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RoboTech: Storming into the U.S. Market

In early 2017, Pat Chen was in her office in the heart of Singapore's Science Park, working past midnight again. Her company, RoboTech, had just closed the books on its third successful year in the United States, selling an innovative robotic device for spinal surgery. As the dominant player in its segment, RoboTech had again exceeded its sales and profit budget.

Despite the positive financial results, Chen was concerned. Her management team had told her that to protect RoboTech's strong position, the company needed to make major investments that could again plunge it into a loss situation. Reflecting on her 18 years as RoboTech's CEO, Chen knew she had met many big challenges—engineering a turnaround, tackling a slumping business segment, and implementing a major diversification. However, deciding what to do right now felt like the most important strategic decision of her career.

Company and Product Background

In 1999, financed by her family and a bank, Chen took over a small, struggling industrial robotics company. It was a big risk for a 29-year-old mechanical engineer who had only seven years' work experience in the semiconductor industry and an MBA she had earned at night. But as a hardworking, competitive risk taker, Chen believed she could turn RoboTech around.

The Company: From Operational Turnaround to Strategic Transformation

Chen's first move was to focus on developing specialty robotic devices. Linking RoboTech's expertise in motors, motion control, and sensors with recent advances in miniaturization, she led the company to develop an expertise in miniature robotic devices that were small, precise, and extremely strong. Over several years, its capabilities in fine welding applications requiring accuracy to 10 microns helped RoboTech become the leading supplier of aircraft-welding robots.

Eventually, competitors caught up with its technology, and particularly during the financial crisis in 2008 and 2009, once-lucrative contracts became unprofitable. Chen's experience of price wars in the semiconductor market led her to consider diverting funds from current operations to new applications.

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After much research, she focused on robot-assisted surgery. Noting that orthopedic surgery demanded extreme accuracy, Chen decided to focus on spinal surgery, a field in which robotic surgical devices had not yet been developed.

Due to the complex nature of spinal anatomy, surgical precision for it was even more essential than it was for knee replacements, where surgical robots were already effective. Unlike surgeons performing knee replacements, spinal surgeons often could not see the body parts on which they operated. Chen saw parallels with RoboTech's aircraft-welding robots' ability to make accurate placements in sites not visible to the operator.

The Innovation: Leveraging Capabilities, Developing Partnerships

While Chen felt RoboTech had the technological capability to develop the surgical arm that guided the tools and implants, she knew it would need help with the software controlling the device's delicate movements. After months of searching, she connected with an old mentor from Singapore University, who introduced her to a team working on 3-D imaging software for advanced medical robotics. Chen described the groundbreaking nature of the innovation they called the Kinetics System:

Before spinal orthopedic surgery, orthopedic surgeons use pre-operative imaging to familiarize themselves with the patient's anatomy. During surgery, visibility is often poor, so they constantly update the imaging. But the Kinetics System's preoperative software allows the surgeon to create an exact map, eliminating the need to adjust or update it during surgery. Its mechanical guidance system enables him to direct drills and implants to their exact planned location within 1.5 mm of accuracy. It's a huge breakthrough!

In exchange for developing the Kinetics software and for providing ongoing updates and support, the Singapore University team received a fee of \$5 million, plus 10% of the sales price for each machine sold. RoboTech capitalized the acquisition fee and planned to expense it over five years.

But to achieve the desired performance, the Kinetics System also required a range of analytical tools, data sources, guidance systems, tracking tools, and verification technologies that were well beyond RoboTech's capabilities. For example, one piece of software displayed a catalog of surgical instruments and implants, presented virtual views of the chosen implant from various positions, and through computer-generated simulation, allowed the surgeon to design and practice the surgical technique before performing the actual procedure. This was just one of the specialized components supplied by RoboTech's partners, whose products represented almost half of the prototype's cost of goods sold.

