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Mazor Robotics:
Seeding and Expanding a Medical Technology Company

Abstract

We examine how Mazor Robotics, an Israel-based medical device company, evolved and managed strategic and organizational challenges. As a start-up company operating in the global medical device industry in general challenges varied from how to develop and commercialize an innovative product, scale it up, and build a global organizational system. Our analysis of this company over the years unravels how the company's managers strategized and illuminates the challenges in crafting a business strategy, building a viable business model, crafting an appropriate mode of entry, and developing a pricing strategy. We conclude with a forward-looking analysis that sheds light on potential pathways the firm may pursue in an effort to build a lasting business enterprise in the global medical device industry.

On January 5, 2015, the Israeli-based medical device company Mazor Robotics announced in the fourth quarter ending December 31, 2014 report that it had delivered six Renaissance systems. The company, which makes miniature bone-mounted positioning systems for orthopedic procedures, sold two of these systems in the U.S. This system uses robotic procedures to guide surgery and according to company documents has been used to perform 70,000 implants all over the world. The Renaissance™, the next generation of SpineAssist[1] system [Mazor's first product] aims to improve the accuracy of implant surgery and attempts to eliminate potential nerve damage.

The company report states that it has a 99% success rate in spine stabilization versus 86-90% if the system is not used. One of the advantages of robotics in surgery is that is makes procedures more minimally invasive, such that less muscle is cut and less tissue exposed. As a result this can make for shorter hospital stays, lessen the risk of infection and help cut medical costs.

The systems, transforming spine surgery from a freehand procedure to robotic-guided procedures, initially sold for between $500K and $700K[2] and then were upped to an average price of $829K, and with complementary devices at a $1 million tag. The revenue model is shown in Exhibit 1. As of October 30th 2014, the installed-base of 77 Renaissance systems deployed worldwide are being used to insert over 60,000 implants. Currently 46 Renaissance systems operate in the U.S., Mazor's primary growth market, and are concentrated in several areas including major cities such as San Francisco and Atlanta.[3] The company's core technologies include surgical robotics, new procedures using these technologies, robotic-guided implants, and medical 3D imaging for surgery. Evidence has been gradually accumulated about the health and economic benefits of the Renaissance.

The Founding of Mazor

The origins of the company can be traced back to the robotics engineering lab of Prof. Moshe Shoham, the Medical Robotics Laboratory Head at the Faculty of Mechanical Engineering, Technion – the Israel Institute of Technology.[4] Prof. Shoham developed a miniature surgical robot that is affixed to a patient's bone during spinal surgery. This enables the physician to perform medical procedures with higher precision. The company was formally incorporated in the State of Israel on September 12, 2000 by Prof. Shoham and Mr. Eli Zehavi, a former Vice President of Engineering at Elscint, a company that had been a major player in the early days of computerized tomography (CT) and magnetic resonance imaging (MRI). Mazor was founded through the Technion's incubator, T3 – Technion Technology Transfer, which shepherds innovative technology developed at the Technion to commercialization in global markets. Up to 2002, the company operated out of the incubator's offices at the Technion.

The original name chosen for the company was M.A.S.O.R. Surgical Technologies (Masor is the Hebrew word for a saw). The company's name was later changed to Mazor Surgical Technologies (Mazor means a cure in Hebrew). This name has a similar sound but a much more positive meaning. In 2010, the company took its current name of Mazor Robotics.

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1 SpineAssist® ; hereafter: SpineAssist.

2 Strong sales for Mazor Robotics. Calcalist, 2014. Available in Hebrew at: http://www.calcalist.co.il/markets/articles/0,7340,L-3642315,00.html [Last accessed 19 August 2015].

3 Ibid

4 Mazor Spinal Surgery Device gets FDA Approval. Israel Hi-Tec Investment Report, 2005. Avilable at: http://www.ishitech.co.il/1005ar9.htm [Last accessed 19 August 2015].

The Medical Devices Industry

This section presents a brief overview of the medical devices industry.

The U.S. Food & Drug Administration (FDA) defines medical devices as "*any instrument, apparatus, or other related article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease*."[5][6]

Medical devices can range from tongue depressors to lasers for surgery or pacemakers involving micro-chips.

The global medical devices industry is made up of more than 27,000 firms operating in 67 markets and employing about one million people. Exhibit 2 presents the medical devices market by segments. In addition, medical devices comprise 'in-vitro diagnostic products general purpose lab equipment, reagents, and test kits,[7] which may comprise monoclonal antibody technology. Certain electronic products which are radiation-releasing which have medical applications and claims also meet the definition of a medical device. These, inter alia, include diagnostic (ultrasound) products, x-ray equipment and medical lasers.[8] Within this broad definition, the FDA regulates approximately 1,700 different types of medical devices.

Historically, the medical industry has shown stable growth, which is predicted to continue. Global sales are expected to reach US $434.4 billion by 2017, representing an annual average growth rate of 7.1% from 2012.[9] This growth is even more impressive in light of persistent political pressures to contain health-related expenses and the market demand for more effective products. Some of the largest segments of the market are devices for cardiovascular, orthopedic, and renal/diabetes care, specialized surgery, and endoscopy. In 2011, the main product categories were disposable (15%), diagnostics (e.g., MRI and CT-scan) (27%), patient aids including hearing aids and pacers (12%), orthopedics (11%), dentals (7%), and other medical equipment (28%).[10] Adjacent product categories whose products are not typically considered medical devices include pharmaceuticals, nutritionals, personal care products, hospital supplies, clinical information systems, and life sciences research equipment.

