Case #2

CASE 4

OR Solutions Reaches a Crossroad

As Jack Ferguson walked from the parking lot toward the offices of OR Solutions, he wondered what 2008 would bring for the medical device company, located in an upscale suburb of Tulsa, Oklahoma. Jack stopped by his office, briefly checked his email, grabbed his briefcase, and walked down the hall toward the OR Solutions boardroom. Jack looked around the boardroom and sighed heavily; it was quiet and serene now but he knew the serenity would not last long.

In an hour he and his business partner, Tom Marshall, would meet with consultants Michelle Brown and Greg Anderson from Market Research, a regional marketing consulting firm, to discuss the future direction and organization of OR Solutions, one of their largest projects. A few years earlier, prospects for OR Solutions seemed so bright; however, now its future success was in jeopardy.

Jack Ferguson, a serial entrepreneur, had worked in software development for nearly 20 years, starting and running several profitable companies. His vision and attention to sound business practices had made him a master at helping to turn around companies in difficulty. Although he lacked direct experience in healthcare,

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*At the request of the organization, names, locations, and financial data have been disguised. Used with permission from the company.

his entrepreneurial instinct told him that technological innovations were part of the solution. OR Solutions' technological innovation, the OR Surgical System, could make a great contribution toward improving efficiency and quality in healthcare.

Tom Marshall was an experienced engineer of medical devices. He had designed an infusion therapy monitoring system for the OSU Medical Center in Tulsa, Oklahoma; the largest hospital in the area with 331 licensed beds and over 6,000 inpatient surgeries, 5,000 outpatient surgeries, and 12,000 patient admissions. When OSU Medical Center surgeons and operating room nurses detailed the inefficiencies and safety issues of the current minimally invasive surgery (MIS) operating procedures, the University Research Foundation contacted Tom for ideas. His idea was the OR Surgical System, currently the only product of OR Solutions.

History of OR Solutions

In 2000, Tom began working with the University Research Foundation to develop a single surgical control system that would (1) integrate and provide a single point of control for all electrosurgical devices used in minimally invasive surgery (MIS) procedures–regardless of manufacturer, and (2) activate a closed-loop smoke evacuator to automatically clear the surgical field when using the operating devices that often generated smoke, making it difficult for the surgeon to see.