As Chen signed contracts with each of these partners, she recognized that while outsourcing reduced the company's investment needs, it left it vulnerable to its suppliers, particularly on price. Meanwhile, RoboTech's development of the core surgical machine turned out to be a \$45 million "bet your company" R&D investment that required it to tap its entire cash flow and appreciably increase its debt. Even though the company planned to write off that investment over five years, the elevated R&D expenses led to reported losses, something that Chen's conservative family investors particularly disliked. But by early 2011, RoboTech had a working spinal surgery robot.

The Industry and Competition

Due to growth in the elderly population, there was a rapid increase in demand for orthopedic surgery, including osteoporosis, arthritis, and degenerative disc disease. Within that market, spinal surgery seemed a promising niche.

The Orthopedic Spinal Device Business

Spinal surgeries sought to decompress a pinched nerve root or stabilize a joint by implanting screws, rods, or wires or by inserting bone grafts, spacers, or bone cement to provide relief from pain. Because accurate and safe placement of the implants in hard-to-reach target areas was so challenging, traditional spinal surgery had a high failure rate. Although surgeons defined success as whether the spine fused or the disc was removed, and so reported success rates as high as 98%, studies tracking reduction in patients' pain reported far less positive outcomes. One widely cited study suggested that two years after spinal surgery, about a quarter of patients were dissatisfied with the results.¹

Worldwide, of the 78 million people who suffered from untreated back pain—11 million in the United States alone—many were candidates for back surgery. In 2012, the global market for orthopedic medical devices was \$34.5 billion, with spine devices accounting for about 20% of the total.² In the United States, 451,000 spinal fusions were performed in 2012, making it the fifth most commonly performed procedure.³

Competitors in the Orthopedic Device Space

A few large players dominated the spinal device business, offering surgical tools and implants used in traditional surgery. Medtronic led the segment with a 41.7% share, followed by DePuy Synthes (Johnson & Johnson's orthopedics organization) with 24.3%, and Stryker with 10.1%.⁴

Several factors had kept these companies from developing orthopedic robots: the robots' high cost, the lack of clinical evidence proving their superiority, and the long learning curves needed for surgeons to master the new techniques. But many industry experts believed as the technology improved and surgeons became more comfortable using it, hospitals would invest in it.

Two small companies had already launched robotic orthopedic devices. Mako Surgical, founded in 2004, had launched a knee replacement system in 2006. It cost \$750,000, not including implants or service.⁵ After going public in 2008, Mako immediately launched a successful hip replacement robot. In 2012, NavioPFS received FDA approval for its knee implant device, which was priced at \$450,000.⁶ Unlike Mako, this system let surgeons use implants of their own choosing.

RoboTech's Decision: Assessing Potential, Developing Strategy

In 2012, after two years of clinical trials, RoboTech's device was approved in Singapore. Chen now wanted to quickly leverage RoboTech's first-mover advantage in robotics for spinal surgery, and this meant entering the U.S. market, which accounted for more than a third of the global potential.

The U.S. Market

Chen created a team to evaluate the U.S. opportunity. It found that about 360,000 thoracic or lumbar procedures—the Kinetic System's focus areas—were completed annually in the United States. Surgeons performed these operations in facilities ranging from small surgery centers to giant teaching hospitals. The team estimated 1,000 to 1,500 of these institutions could afford the proposed system price of \$869,000, an annual four-year service contract at \$55,000 after year one, and disposables at \$1,800 per procedure. It also estimated that each hospital would perform between 75 and 85 procedures annually.

While the initial projected gross margin for machine sales was only 45%, primarily due to RoboTech's heavy reliance on outsourced components, service contracts and disposables would be more lucrative. With estimated gross profit margins of 70% and 60%, respectively, overall profitability

was expected to rise as the installed base grew. This assessment was speculative, however, especially because of the major systemwide changes unleashed by recent U.S. health-care legislation.