In-vitro diagnostics (i.e., tests that can detect diseases, conditions, or infections) are expected to be the fastest selling segment by 2018. Sales may reach close to 55 billion dollars, far outpacing imaging technologies and cardiac devices. Estimates are positive regarding the growth rate of the of the surgical robotics segment as it had the largest revenue share in this respective period. In 2011 the global medical robotic systems segment was worth USD 5.48 billion, whereas in 2018 it is expected to reach USD 13.64 billion, representing growth at a CAGR of 12.6% from 2012 to 2018.[11] The market forecasts for this and other segments is that the medical device industry will be propelled to the forefront. In 2012, the global market for

[5] Products and Medical Procedures. U.S. Food & Drug Administration. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ [Retrieved on 19 August 2015].

[6] Ibid.

[7] Ibid.

[8] Ibid.

[9] Global Industry. Worldwide Medical Device Market Reports, 2014. http://www.reportsnreports.com/reports/142514-the-outlook-for-medical-devices-worldwide.html [Retrieved in 19 August 2015].

[10] Life Science Industry. Industry Canada, 2013. Available at: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html [Retrieved on 19 August 2015].

[11] Steven Almany and Mario Colombo, Drug eluting stents: a paradigm shift in the medical device industry, February 16, 2006.

medical devices, excluding in-vitro diagnostics, was valued at US$327.7 billion. At the time, the U.S. was the largest market with the greatest coverage. Figures indicate that the U.S. share was 118.9 billion dollars, which corresponded to 36.3% of the total market. The ten leading markets in 2013 are shown in Exhibit 3. The U.S. was also the global leader in medical devices, in that 16 out of 25 top companies were located there.

In recent years, the Brazilian, Indian, Chinese and Russian markets have grown rapidly, with a total market value in 2012 of US $26.2 billion. While Chinese spending per capita has remained low in absolute terms at US $10.5 as assessed in 2012, the market was the 4th largest worldwide and was forecasted to become the second largest by 2017. [12]

The medical device industry has recognized the great untapped potential of emerging markets.[13] In recent years, the market in the U.S., Europe and Japan has stagnated due to saturation and the global economic crisis. This has prompted the medical device industry to look elsewhere, for instance China where CAGR growth from 2006-2009 was almost 15% compared to around 6% elsewhere in the world. These emerging markets are generating sales not only because of increased sensitivity to health issues that can be resolved through medical devices but also because they are excellent locations to build facilities and solidify company positioning on the international market. Countries that are building new hospitals and other facilities, or implementing health plans are helping to spur business in this sector. China's most recent Five Year Plan, for instance devolves roughly 40 billion dollars to the health system. Similarly India has plans to increase its health-related spending by 2.5% by 2017.

The trend towards increasing health expenditures, as well as new regulations and a more inviting environment in many emerging markets, have also generated new opportunities for medical firms. Firms will need to build more flexible, yet aligned, structural systems to better compete in a changing global environment characterized by growth of emerging markets, health care reform, reimbursement cuts, new tax regulation in the U.S. and cost constraints. This would require some restructuring efforts as well as further reliance on cooperative strategies to more efficiently and effectively manage the value-chain activities (e.g., R&D, manufacturing, logistics, and marketing).

Market Opportunities for Back Pain Relief

Low back and neck pain is a common problem and constitutes an enormous social, psychological, and economic burden In the U.S., back pain is the main cause of disabilities in 19 to 45 year olds. Back pain is also one of the most frequent occupational hazards and ranks #2 in reasons for missing work. Both men and women suffer from back pain which comes right after headaches as the second most common neurological ailment.[14]

According to the National Institute of Neurological Disorders and Stroke, the overall spending of people in the U.S. on treatment of lower back pain is estimated at $50 billion per year. The inter-vertebral discs undergo a process of desiccation, diminishing their flexibility and decreasing their ability to cushion the vertebra. In addition, the aging of the population is a key driver of back-pain demographics. With baby-boomers having just turned 65, there is a higher proportion of the elderly among sufferers from musculoskeletal complaints. According to an article published in the Orthopedic Network News in October 2012, 40% of spine patients were 65 and older. Mazor's own evaluation of the market suggested that roughly 90%

[12] Robert Gold, "Healthcare: Products & Supplies," *Standard & Poor's*, March 10, 2005, p. 7.

[13] "Frequently Asked Questions": http://www.unmc.edu/irb/source_documents/fdafaq.htm [Retrieved on 19 December 2005].