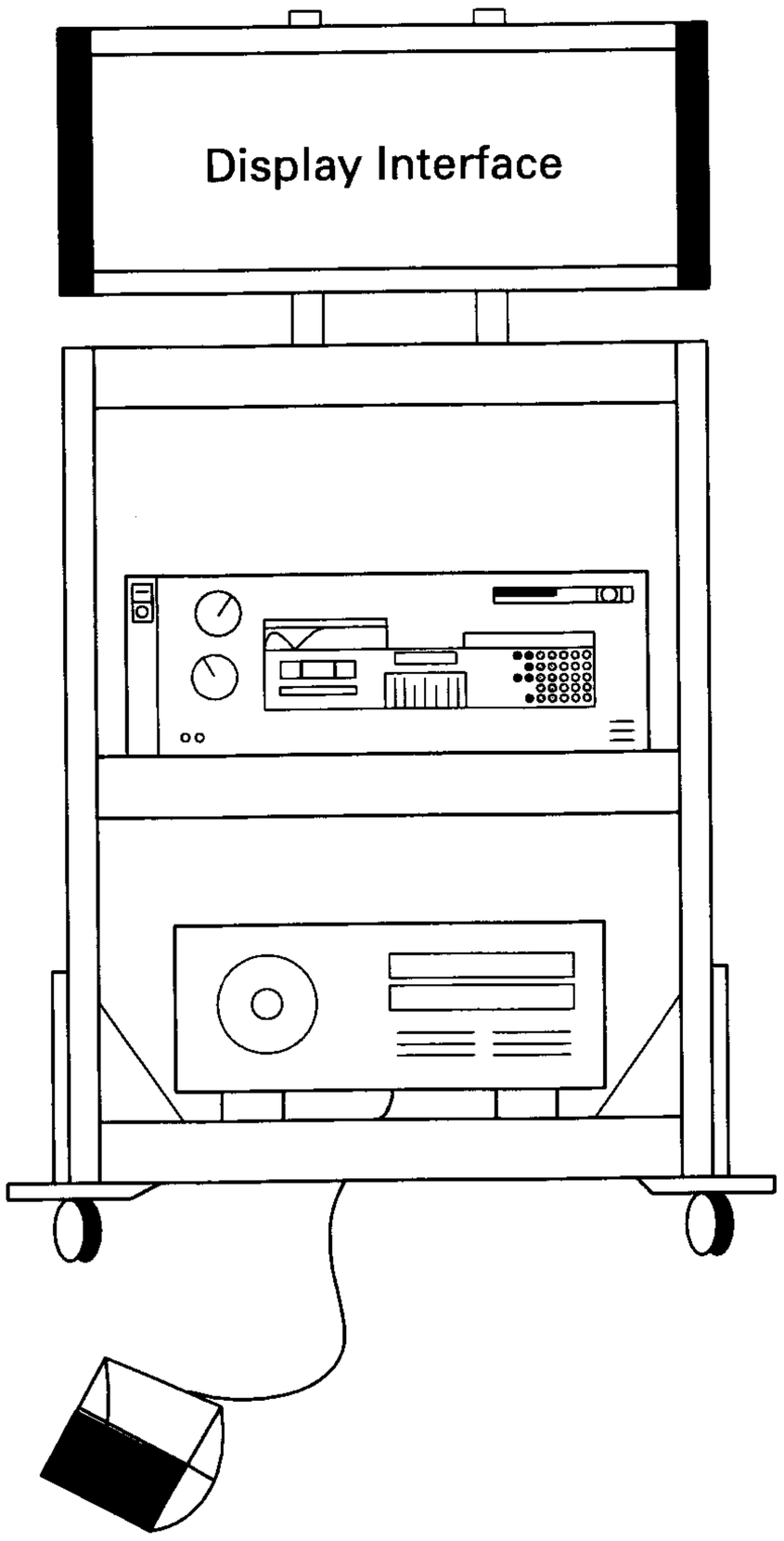
Minimally Invasive Surgery Marketplace

Minimally invasive surgeries (MIS), or "bloodless surgeries" as they were sometimes known, accounted for about 30 percent of all surgeries in the United States. MIS procedures were performed across a variety of surgical specialty areas and were considered to have less associated complications than open surgeries. A surgeon performing MIS used a number of electrosurgical devices that performed different functions such as cutting, coagulating, and sealing. For each surgical function, separate instruments (often manufactured by different device companies) each had its own foot pedal to operate the function. The foot pedals were generally out of the sight of surgeons and pedal operation could be somewhat confusing, partly because each device manufacturer used its own standards. In fact, the nurse would often have to crawl under the surgical table to press the foot pedal to let the surgeon know which instrument was attached to which pedal. Application of a wrong pedal during surgery could have serious consequences (for example, cutting instead of coagulating). Other problems included injuries related to heat, insulation failure, and reduced visibility as well as possible health consequences related to smoke generation during surgery.

According to the Director of the Oklahoma Institute of Minimally Invasive Surgery, "A typical MIS procedure requires electrosurgical devices such as harmonic scalpels, lasers, and others functions with no designed method for coordinating the use of the instruments and the only way to know which pedal is pushed is by the sound it makes, which is often too late."

Tom worked on an idea to coordinate the group of surgical devices required in MIS into one central operating unit and built the OR Surgical System, illustrated in Exhibit 4/1. Tom realized the potential of the OR Surgical System and believed that thousands of these devices could be installed in hospital operating rooms all over the world. In fact, after seeing a demonstration of the OR Surgical System, Ralph V. Clayman, Professor and Chair of the Department of Urology at the University of California, said, "Congratulations, you have built a better mousetrap . . . it is no surprise that the world is beating a path to your doorstep."