The U.S. Regulatory Environment

In 2010, the U.S. Congress had passed the Patient Protection and Affordable Care Act (soon dubbed “Obamacare”) to offer health-care access to all citizens. Leveraging the private insurance market, the act required everyone to purchase coverage on health insurance exchanges, guaranteeing no one could be turned down for coverage. Subsidies were offered to low-income individuals and families. The U.S. government estimated that by 2019, over 30 million previously uninsured people would be covered.⁷

The RoboTech team focused on how the legislation would affect reimbursement processes. The existing fee-for-service model, which offered reimbursement to hospitals, physicians, and other care providers for each intervention, had often resulted in fragmented care, with little incentive for cost savings or cross-provider coordination. This model was being replaced by reimbursement based on quality of care as measured by patient outcomes, improvements on specific metrics (e.g., reduced hospital admissions), provision of preventive care, and use of health-care IT systems.

The government’s goal was to convert 30% of fee-for-service Medicare payments to value-based payments by the end of 2016.⁸ Because 40% of patients undergoing spinal surgery were over 65 and covered by the government’s universal aged care program, Medicare, RoboTech decided to work within that payment paradigm. Furthermore, Medicare reimbursement coverage and levels were likely to become the standard followed by most private insurance providers.

The current system assigned codes and set reimbursements for each medical condition. Doctors and hospitals received payments based on the set rate, regardless of actual treatment costs. Reimbursement for spinal surgery ranged from \$40,000 to \$60,000, depending on the procedure. But because there was no reimbursement for capital costs such as the Kinetic System, RoboTech would have to prove its device could improve operating time, patient recovery, or other quantifiable benefits that would repay the initial equipment cost.

Launch Decision and Entry Strategy

Stalled industrial sales, falling prices, and R&D investment write-off had all taken a toll on RoboTech’s earnings. With creditors becoming nervous and some family members inquiring if their investments were secure, Chen was anxious to exploit the new opportunity.

When the market-entry team estimated that RoboTech U.S. could sell 25 units at \$869,000 in its first year, Chen decided to pursue FDA regulatory approval. Her U.S. regulatory consultant sought fast-track consent for a device “substantially equivalent” to an existing approved device. Leveraging the proven effectiveness of existing robotic surgery devices, as well as its own successful clinical trials, RoboTech obtained marketing approval in eight months.

In September 2013, Chen established a subsidiary, RoboTech U.S. She set up a sales office in Chicago, where she interviewed candidates for the U.S. Sales Director position. From a dozen finalists, she chose Brian O’Hanlon, a regional sales manager with 20 years’ experience at orthopedic device heavyweight Zimmer. Together, they developed a three-year U.S. sales strategy and budget. The 2014 plan targeted the entry team’s forecast of 25 units.

In January 2014, after hiring his team of six sales representatives, a service tech, and four staff in office, training, and support roles, O’Hanlon began implementing a three-pronged strategy focused on targeting key facilities, training orthopedic surgeons, and educating patients. He first planned to

contact top academic hospitals, not only because of their influence, but also because they were highly competitive. O'Hanlon believed if he could get one or two to commit to the device, a domino effect would bring the others along.

Meanwhile, the training manager opened a center to offer hands-on experience to leading surgeons, who would in turn advocate for the system at their hospitals. In parallel, O'Hanlon contacted a public relations company to present spinal surgery candidates with information about the new technology. Lacking the funds to support a major marketing program, he also asked the PR firm to obtain press coverage emphasizing this breakthrough innovation and patient success stories.

Implementing the Strategy: Early Wins, Emerging Worries

In early 2017, three years after its U.S. launch, Chen was pleased with RoboTech's progress. (See **Exhibits 1a and 1b** for RoboTech's U.S. subsidiary and parent income statements and **Exhibit 2** for Robotech's balance sheet.) But a few clouds were gathering on the horizon.

The First Year: Sales Success and Systems Stress

Following a strong launch, RoboTech shipped 24 systems in 2014. At the end of 2014, it had six more on back order. Industry analysts were bullish about robotics implant surgery. One predicted it would become the de facto standard in knee and hip surgery within five years and in spinal surgery a few years later. Another suggested that once penetration reached 35%, hospitals without these systems would risk losing their best doctors.

