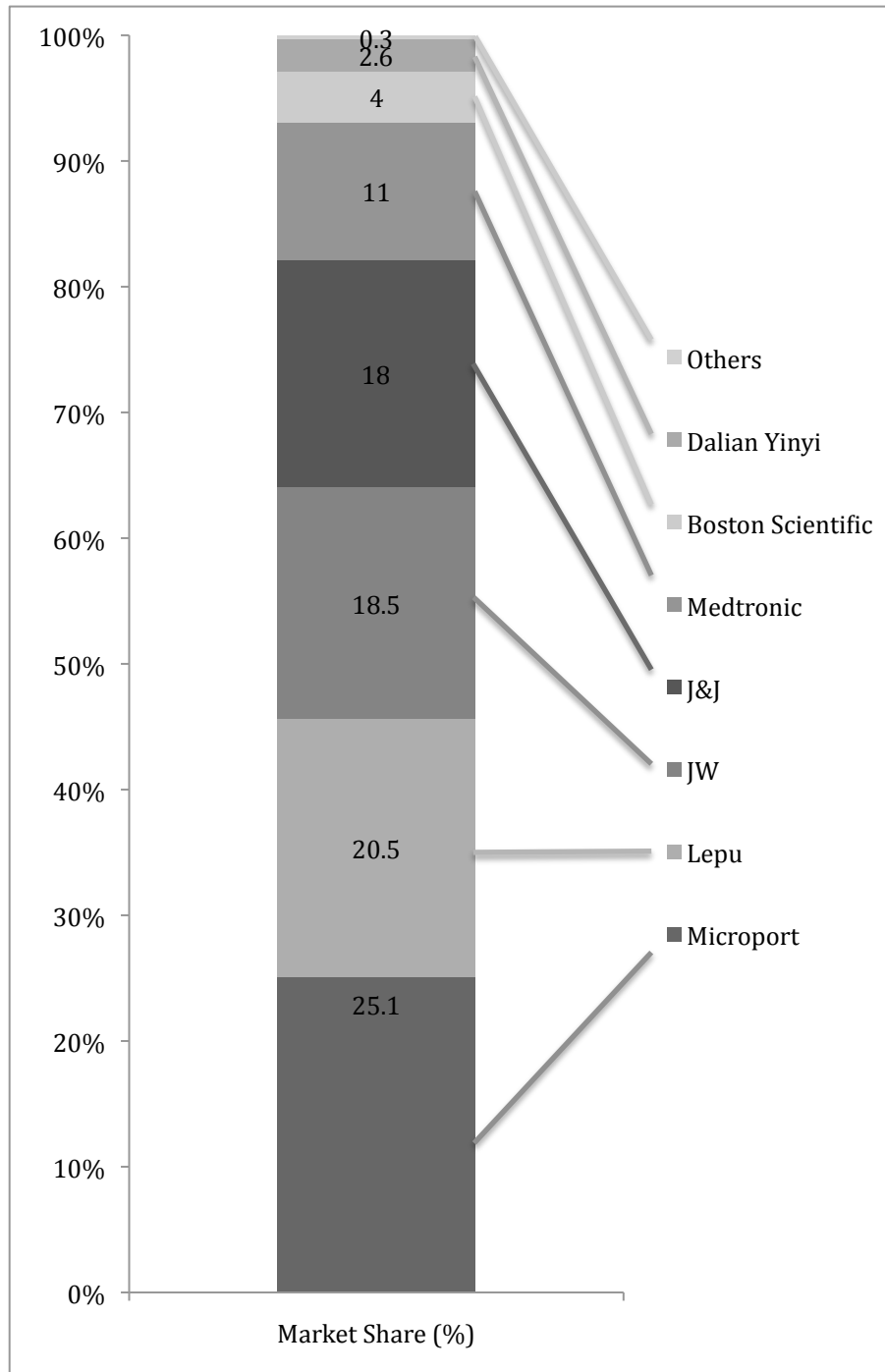
Percutaneous Transluminal Coronary Angioplasty (PTCA): To reestablish blood flow in a blocked artery, doctors inflate a balloon dilation catheter at the site of the blockage.