Exhibit 4/1: The OR Surgical System



"Problem is," Jack mused, "no one is beating a path to our door." Jack opened his briefcase and took out several files. As he seated himself at the boardroom table, he began to review the files. Jack recalled the summer of 2004, when he first met Tom Marshall. Tom's exuberance concerning his new product was infectious. Jack smiled as he remembered the enthusiasm with which Tom explained the details of the OR Surgical System. Tom was in the final development and testing stages. He had already invested $2.5 million of his own funds and a working prototype had been completed. Jack recognized that Tom had a great new product and the passion and expertise to make it work. Even in their initial meeting, Jack understood the potential of the product and its possible impact on reducing surgical errors and improving the efficiency of surgical procedures. In addition, he thought it could be tremendously profitable and could lay the foundation for a multiproduct medical equipment company. However, the business model and strategic plan for this product was undefined.

After successful animal testing, Jack helped Tom to raise an additional $2 million of "angel investment" and in return negotiated 15 percent ownership of the company. They worked to develop the business model and create a strategic plan. Together they founded OR Solutions, LLC and sought Federal Drug Administration (FDA) approval for the product. The OR Surgical System received FDA clearance as a Class II medical device in fall 2005. Production began, and in January 2006 the first human surgery using the device was demonstrated with great success at Oregon University.

The Business Plan

Jack opened the file containing his original business plan and turned to the market analysis section. Once again he looked at the description of the healthcare market. According to American Hospital Association (AHA) in 2003, nearly 3,860 of the 5,944 hospitals in the US had one or more operating rooms. More than 29,750 operating rooms were used to perform 27 million procedures of which an estimated 30 percent were MIS (AHA Annual Survey Database, FY 2003). "Wow, that's lots of market potential. The increased efficiency and safety that the OR Surgical System provides should be obvious to hospital administrators as well as surgeons," Jack remembered thinking. He had speculated, "All that OR Solutions needs to do is demonstrate the product to a few influential surgeons and the OR Surgical System would sell itself – this devise solves a lot of operating room problems." (See Exhibit 4/2 for a list of potential users of the OR Surgical System.)

Jack noted that his initial optimism was evident in his sales projections as he re-examined the original plan. The sales projections for FY 2007–08 were 83 per month for a total goal of 1,000 units and upwards of $35 million in revenues (see Exhibit 4/3). Yet, sales were sluggish.

As he was getting discouraged, Jack turned the page to his cost and pricing projections (Exhibit 4/4). He spoke aloud, "These figures still looked pretty close to actual – the margin was there even if the sales volume wasn't. The price was $30,000 for one operating room outfit; it wasn't like this was outrageous."

Exhibit 4/2: Target Customers

Target Customers

Hospitals Providing the Following Procedures

- Obstetrics and gynecology
- Urology
- Colon and rectal
- Cardiovascular
- Otolaryngology and head and neck
- Ophthalmology
- General studies
- Orthopedics
- Neurosurgery

Influences and Recommenders

- Physicians
- Head Operating Room Nurses
- Hospital Administrators
- Hospital Physical Plant Personnel
- Industry Consultants

Source: Company data.

Exhibit 4/3: Sales Projections for the OR Surgical System Device, Original Business Plan FY 2004–05

	Total Operating Rooms (US)	Projected Sales (# of units)	Annual % Growth in Sales	Sales Per Month (# of units)	Revenue	Net Income
FY 2005	29,735	10	—	4	$337,917	($130,125)
FY 2006	29,735	250	400%	21	$8,827,083	$2,827,954
FY 2007	29,735	500	100%	42	$17,600,000	$3,520,000
FY 2008	29,735	1000	100%	83	$35,200,000	$7,040,000
FY 2009	29,735	1700	70%	142	$59,840,000	$11,968,000

Source: Company data.

Exhibit 4/4: Production Costs and Price Projections, Original Business Plan FY 2004–05

Component	Cost to Produce	Sales Price
Main Control Unit	$1,400	
Master Control Unit	$500	
Remote Control Unit	$100	
Industrial Grade PC	$3,000	
Surgical System Cart	$1,000	
Total Sales Price		$29,500
Additional Components		
Interface Assembly	$225	$750
Smoke Evacuator	$1,200	$2,500
Disposable Tubing Package	$25	$50

Source: Company data.