[14] Rubin D.I. Epidemiology and risk factors for spine pain. *Neurologic Clinics*, 25(2): 353-371, 2007.

of all 30+ year olds are afflicted with some form of back problem, and in 2003 it was estimated that fusions account for roughly 36% (615,000) of surgical spine procedures worldwide. However, the spine is only one segment that could benefit from Mazor's technological products and the estimated growth for the various segments that constitute the orthopedic market for that year is shown in Exhibit 4. A recent report by HarrisWilliams&Co. estimated that the worldwide orthopedic products market accounted for US$ 35.5 billion with a CAGR of 4.5% from 2007 to 2013 and a forecasted growth of 3.5% annually to reach US$ 38.0 billion by the year 2015.[15]

During the initial phase, back pain is usually treated with lifestyle modifications, oral medication, physiotherapy, acupuncture, and chiropractic manipulations. Patients whose treatment has failed after six months, whose condition is exacerbated, or whose condition is insufferable (e.g., intolerable pain or incontinence) become candidates for surgery either in outpatient clinics or in the hospital.

According to the same article published in the Orthopedic Network News in October 2012, there were about 1.25 million spine operations performed in the U.S. annually. Over half were fusion surgeries.[16] This can often diminish or even eliminate the pain.

Minimally invasive techniques for performing surgical procedures, known collectively as laparoscopic surgery, have been a key advancement in the field over the past 30 years. These techniques apply image-guided surgical systems and have a number of advantages for patients, surgeons, and hospitals.

For patients, these techniques lead to: (i) reduced procedure-related blood loss, pain, and scarring at the incision site; (ii) fewer complications, such as infections; (iii) faster recovery times and shorter post-operative hospital stays; and (iv) better esthetic outcomes. From the surgeon's standpoint, these techniques can reduce procedure-related complications and can reduce risks associated with more invasive procedures. For the hospital, these procedures can result in a reduction in the time a patient needs to stay for supervision, less complications, and a higher level of patient satisfaction. Minimally invasive techniques also have disadvantages or limitations, which include: 1) restricted or even no line-of-sight at the anatomical site; 2) cumbersome surgical instruments; 3) dependence on 2D imaging for 3D surroundings; and 4) limited operating space. Overcoming these issues requires a long learning curve for the surgeon, increased intra-operative use of x-ray radiation, and longer operations. As such, while minimally invasive approaches have been adopted at higher rates by surgeons, particularly in those fields where procedures can be performed within existing anatomical cavities, only about 10% to 15% of these procedures have been enacted.

Robotic-assisted surgery has been growing rapidly, and is used in a broad range of medical fields (e.g., urology, radiology, gynecology, cardiothoracic surgery, general surgery, radio-surgery, and cardiology). Commercializing "robotic-assisted" technologies throughout the medical sector fosters more extensive use in minimally invasive prostatectomy and hysterectomies. Robotic technologies can increase the number of patients who can undergo minimally invasive procedures, and thus lead to a positive impact on both them and the economics of spinal fusions, due in large part to smaller incisions which are associated with

[15] Orthopedic Industry Overview. Harris Williams & Co. Ltd, 2014. Available at: http://www.harriswilliams.com/sites/default/files/industry_reports/orthopedic_industry_overview_5.20.14.pdf [retrieved on 19 August 2015].

[16] In this technique, "one or more of vertebrae of the spine are fused together" to remove the motion of the natural joint between these vertebras. See http://www.knowyourback.org/pages/treatments/surgicaloptions/spinalfusion.aspx [Retrieved in 8 October 2015].

reduced procedure related trauma, fewer infections and post-procedure complications, and shorter recovery and hospitalization periods.

Challenges in Crafting a Competitive Strategy

The medical devices industry looks for applications that meet the following criteria: 1) high reliability and accuracy, 2) low cost (i.e., cost-effective solutions), 3) user friendly devices, and 4) a strong presence in medical centers that adopt the device within the community. This has led to an orientation that would pursue a leading position through the delivery more accurate and user-friendly systems.

Initially the novel idea behind the company was to develop a miniature robot to perform complicated surgery with greater precision than human surgeons, lower invasiveness and reduced exposure to radiation.[17] It was based on Prof. Shoham's idea for leveraging bone-attached rigid fixtures and mounting a robot that would position and orient a surgical instrument or guide a tool precisely to the target procedure location.[18] The technology would allow surgeons to create a detailed blueprint of the patient's body prior to surgery, and benefit from the robot's accurate guidance during the procedure itself. On June 18, 2013, Prof. Shoham was awarded the Thomas A. Edison Patent Award of the American Society of Mechanical Engineers (ASME) for his invention of the miniature surgical robot.

By 2003 the company had completed a prototype. The field of image-guided surgery using robotic systems was several years away. The closest competition came from navigation systems. That year, Mr. Ori Hadomi joined the company and become CEO.