But market success came with costs. The Chicago office was overwhelmed by sales requests and technical inquiries, resulting in long delays and embarrassing communications breakdowns. The rush of orders exceeded Singapore's production capacity, and fulfillment ran months behind promised delivery dates. Furthermore, the training center was at capacity, with a months-long waiting list. Yet orders continued to roll in. When Chen committed to expanding manufacturing capacity to 80 units during 2015, O'Hanlon felt confident in budgeting sales of 60 units. If the continuing changes in health-care reimbursement did not disrupt demand, the goal seemed achievable.

Reimbursement Reverberations and Cost Concerns

As reimbursement practices moved toward a "bundling" model, health-care providers adapted to receiving a single procedure payment covering facility fee, physician's fee, anesthesiology, implants, pain management, and postoperative and rehabilitation care for 60 to 90 days. One study found a 30-day bundle for a spinal surgery averaged \$33,522, while a 90-day bundle was \$35,165.⁹ This was far less than the \$40,000 to \$60,000 reimbursement RoboTech had assumed in its forecasts and budgets.

Value-based reimbursement also led to buying decisions shifting from physicians to administrators. As purchasing processes became more complex and time-consuming, RoboTech's sales staff found they had to spend more time managing the sales process than originally estimated. Beyond emphasizing improvements in spinal procedures, they now had to document cost savings associated with lower rates of repeated surgeries and faster recoveries. O'Hanlon conceded he had been unable to scale up his sales force quickly enough to provide the support necessary to address new market needs.

The Second Year: Customer Conversions, Cash Constraints

Notwithstanding these challenges, sales boomed through 2015, creating new strains on the company. In response to financial pressures caused by production expansion, R&D investment, and debt repayment programs, Chen asked whether O'Hanlon could capitalize on market interest by

asking customers to pay a 30% deposit with their order to guarantee their place in the production schedule. While such a request was unheard of in the industry, O'Hanlon understood RoboTech's financial constraints and said he would try.

This unusual request simply added to customers' discontent. New production capacity was slow to come online, and customer irritation at missed delivery promises grew. Still, by year's end, RoboTech had recorded 55 sales, with 20 more units on back order. And as the installed base grew, the sales mix of higher-margin disposables increased. To Chen's relief, the U.S. operation was now profitable.

A Changing Competitive Landscape

Meanwhile, the competitive scene had become more complex. In December 2013, Stryker acquired Mako Surgical.¹⁰ Because of Stryker's strong position in spinal surgery, speculation was rife that it planned to develop a robotic spinal surgical device.

Then, in 2014, a small Israeli company called Mazor Robotics entered the U.S. market with a robotic spinal device whose hardware resembled RoboTech's.¹¹ Although the new entrant attracted wide attention and eventually sold a few units, Chen believed that the Kinetics System software would prove superior.

Finally, in late 2015, Smith & Nephew, a \$4.7 billion U.K.-based orthopedic device company specializing in replacement joints, acquired Blue Belt Technologies, a maker of robot-controlled surgical tools for knee replacements.¹² The acquisition gave the successful European company its entry into the U.S. orthopedic robotic surgery market.

As the industry consolidated, speculation spread that Medtronic was assessing robotic acquisition prospects while also working on its own devices. Clearly, RoboTech would soon face competitors with larger sales forces, stronger customer relationships, broader product lines, and deeper pockets.

Year Three: Developing Demand, Competitive Challenges

Nonetheless, O'Hanlon remained confident, stressing that Mazor, the only company with a directly competitive product, had sold just 10 units in 2015. With his strong order book, a big backlog, a flood of inquiries, and capacity planned to increase to 110 units, he budgeted sales of 100 units in 2016.

As 2016 progressed, the challenges expanded. In May, Medtronic announced an agreement with Mazor covering co-promotion, co-development, and global distribution of its spinal products.¹³ Two months later, Zimmer announced its acquisition of Medtech SA, a French developer of a robotic device already used in 20 hospitals in Europe, North America, and Asia.¹⁴ Its original neurosurgical device had been used in Europe for years, and its spine system adaptation had received European approval in 2014 and FDA clearance in 2016. Because neurosurgery required surgeons to operate in compact spaces with fine movement and limited vision, Chen had hoped to expand RoboTech into this space.