OR Solutions FY 2005–06 to FY 2007–08

OR Solutions' potential appeared promising at its launch in fall 2005, although only 35 units were sold in FY 2005–06. On the other hand, OR Solutions had managed to get these devices into a few prestigious operating rooms and into the hands of some prominent surgeons. According to Jack, "We placed the unit in some great locations but the OR Surgical System was still not 'selling itself.' In addition, we won the Innovation of the Year Award from the Society of Endoscopic Surgeons (SES)."

Jack had worked tirelessly to set up and organize the business *and* develop a viable strategy to launch OR Solutions that was agreeable to both partners. Jack thought that the plan was sound but implementation had not produced the results he had hoped. At the beginning of FY 2007–08, OR Solutions was at a standstill with no real marketing or production activity. Something dramatic was needed or OR Surgical System's first mover advantage would be lost (as well as everyone's investment).

Jack recalled, "My original intention had been to seek out a strategic distribution partner to handle some of the marketing and distribution logistics. However, Tom wanted to market and distribute the product to have more control over operations and revenue and enjoy substantially more benefits. We decided to try to build an internal salesforce that would aggressively move OR Surgical Systems into surgical suites. We hired Henry Spencer as Director of Sales and Marketing."

Henry came with extensive experience, having previously worked with teaching and specialty hospitals as well as military institutions. He targeted and managed the introduction and demonstration of the OR Surgical System to top surgeons. Over the course of the first fiscal year, he had some success and was able to place several machines in operating rooms of major hospitals (see Exhibit 4/5 for placements). In addition, during this period, Henry exhibited the device at several trade shows, including Society of Endoscopic Surgeons (SES) and the Society of American Gastrointestinal Endoscopic Surgeons (SAGES). At these trade shows a number of surgeons expressed interest in the OR Surgical System. Henry would then prioritize the leads based on the size of the hospital, its degree of interest, and a ranking of the surgeons to determine priorities for follow-up and an in-person demonstration of the OR Surgical System. He would try to visit the facility the

Exhibit 4/5: Locations of OR Surgical Systems, FY 2005 and FY 2006

Sample Locations	Number of Units	Total Beds	Total Discharges
OSU Medical Center, Tulsa, Oklahoma	9	331	12,042
Oregon University, Metro, Oregon	2	657	29,305
South Tampa Hospital, Tampa, Florida	2	422	21,015
Providence Medical Center, Tulsa, Oklahoma	2	214	7,849
Trinity Medical Center, Dallas, Texas	4	356	17,677
Providence Hospital, Oklahoma City, Oklahoma	1	349	15,812

day before a surgery appropriate for an OR Surgical System demonstration. Henry soon realized that the demonstrations were helpful for the surgeons but that he would also need to get in front of the hospital administrator to make a sale.

If Henry made a sale, production was initiated by Doug Fischer, Manager of Engineering and Production. Doug was primarily responsible for overseeing the production of the OR Surgical System. Apart from supervision of the day-to-day engineering tasks and documentation, he oversaw the adherence to good manufacturing practice (GMP) and FDA protocol. Contract technicians helped with the assembling of OR Surgical Systems at the OR Solutions offices. Most of the components were purchased through outside vendors and were shipped to OR Solutions for assembly. After the units were fully assembled, they were tested and shipped to buyers. Henry would then assist hospitals to install the OR Surgical System and would train the surgeons and nurses.

Success, however, was limited and by 2006 Jack was convinced that his original strategy of finding a distribution partner would be more efficient, successful, and lucrative. Jack believed that a strategic partner would provide several benefits including marketing, distribution, and sales. However, Tom was the majority owner and he was wary of losing control of the product and ultimately ownership of the company.