Mazor's first product, SpineAssist, was approved by the Food and Drug Administration (FDA) in 2004. In August 2004, Mazor Robotics formed a wholly owned subsidiary in the State of Delaware. As CEO Hadomi said following the announcement of FDA approval:

"*The SpineAssist technology can also be applied to brain and knee surgeries, Mazor's decision is to focus specifically on the spinal area for now…The combination of precision, simplicity and performance reliability will play a key role in the success of the product and company ... Mazor will begin marketing SpineAssist in the final quarter of 2004, at an estimated cost of $100,000 per unit*".[19]

One burgeoning issue at this point in time concerned the potential application of the new technology. As of 2004, there were more than 500,000 spine surgeries performed annually in the United States alone with a growth about 8 percent a year. This created a large potential market for the SpineAssist. According to analysts' reports in 2004, the spinal industry was expected to triple its growth over the following eight years, thus potentially attaining annual sales of $7 billion in 2012. In addition, there was little or no head-to-head competition for such systems, probably due to the technological advances and complexity involved. The two main players, "da Vinci" (Intuitive Surgical) and "Mako Surgical", were surgical robotics companies but neither dealt with the spine. A third company, "Medtronic", sold a navigational device dubbed "Stealth" that could be applied to the spine but was not a robot. Improving standard care through the development of medical devices with higher accuracy implied

[17] Interview with Prof. Moshe Shoam, inventor of Mazor Robot. Bizportal, 2013. http://www.bizportal.co.il/article/370886 [Retrieved on 20 August 2015].

[18] W. Sukovich, S. Brink-Danan, and M. Hardenbrook. "Miniature robotic guidance for pedicle screw placement in posterior spinal fusion: early clinical experience with the SpineAssistR," The International Journal of Medical Robotics and Computer Assisted Surgery, 2(2): 114–122, 2006.

[19] http://www.prnewswire.com/news-releases/robot-for-spinal-surgery-receives-fda-approval-74905852.html [retrieved on 19 August 2015].

different procedures and new FDA approvals. A related issue concerned the need to choose between selling a product and selling a procedure. The company made the choice to own and provide the full "minimally invasive" procedure. By 2007 the firm had 25 employees, 95% of whom were involved in R&D, an FDA-cleared product, and five ongoing installations, three in the U.S. and two in Germany. In August 2007, Mazor Robotics completed its initial public offering in Israel, and its ordinary shares have been traded ever since on the TASE, under the logo MAZOR.

Mazor thus identified a clinical need and a real problem waiting to be addressed in the back pain segment. Navigation systems were available on the market, such as the German Brain Lab, and Medtronic which had a navigation division. 90% of all procedures were conducted in the brain segment and very few in the soft tissue segment.

In crafting its strategy, Mazor's executives had to make decisions with regard to: 1) industry scope (whether to focus on a single market segment such as Spine OR, Orthopedic, OR Neuro); 2) the scope of the product line within a defined segment to develop, as well as the broadest range of users and specialists (e.g., whether to develop applications for specific realms such as Knee, Spine, Neuro, and Trauma); 4) what resources are needed to support each product and market segment choices; 5) whether to pursue a "go alone" strategy, take advantage of consolidation (M&A activities), or form a joint venture alliance with one of the global players in the medical devices industry; 6) what sequence of moves should be enacted and at which pace (for example, an initial decision was made to focus on the spine and concentrate efforts there, but further deliberation suggested that the company should begin with the spine and move to develop the Neuro segment; a key question was why the company decided to target the Neuro segment rather than, for example, knees).

Commercialization Efforts

The USFDA and European Notified Bodies require comprehensive tests. This involves considerable financial outlay and associated risks. While tests and FDA and CE approval are vital, we should note that the road to commercialization of medical devices and technologies may still be full of hurdles. For Mazor products and new procedures these include new patterns, a need for education, a need for product improvement and regulatory limitations.

Barzilay et al. 2006[20] offered some further insights into the product development iterations and improvements while describing the clinical development phase from March to November 2005 of the SpineAssist in two spine centers. The report suggests that the major obstacles were associated with the surgeons, the surgical technique, but also the product itself in terms of software and hardware. Analysis led to improvement on all these fronts. One of the problems was that the clamp had to be tight to the spinous process, which interfered with the entry point and trajectory although it prevented patient mobility. Another surgical problem was that the operation of the robot and acquisition of images were hampered by foreign bodies including gauze. These issues were overcome by improvement in the user friendliness of the software and the robot tools (in particular in their use on soft tissue).

Shoham et al. 2007,[21] in their paper entitled "Robotic assisted spinal surgery: from concept to clinical practice," described several years of product development, animal trials, human cadaver testing and clinical testing of the SpineAssist in detail. They depicted the

[20] Barzilay, Kaplan and Liebergall. Miniature robotic guidance for spine surgery. In Vanja Bozovic (Ed.) Medical Robotics, p. 526, ISBN 978-3-902613-18-9.

[21] M. Shoham, I. H. Lieberman, E. C. Benzel, D. Togawa, E. Zehavi, B. Zilberstein, M. Roffman, A. Bruskin, A. Fridlander, L. Joskowicz, S. Brink-Danan, and N. Knoller. Robotic assisted spinal surgery: from concept to clinical practice. Computer Aided Surgery 12(2): 105-115, 2007.

various difficulties and the corresponding solutions. They covered all areas of product development but in particular focused on mechanical design, CT-to-fluoroscopy image registration, and surgical techniques. SpineAssist was implemented in 65 clinical procedures in the USA, Germany and Israel from April to October 2006 but the findings indicated that improvements were still required.

According to CEO Hadomi, "Mazor's strategy is to provide spine surgeons and patients with the most advanced technologies providing unprecedented accuracy in a truly minimally invasive manner." [22]

From 2007 to 2010 Mazor Robotics' core technology was clinically validated with SpineAssist during thousands of spinal surgeries worldwide and many improvements and modifications were implemented.