Later in 2016, Zimmer had introduced a robotic spinal surgical device.¹⁵ It came out with a new generation of Medtech's neurosurgery robotic device, which could also perform spinal surgery. At \$950,000, this multipurpose device was supported by Zimmer's worldwide sales and service network.

During these frenetic consolidations, Chen met with her old mentor to discuss the evolving situation. When he asked if she had explored the option of selling out, she told him that before Medtronic entered its agreement with Mazor, it had contacted RoboTech. But because Medtronic was well along with its own technology, the price it offered Chen was extremely low, so she had terminated negotiations.

More recently, Johnson & Johnson, the last remaining viable partner among the major orthopedic companies, had entered a joint venture with Verily, Google's life sciences business.¹⁶ These firms were investing \$250 million in Verb Surgical, a project to develop an intelligent digital surgery platform to support multiple cardiac, urologic, gynecologic and pediatric procedures. Judging the days of specialized surgical robots was past, Verb planned to launch its multisurgery robot product in 2017.

At the end of the year, O'Hanlon estimated that competitors collectively had sold 90 spinal systems, 20 fewer than RoboTech's sales of 110 units. In his view, demand exceeded likely industry capacity of 220, a view confirmed by year-end back orders of 30 at RoboTech and an estimated 20 at competitors.

2017: Choices to Make for the Future

As 2017 began, Chen reflected on the preceding three years with a mixture of pride and concern. She was proud of the 2016 sales estimates, earnings that were well ahead of budget, and margins of 47.5% on machine sales in 2016 as RoboTech continued to realize further economies of scale from increased production. The concern arose as she studied two large investment requests, particularly when the prevailing competitive complexity had been exacerbated by political uncertainty following the election of President Donald Trump, who had promised to "repeal and replace Obamacare."

The most pressing demand was from her R&D director. With Medtronic's support, Mazor had just introduced an improved spinal robotic system. Furthermore, it was rumored to be developing a related system for neurosurgery. In response, RoboTech's R&D director proposed investing an additional \$18 million to accelerate hardware and software programs to upgrade the existing spinal system, and a further \$85 million to develop a third-generation device supporting both spinal and brain surgery. The R&D director expected the new-generation spinal device could be on the market within a year and the combined unit, a year later. She argued the rapid pace of technological development meant RoboTech needed a combined unit ready for the market by 2019 to avoid being shut out of future growth.

Competing for funding was an urgent request from O'Hanlon, who stressed the need to hold off rising competitive pressure by boosting his sales force from 30 to 45. And with almost 200 RoboTech devices installed and a comparable number to be delivered in the next 18 months, he argued that RoboTech's shaky reputation would be further impaired unless he opened two new service centers and doubled service staff to 28. O'Hanlon also proposed lowering RoboTech's device price by \$120,000 to match Stryker's offering and to undercut Zimmer's price. His proposals for new sales offices, service centers, and a warehouse would require a \$5 million investment, while his recommendations on operating expenses and prices would decrease the 2017 net earnings forecast by almost \$25 million.

Chen was certain these investment requests would not only require the company to assume additional debt, but would also plunge it back into a loss position that could be mitigated only partially by the Industrial Division, whose revenues and profits had declined precipitously. And this prospect would undoubtedly disturb her conservative family members who had invested in RoboTech. It was going to take strong arguments to convince them that, just as it had done seven years earlier, RoboTech could not only survive such bold investments, but could also emerge from the losses and thrive. But in this challenging market situation and competitive environment, could she really make the case that it was time, once again, to "bet the company"?