After considerable discussion, Jack and Tom agreed to explore the possibility of creating a strategic alliance to market and distribute the OR Surgical System. In 2006, Jack sent out approximately 20 letters to organizations he considered viable options for potential partnerships. In these letters he introduced the product and called for interested parties to set up meetings to discuss the OR Surgical System in greater depth.

After numerous meetings with potential partners, Jack and Tom had narrowed the list of potential partners to five. Four of the organizations were interested in strategic partnerships in which they would assume all of the marketing responsibilities and the fifth was interested in a purchase. Jack understood that purchase of OR Solutions by another company was not likely to be an acceptable option from Tom's perspective; however, at some point in time it might be the only option as the technology aged. Being "bought" was a last resort as far as Tom was concerned.

From Tom's point of view, the ideal situation allowed Jack and Tom to maintain some ownership and Tom and Doug to continue to oversee the engineering and production side of the business. The list of potential partners included Stryker, Smith and Nephew, Ethicon Endo Surgery (a division of Johnson & Johnson), and Storz. In Jack's mind there was no clear answer to the company that would lead to the most successful partnership, for each had its own appealing attributes. Jack began to flip through all of the print material he had for each company (Exhibit 4/6).

STRYKER

Stryker, a Fortune 500 company, was the largest organization that they were considering as a partner. In 2006, 34 percent of its sales were international, leading Jack to believe that they would have a global presence with which to market the OR Surgical System. However, Stryker was primarily focused on orthopedics. Its orthopedic products including implants, powered surgical tools, and operating

Exhibit 4/6: Potential Partnering for OR Solutions

	Stryker	Smith & Nephew	Ethicon Endo-Surgery	KARL STORZ Endoscopy America Inc.
Revenue	$5.1billion	$2.8 billion	$3.376 billion	$100 million
Location	Global	Global	Global	Germany (HQ), Global
Salesforce	15,000 (Global)	9,600 (Global))	600 (Global)	1,700 (Global)
Divisions	Endoscopy Orthopedic Med Surg Equip, Digital imaging systems	Orthopaedic, Endoscopy, and Advanced Wound Management	Minimally invasive and open surgical procedures, General and bariatric surgery	Endoscopy, Minimally invasive surgery

room equipment made up 80 percent of the company's sales in 2006. Medical and surgical products only accounted for 38 percent of its total sales and about a third of these products were operating room equipment. Stryker's size and success posited them well to invest in progressive technologies; however, their investments had focused on products such as navigation, digital imaging, bone morphogenic proteins, artificial spinal discs and gastrointestinal equipment with little emphasis on MIS equipment.

Smith & Nephew

Smith & Nephew, another potential partner, had a 150-year history in advanced medical device development and reported $2.279 billion in revenue in 2006. Smith & Nephew was heavily focused in the orthopedic market as well as endoscopy and advanced wound management technologies. Smith & Nephew was an industry leader in four Global Business Units – Orthopaedic Reconstruction, Orthopaedic Trauma & Clinical Therapies, Endoscopy, and Advanced Wound Management. The four units jointly offered over 1,000 products.

Ethicon Endo-Surgery

Ethicon Endo-Surgery (EES), a division of Johnson & Johnson, reported $3.376 billion in revenue for 2006. EES proclaimed itself to be leading the charge in advancing MIS procedures. Its focus was on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, gynecology, and surgical oncology. One of its biggest assets was its major contribution to the continued growth of Johnson & Johnson's Medical Device and Diagnostics segment.

Karl Storz Endoscopy America Inc.

Storz was the smallest of the potential partners with fewer than 1,000 employees and approximately $100 million annually in revenue. The company's focus was on

Exhibit 4/7: Financial Performance

	FY 2005–06 Actual	FY 2006–07 Actual	FY 2007–08 Actual
No. of units sold plus accessories	5	32	0
Revenue	$ 140,000	$910,000	$395,000
Costs of goods sold	$ 55,000	$368,000	$142,000
Gross margin	$ 85,000	$542,000	$253,000
Selling, General, and Administration[a]	$ 210,000	$493,000	$311,000
Net Income/(Loss)	($125,000)	$ 49,000	($58,000)

[a]Includes: all salaries, consultants, rent, travel, sales commissions to distributors, and laboratory equipment.

endoscopic instruments as well as digital imaging and data archiving. It was still a family-held business that included 18 worldwide affiliates and five manufacturing facilities. The range of endoscopic equipment for human and veterinary medicine plus industrial applications encompassed over 8,000 products.