During 2007, SpineAssist implant placement accuracy improved not only in the lumbar spine but also the thoracic spine, and presented new solutions for the cervical vertebrae which complemented the existing SpineAssist lumbar and thoracic spine applications, and launched a new miniature robotic device mounted on a bed that enables a minimally invasive spine procedure to take place at the same high level of accuracy.

In 2008, Mazor launched a new add-on software product called C-InSight™, an innovative 3D imaging system for the operating room, and received FDA Clearance in August of the same year.

In 2009, the company focused on clinical validation in more than 10 select international centers including the leading hospitals mainly in Europe. In June 2009, an agreement was signed with Charité Medical University Berlin to conduct clinical trials at the largest hospital in Germany. In September 2009, the ethics committee of the Ludwig-Maximilian-University of Munich, Germany approved the multi-center trial. This was the first clinical trial on the GO-LIF procedure and it was aimed at assessing safety and efficacy. In February 2010, the multi-center trial was successfully completed.[23] With respect to the 3D software product C-Insight, the company had conducted a few studies to demonstrate the clinical value of 3D imaging over the standard 2D available in the vast majority of hospitals. It started in Israel, continued at the Hannover Medical School in Germany with the goal of study initiation in the U.S. CEO Hadomi stated: "3D is a demand we have heard from surgeons for many years. We are delighted that we are able to deliver 3D which satisfies their needs...yet upgrading 30,000 C-arms in the USA to 3D is a completely different story" [24]

Overall it took almost three years to complete the improvements, modifications, redesign, develop new add-on products and redesign the clinical procedures to finally have the right product. In 2011, the company announced the launch of Renaissance™, the next generation of its Robotic Surgical Guidance Systems which was clinically validated with SpineAssist. The company announced that the SpineAssist had been used successfully in over 2,000 spinal operations globally and that over 12,000 implants had been placed. According to a study of 14 centers worldwide, the Mazor Robotics technology outperformed freehand spinal surgery in

[22] "Mazor Launches New Product: A Bed Mounted Miniature Robotic Device", Company press release. October 16, 2007. "Mazor Launches New Product: A Bed Mounted Miniature Robotic Device", Company press release. October 16, 2007.

[23] Birkenmaier, Suess, Pfeiffer, Burger, Schmieder and Wegener. The European multicenter trial on the safety and efficacy of guided oblique lumbar interbody fusion (GO-LIF). BMC Musculoskeletal Disorders. 2010.

[24] As 3D imaging costs drop, will surgical revision rates drop too? Mazor's C-InSight transforms hospitals'. 2D C-arms into 3D. Company press release. April 28, 2010.

terms of placement accuracy with lower neurological risk.[25] Having the right product, and with the launching of the Renaissance, the company began to work intensively on raising capital again and exploring its way back into the U.S. market, in addition to efforts to develop business in countries such as Germany, Russia, Vietnam, China, and India. The challenging process of commercialization was succinctly described by Ladenburg Thalmann, investment banking services, in their analyst's report:

"The Renaissance's predecessor, the SpineAssist, first began receiving approvals and clearances in June 2004. While there have been a number of iterations and improvements developed from the first approvals, the Company did not begin to sell systems until 2008 in rest of the world and did not begin to sell into the U.S. market until mid-2010 and officially launched their newly branded, third generation, Renaissance system worldwide in mid-2011."[26]

The Product and Technology

Over the years and in particular in 2010, Mazor's executives engaged in a pervasive evaluation of the challenges involved in scaling up the business. Based on an encounter with Lonnie Smith, the head of Intuitive Surgical, Mazor decided upon a follow-the-leader strategy, since Intuitive was one of the top companies in the development of robotic systems for minimally invasive soft tissue surgery on organs such as the prostate, heart, kidneys and liver. Smith analyzed the differences between the two companies in terms of turnover and market value (Intuitive's annual sales were $1.1 billion in 2009 and hit a high of $13.5 billion in trading volume) and suggested that Mazor should focus on a reliable and practical product that would satisfy customer needs in exchange for a premium price. [27]

The same line of thinking was suggested by Christopher Sells, who served as vice president (VP) for sales at Intuitive Surgical for seven years but became VP for U.S. sales at Mazor. Sells had told Hadomi that he would not join the Mazor staff unless the company was positioned in a different way. This attitude might be interpreted as counter intuitive but more in-depth analysis shows that Mazor marketing had been influenced by hospital organizational politics:

"*I am in the robotic surgical industry, and I've known the hospital equipment market for years. I had no doubt that this system was worth many hundreds of thousands of dollars to hospitals. It has clinical and economic value and advantages, which can be easily quantified and estimated. A half-million dollar price tag is provisional and it will not necessary remain that over time*." [28]

Sells' argument was that doctors are only employees in a firm run by the hospital directors. When equipment costs $100,000, the decision is not made by them but by middle management and above, and procurement managers are trained to say no. This makes the sales process long and tedious.[29]

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25 Retrieved from http://doctorsofsarasota.com/service/mazor-robotics. 21 September 2015.