Restenosis: The re-narrowing of the treated artery.

Thrombosis: The formation of a blood clot inside a blood vessel or heart cavity. A blood clot or thrombus that forms within a stent is known as stent thrombosis.

Source: Biosensors International, "Glossary of Terms Used in Connection with Drug-Eluting Stents," biosensors.com, <http://www.biosensors.com/intl/Glossary-Terms> (September 17, 2012).

Exhibit 5
Market Share of Competitors in China's DES Market, 2009



Source: Chart compiled from data in “China Medical Devices: Stents that Sell: Opportunities in China and Beyond,” Morgan Stanley Research, December 13, 2011, p. 84.

Exhibit 7
Biosensors Financial Summary, 2007-2010

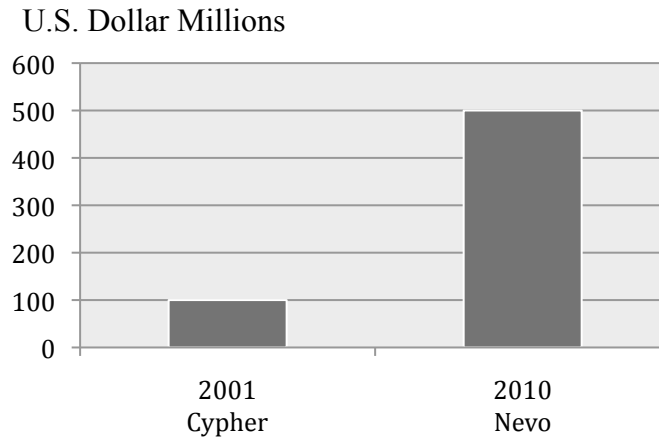
U.S. Dollar Millions

	2007	2008	2009	2010
Net Sales	34.35	44.32	118.96	116.18
Gross Profit	14.29	20.61	89.49	84.40
Net Profits/Loss	-32.29	-31.56	-1.12	32.05

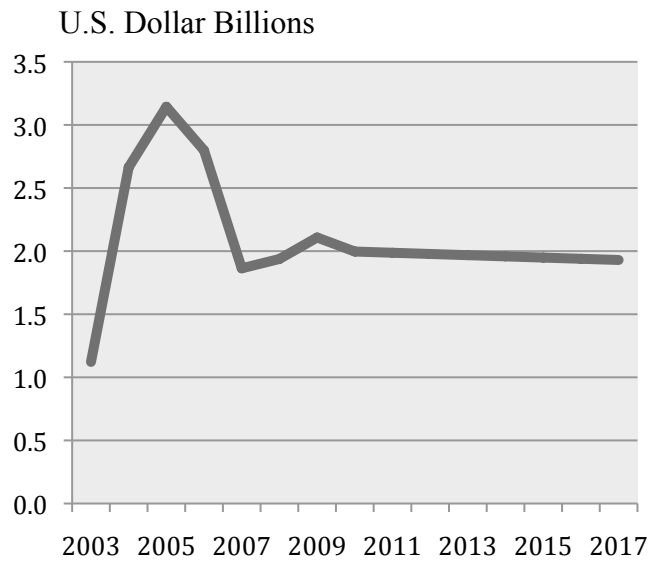
Source: Table compiled from data in “China Medical Devices: Stents that Sell: Opportunities in China and Beyond,” Morgan Stanley Research, December 13, 2011, p. 5.

Exhibit 8
Estimated Cost for U.S. Approval of DES Versus U.S. DES Market Value
(Based on J&J's experience with its Cypher and Nevo DES)

Cost of DES Approval in the United States



DES Market Value in the United States



Source: Biosensors International.