Reality in 2007

Walking back to the boardroom table, Jack looked at the current organizational chart and sighed. Henry Spencer was no longer actively marketing OR Solutions. If a healthcare organization approached OR Solutions, they could still contract with Henry who would introduce, demonstrate, and sell the product, but he was no longer on OR Solutions' payroll. Doug Fischer was still working in a production capacity for OR Solutions but was becoming more and more involved with other projects outside OR Solutions. Over the past couple of years, OR Solutions had gradually dwindled from a team of 20 to just two in the organization. Only he and Tom were left.

Finally, Jack reviewed OR Solutions' financial performance (Exhibit 4/7). "We had some revenue but plenty of expenses as well. What would 2008 bring? No expenses but no revenue either?" He knew that decisions needed to be made and soon. What would an effective partnership look like? Should they just sell the company? Would they be able to get a price that was what OR Solutions was really worth?

Jack placed the files back on the table in neat stacks and looked at his watch. Tom should be arriving at any moment. Jack knew that Tom was extremely wary about bringing in an outside consulting firm. He reminded himself, "Tom has invested years as well as financial equity into the OR Surgical System and he was very concerned about the fate of his product. His original intention was to grow the business around the product and create an independent entity for marketing the product. Despite the lack of success, Tom still feels that OR Solutions should be taking the product to market with a new salesforce and should stay in complete control of the future of the OR Surgical System. The OR Surgical System was his product, 'his baby,' and he does not want to let go of it to someone else."

Jack, on the other hand, had become convinced that his initial strategy of partnering with a larger entity for marketing and distribution logistics was the right

way to go – indeed – the only alternative left for OR Solutions. He knew, however, that he was going to encounter resistance from Tom to any major overhauls in the organization or strategy.

Jack had asked Michele and Greg from Market Research to react to the information about the company and the possible partners he had compiled, and to help Tom and him to strategically think through the issues. Jack was hopeful that the Market Research consultants' "outsider perspective" might shed new light on the best course of action.

The Meeting

"Tom, I'd like to introduce you to Michelle Brown and Greg Anderson from Market Research, the marketing research company assisting us in strategic thinking about OR Solutions." Jack continued, "Our discussions today are on the development of a strategy for the future of OR Solutions. I believe some strategic thinking with outsiders who have marketing expertise – but without personal interests in the company – might help us to put the issues in perspective and help to determine the best course of action. I think we need to develop what I'd call a 'tipping point strategy.' If we can just reach the tipping point for the OR Surgical System, sales will take off and increase revenues significantly."

The Strategic Thinking Session

Jack passed out hard copies of the files he had been reviewing. "These are the same materials I emailed earlier this week to bring everyone up to speed on OR Solutions."

Greg suggested, "Perhaps I can go to the white board and we can summarize the strengths and weaknesses of OR Solutions. I'll make two columns and anyone can call out what they perceive to be a strength or weakness of OR Solutions and I'll record them." After 15 minutes of discussion the white board contained the strengths and weaknesses shown in Exhibit 4/8.

Tom broke a momentary silence, "Well, we have a whole lot of weaknesses, but I still believe we have a winner."

Jack agreed, "This product could change MIS, reduce errors, and increase surgical quality and outcomes! I think we have a great product, as well. There are a number of applications for the OR Surgical System and the number of MIS devices is growing in proportion to growth in MIS procedures. In 2005, the market for electrosurgical devices and instruments totaled approximately $12 million and is projected to increase to $18.5 by 2011." He concluded, "Obviously there's a lot of work to be done, and OR Solutions needs to achieve a substantial growth and profitability very soon. Tom, why don't you share your thinking on what our strategy should be?"