26 Initiation analytic coverage by Ladenburg Thalmann. Mazor Robotics Ltd. Analyst report. Feb. 21, 2012.

27 Yoram Gabison. Mazor boosts sales thanks to strategy lesson from competitor. Haaretz. July 29, 2010.

28 Mazor sees FDA nod for SpineAssist brain surgery use. Hillel Koren. Globes online. Available at: http://www.globes.co.il/en/article-1000577761. July 28, 2010. [Last accessed 20 August 2015].

29 Mazor boosts sales thanks to strategy lesson from competitor. Yoram Gabison. Haaretz, July 29, 2010.

Thus, the new marketing approach was to define the Renaissance as expensive equipment to be sold to hospital while highlighting the strategic and not only the clinical value of the product. This aimed to increase demands for the Mazor system by creating competition between hospitals – a technique developed by Intuitive Surgical. Apparently the tactical move was successful.

In an interview, CEO Hadomi noted:

"*The company's management discussed other strategic factors, on the basis of which the updated price was set. I am pleased that the new model has been proven. The sales process used to take a year on average, whereas with the new approach, we have sold two systems in three months*."[30]

In a company press release on June 6, 2011 it was also noted:

"*Renaissance features an entirely new design and human interface, as well as next-generation hardware and software technologies. These are designed to increase surgical safety as well as extend the range of clinical applications...Renaissance also serves as a platform that will support future clinical applications, such as robotic-guided cranial surgeries…With the launch of Renaissance, we have set the bar even higher and will allow surgeons to significantly improve the standard of care they can provide for their patients…The launch of Renaissance is particularly exciting for Mazor Robotics, as not only will it provide additional clinical benefits, but it is a key milestone for us, coinciding with the company's current rapid growth in the USA as well as in Europe and Asia*."[31]

From this point onwards sales grew, not just in the U.S., but elsewhere internationally including Germany, Russia, Vietnam, and India.

However, even though the new business model based on equipment sales was apparently doing well, a number of issues remained. The first concerned the limited number of centers for back surgery, including in the United States. This created boundaries for growth potential. The second concerned changes in the company's business model; in a 2-year period, Mazor switched its business model twice. In the first half of 2009 it switched from an equipment sales approach to a surgical procedure revenue-based model, but then switched back to the original equipment sales model.

Despite its early success in generating sales, it became clear that the company's growth was relatively slow. From $20 million of sales in the 2013 calendar, Mazor only reached $21 million in 2014. At that level of sales, the company was not just far from breaking even, but also very far from realizing its vast market potential. It was estimated that its penetration represented less than 2% of the market potential for this product.[32]

As of 30 September 2014, Mazor has sold 77 systems globally. Of these, 46 are located in the U.S. The cost is approximately $1 million per unit, which represents a significant investment for any hospital, but one which has proved worthwhile. "Renaissance has been used in 4,000 operations and zero cases have led to long-term nerve damage. There are

[30] Ibid.

[31] Mazor Robotics Launches Renaissance™, the Next Generation of Its Highly Accurate Robotic Surgical Guidance Systems. Company press release. June 6, 2011.

[32] Mazor Robotics Announces First Quarter 2014 Financial Results. http://mazorrobotics.com/mazor-robotics-announces-first-quarter-2014-financial-results/ [retrieved oin 20 Aug 2015].

probably some 200 to 400 patients whose lives we saved." [33] The accuracy of surgery is as high as 98 percent,[34] up from 60 to 90% in traditional methods. [35]

CEO Hadomi noted during the launching of Renaissance the next generation of Mazor' core technology:

"*With thousands of successful surgeries performed with our systems to date, Mazor Robotics has defined an entirely new approach to safely conducting spine surgery...With the launch of Renaissance, we have set the bar even higher and will allow surgeons to significantly improve the standard of care they can provide for their patients*."[36]

The Way Forward

Ori Hadomi commented on the 2014 financial results as follows:

"We are still at the very early stages of developing the robotic spine surgery market and continue to experience a high level of interest and sales activity in the Renaissance system in our key markets. We remain confident that with strong data supporting the clinical and economic benefits of the Renaissance system and continued sales and marketing efforts we will expand our presence in these markets over the longer term".[37]

To sustain growth, Mazor will have to succeed on several fronts. It will have to increase physicians'and the public's awareness of the benefits associated with its products for all stakeholders, including patients, operating room staff and hospitals. It will have to convince many hospitals that the merits of its systems justify the significant capital expenditure involved in their acquisition, while continuing to influence surgeons to abandon hands-free procedures in favor of the company's image-guided solution. It will have to continue setting up efficient distribution channels, especially in Europe and APAC. It will have to sustain its technology leadership by continuing to introduce new product innovations. Finally, as a public company expanding its franchise while generating revenues that can ensure its continuous growth is a particular challenge. Can it generate enough income to fund its growth? The company's leaders have voiced their commitment to build a medical devices company, rather than seek a quick exit. But can Mazor rise to these challenges while remaining a small independent company based in Israel?