Exhibit 1a Income Statement for RoboTech U.S. (U.S. \$000)

| Year Ending | 12/31/2016 | 12/31/2015 | 12/31/2014 |
|-----------------------------|-------------------|-------------------|-------------------|
| Revenues | \$117,059 | \$55,871 | \$22,584 |
| Cost of sales | <u>55,009</u> | <u>28,141</u> | <u>12,424</u> |
| Gross Profit | <u>62,050</u> | <u>27,730</u> | <u>10,160</u> |
| <i>% of revenue</i> | 53% | 50% | 45% |
| Operating Expenses: | | | |
| Research and development* | 4,044 | 3,089 | 10,004 |
| Selling and marketing | 12,111 | 4,987 | 1,600 |
| General and administrative | 6,056 | 2,494 | 800 |
| Software acquisition* | 0 | 0 | 1,000 |
| Software licensing fee | 9,559 | 4,779 | 2,086 |
| Total operating expenses | <u>31,770</u> | <u>15,349</u> | <u>15,490</u> |
| <i>% of revenue</i> | 27% | 27% | 69% |
| Operating Earnings | <u>\$ 30,280</u> | <u>\$ 12,381</u> | <u>(\$5,330)</u> |
| Depreciation | 3,530 | 2,325 | 1,575 |
| Interest expense | 566 | 1,013 | 1,316 |
| Pretax Profit (Loss) | <u>\$ 26,184</u> | <u>\$ 9,043</u> | <u>(\$8,221)</u> |

* Major initial R&D investment and software acquisition expensed over 2010-14.

Exhibit 1b Income Statement – RoboTech Corporate (U.S. \$000)

| Year Ending | 12/31/2016 | 12/31/2015 | 12/31/2014 |
|--------------------------------------|-------------------|-------------------|-------------------|
| Revenues: | | | |
| RoboTech U.S. | \$117,059 | \$ 55,871 | \$ 22,584 |
| RoboTech Industrial | 84,378 | 120,541 | 150,676 |
| <u>Total Corporate Revenue</u> | <u>201,437</u> | <u>176,412</u> | <u>173,260</u> |
| Pretax Profit (Loss): | | | |
| RoboTech U.S. | \$26,184 | \$ 9,043 | (\$ 8,221) |
| RoboTech Industrial | 3,797 | 6,629 | 11,301 |
| Total Corporate Pretax Profit | <u>29,981</u> | <u>15,672</u> | <u>3,080</u> |
| Taxes | \$ 6,296 | \$ 3,291 | \$ 647 |
| Total Corporate Net Income | <u>23,685</u> | <u>12,381</u> | <u>2,433</u> |

Exhibit 2 RoboTech Consolidated Balance Sheet (U.S. \$000)

| Year Ending | 12/31/2016 | 12/31/2015 | 12/31/2014 |
|------------------------------|---------------|---------------|---------------|
| Current Assets: | | | |
| Cash and cash equivalents | 5,310 | 3,755 | 4,575 |
| Short-term investments | 1,299 | 1,181 | 1,125 |
| Receivables | 15,054 | 8,580 | 4,720 |
| Other current | 292 | 266 | 515 |
| Inventory | 9,165 | 7,350 | 5,940 |
| Total Current Assets | <u>31,120</u> | <u>21,132</u> | <u>16,875</u> |
| Non-Current Assets: | | | |
| Prepaid leases | 1,636 | 1,498 | 1,775 |
| Property and equipment (net) | 44,275 | 41,896 | 38,730 |
| Other | 410 | 250 | 315 |
| Total | 46,321 | 43,644 | 40,820 |
| Total Assets | <u>77,441</u> | <u>64,776</u> | <u>57,695</u> |
| Liabilities: | | | |
| Short-term payables | 3,586 | 4,122 | 3,435 |
| Short-term debt | 3,547 | 6,819 | 8,645 |
| Long-term debt | 5,082 | 12,294 | 16,455 |
| Total Liabilities | <u>12,215</u> | <u>23,235</u> | <u>28,535</u> |
| Equity: | | | |
| Retained earnings | 52,436 | 28,751 | 16,370 |
| Paid-in capital | 12,790 | 12,790 | 12,790 |
| Total Equity | <u>65,226</u> | <u>41,541</u> | <u>29,160</u> |

Endnotes

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