Tom responded slowly, "Well, I think we would all agree that this discussion so far has been very sobering. Jack, it seems to me, even though I'm not the business

Exhibit 4/8: Strengths and Weaknesses

Strengths

- Great product with no close competitor.
- Patented technology.
- Tom's engineering skills.
- Jack's entrepreneurial experience and expertise.
- Some ability to raise additional capital.

Weaknesses

- Inability to meet the sales quota and short term focus on sales.
- No sales force.
- No in-house production capability.
- No support organization/staff.
- No real expertise in health care marketing.
- Company had not made a profit.
- Finances are strained.
- At some point the OR Surgical System will be duplicated in some form by a large competitor.
- The OR Surgical System was reasonably complex and only MIS surgeons "get it."

guy in the room, that at this point we probably need to hire some competent sales people to go out there and sell the product. But that's my view, and I'd like to hear what others have to say."

"Well, Tom, I think that's an interesting view and definitely one option," said Greg.

Jack added, "I think our previous sales people needed more experience and understanding of our customers and who, in the hospital, makes the final decision to purchase medical equipment. I still think our primary customer is the physician but they probably do not make the final decision – but rather pressure hospital administrators – who have all the physicians pressuring them for something!"

Tom said, "I don't think we can reach the physicians or the hospital administrators without an informed and committed salesforce and I think our product needs to be the sole focus of the person doing the selling."

Jack stated, "In addition, I feel there is a need to formulate a radically new promotional plan – we need to develop physician-focused catalogs and newsletters. We have to be a lot more aggressive. Now, on the other hand, I think we should also think about the amount of time and money it would take to develop a trained salesforce and maybe also put the option of a partnership on the table. Michelle, what do you think?"

"I agree to a certain extent," Michelle responded. "Tom, we are aware that the OR Surgical System is your 'baby' and you have nurtured the idea from inception. One option, at this point, might be to hire new sales and marketing staff, provide better training, and offer substantial sales incentives. If you can successfully do these things, the company should grow and there will be an increase in the profitability."

"Been there, done that!" Jack interrupted. He continued, "Given OR Solutions' current funding limitations, I think we should look at the most expedient means

of capitalizing on our available opportunities. It seems to me that the most viable option would be to align with a well-funded organization already in the medical device market. I believe that our technology, both current and next generation, represents a vital piece of the puzzle for companies that provide equipment and technology to today's operating rooms. As such, OR Solutions should seek a partner, such as a Ethicon, with the appropriate sales and distribution channels, experience, and financial and human capital to accelerate our product's adoption. We have an opportunity to make the OR Surgical System the standard of care in operating rooms throughout the world. At the same time, I fully anticipate ongoing roles in the partner's organization and fully desire to be financially and strategically aligned with whatever partner we select." Jack concluded, "I propose that this strategy will substantially increase our market share and provide us with the much needed financial support."

"Jack and Tom, you asked us about various options," Michelle said. "I guess this discussion highlights that OR Solutions could try to develop a salesforce or it could adopt a partnership strategy. Both options would entail substantial changes and will raise concerns and issues that must be addressed."

She continued, "Perhaps another option is to acquire another medical equipment company with existing and excellent hospital contacts. I understand that OR Solutions currently does not have a great deal of financial strength, but it would solve the problem of having to build a salesforce and develop hospital relationships from scratch."

Jack summarized: "So we have several ideas. I believe the primary strategies identified are to develop an internal salesforce, partner to gain an existing salesforce, buy an existing company with an established reputation with hospitals, or perhaps sell the company. Growth is the primary issue." He continued, "I think we all would agree that before making a decision we will have to deal with a number of issues. Here's what I would propose. I'd like each of us to further think strategically and analyze our situation and develop recommendations as to how we should proceed. We could all meet in two weeks with our recommendations. We can check our calendars and email-confirm the specific time and venue for our discussions."

Tom joined in, "Agreed. In two weeks, we will reconvene and determine a best course of action to make OR Solutions the success that we know it can be."