Signs of threat emerged in the in 2013 financials[38] and the consecutive financials in 2014,[39] Mazor has sustained net losses in every fiscal year since 2000, including a net loss of $20.5 million for the year ending December 31, 2013 and $11.6 million for September 30,

[33] Mazor Robotics: Revolutionizing the World of Surgery with Robot Side-Kicks. The Israel Latin America Chamber of Commerce. PAUL SANCHEZ KEIGHLEY. 2013. http://www.camaraisrael.org.il/?CategoryID=263&ArticleID=867. [Retrieved on 21 August 2015].

[34] Premier Mazor Robotic Technology Purchased by Tri-City. Tri-City Medical Center. 2012. http://www.tricitymed.org/news/2012/mazor-robotic-purchase/ [Retrieved on 21 August 2015]

[35] Mazor Robot Inventor Speak. Bizportal. Avi Shauli. 2013. http://www.bizportal.co.il/article/370886 [Retrieved on 21 August 2015].

[36] "Mazor Robotics Launches Renaissance®, the Next Generation of Its Highly Accurate Robotic Surgical Guidance Systems", Company press release. June 06, 2011.

[37] Mazor Robotics Reports Orders for Six Renaissance Systems During the Fourth Quarter of 2014. Available at: http://www.benzinga.com/pressreleases/15/01/b5117460/mazor-robotics-reports-orders-for-six-renaissance-systems-during-the-fo [Retrieved on 21 August 2015].

[38] Mazor Form 20F-Q4-13. Available at: http://s3.amazonaws.com/mazor_robotics/wp-content/uploads/2014/12/Q4.13-Annual-report-20-F.pdf. [Last accessed 21 August 2015]

[39] Mazor Announced Q3-14. Available at: http://s3.amazonaws.com/mazor_robotics/wp-content/uploads/2014/12/Q3.14-Financial-Results.pdf [Last accessed 21 August 2015].

2014. As of December 31, 2013, the total shareholders' equity was $64.1 million but dropped to $56.9 million as of September 30, 2014. The accumulated deficit as of December 31, 2013 was $72.5 million which rose to $84.1 million as of September 30, 2014. The expectations are for incurring continuous substantial net losses for at least two more years as they expand their marketing efforts in the spine and neurosurgery products market and further commercialization of Renaissance, and continue to develop the corporate infrastructure required to sell and market their products and invest in product development. Any failure to achieve and maintain profitability will continue to have an adverse effect on the company shareholders' equity and working capital and could result in exploring an M&A, which is commonplace in the orthopedic and spine device market.[40, 41]

In 2014, several big Med-Tech companies were involved in M&A on a large scale involving billion dollar transactions. This could drive Mazor to be involved in a merger in the next two years. One impetus is the forecasted growth of the technology market in 2018 to $440 billion.

One of the largest transaction announcements was for the Zimmer ($4.6 billion revenue) attempt to take over its rival Biomet for $13.4 billion (4.2x revenues of $3.2 billion). In the orthopedics sector, Smith & Nephew acquired the publicly held ArthoCare Corp. for $1.7 billion (4.6x revenues of $373 million) which constituted its largest acquisition to date. Unexpectedly, Wright Medical Group and Tornier (based in the Netherlands) merged for a combined value of roughly $3.3 billion. Rumors had been flying that these companies would be swept up by other giant Med-Tech companies such as Smith & Nephew, Stryker, J&J, and Medtronic. Finally, the Med-Tech bulldozer Stryker ($9.5 billion in revenue) reinforced its hip and joint implant sector by acquiring the privately held Small Bone Innovations at a price thought to be $375 million (7.5x 2013 revenues of $48 million).[42]

According to an M&A report by Dyrda (2014),[43] two mechanisms underpin this M&A surge. There is downward pressure on reimbursement and pricing, costly procedures such as knee and hip implants, and greater commoditization, which is also true for spine surgery. The second mechanism concerns continued growth. When large companies merge they can maintain prices and margins on their core commodities but they still need to actively ensure their top-of-the-line product earnings.

Recently, robot assisted surgery has been riddled with doubts, primarily as a result of the FDA probe of Intuitive Surgical's key Da Vinci devices. Nevertheless, robot-assisted minimally invasive procedures remain in great demand: robot-assisted procedures across the world surged from 1,000 in 2000 to 550,000 in 2014.

As the sizable companies in the orthopedic market look at better ways to use their capital, they may conclude that M&A may be less profitable than investment in their own R&D and/or expansion of their sales force. It is likely that acquirers of small- and mid-sized companies will include Stryker, Synthes (J&J), Medtronic, and Zimmer which are interested in companies specializing in extremities.

As a small-to-mid-size player and leader in the spine market with some level of financial risks, Mazor is an acquisition target for any of the above companies. After the incredible 14 year run for Intuitive Surgical and the recent acquisition of MAKO Surgical Corp. by Stryker Corp., Mazor Robotics Ltd. maybe the company investors are looking for.[44]

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40 Medical Technology M&A; Market on the upswing?, Deloitte December 3rd 2014.
41 Jamie Hartford. Medtech's Biggest Moves in 2014. 2014.
42 Deal making in orthopedics. Paul Teitelbaum. August 7, 2014
43 Laura Dyrda. Spine & Orthopedic Device Company M&A: 2014.
44 Harlan Kessler. Mazor Robotics: The Medical Renaissance Is Underway. 2013.

Thus, one of the potential acquirers is Stryker Corp,[45] although it has not fared well in the last two years. It has been negatively affected by hip implant recalls but it did win a key patent settlement battle with Zimmer Holdings, and was able to enter the Chinese market by acquiring Trauson Holdings, and has stepped into robot-assisted surgery by its acquisition of MAKO Surgical in late 2013 and Small Bone Innovations in mid-2014.[46]

According to a Stryker spokeswoman:

"*Robot-assisted procedures have the potential to aid hospitals and patients as they may reduce costs by shortening hospital stays and recovery periods and may reduce the amount of rehabilitation and medication...Stryker believes that orthopedic surgical robotics provides an opportunity to expand and grow significantly from its position today and has the potential to become a game-changing technology in the longer term." In mid- 2013, Stryker CEO Kevin Lobo told analysts that the company was also "open to acquisitions within spine*."[47]

According to market analysts, this type of robotic surgery could grow substantially to become Stryker's fourth pillar of growth. The opportunity for Stryker to leverage the significant adoption of Mazor's Renaissance System in the U.S. market would be the first surgery solution of its kind. Looking further into the future, Stryker may be able to leverage Mazor's platform to drive sales through additional applications such as brain surgery. Given the success of robotic platforms in other areas of surgery, e.g., Intuitive Surgical in urology (mainly prostate) and OB-GYN and MAKO in knees/hips, Mazor can replicate this model in the spine given a strong value proposition and the scant current competition.

As the Stryker spokeswoman stated:

"Mazor has established a unique and compelling technology platform in robotic assisted surgery which we believe has considerable long term potential in joint reconstruction. The acquisition of Mazor combined with Stryker's strong history in joint reconstruction, capital equipment (operating room integration and surgical navigation) and surgical instruments may help further advance the growth of robotic assisted surgery. The combined expertise could offer the potential to reduce variability and allow the surgeon to perform the surgery with greater accuracy providing enhanced patient care with less pain and quicker recovery. More consolidation in the Spine & Orthopedic market is quite likely over the next few years. The smaller acquisitions will happen since the big companies will need to make sure they are participating in the new growth areas. For the next three years, you are going to see an increased number of small to mid-sized acquisitions in niche areas."[48]

Mazor's top executive team are left with a substantial strategic choice – which path is more suitable for scaling up a small-sized firm in the medical device industry and its corresponding segments where larger firms operate. Building a sustainable, scaled-up company that strives to penetrate is a serious challenge for Mazor, as it is for many other companies around the world.

[45] "Is Mazor next in line for acquisition?" Nir Zalick. Available at: http://www.calcalist.co.il/markets/articles/0,7340,L-3613059,00.html. [Retrieved on 21 August 2015].

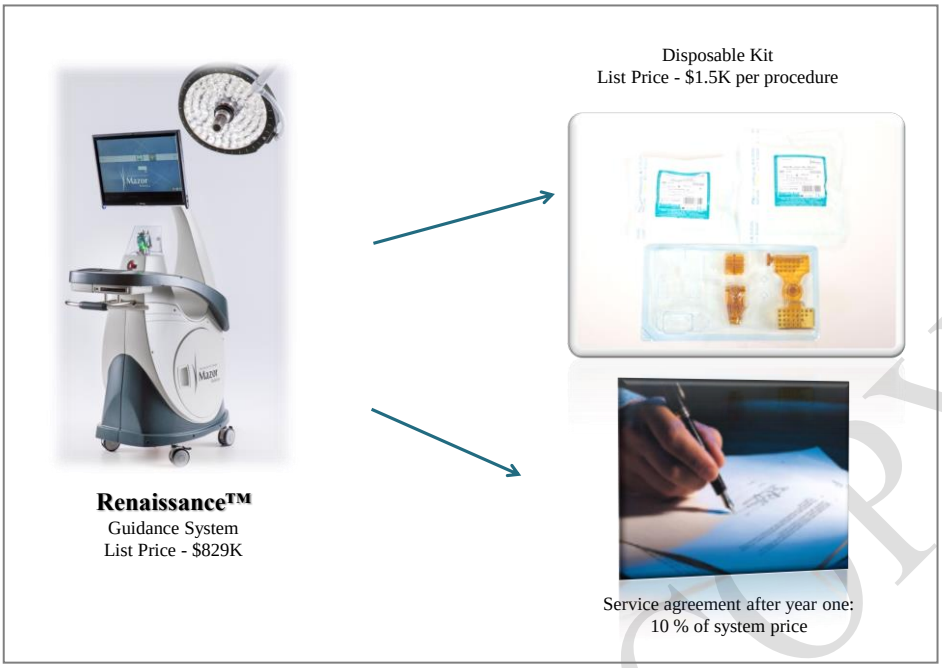
[46] "About Stryker". Available at: http://orthostreams.com/wp-content/uploads/2014/02/Profile-of-Stryker-2014.pdf. [Last accessed 21 August 2015].

[47] http://www.odtmag.com/issues/2014-07/view_top10-orthopedic-device-firms/2-stryker [Retrieved in 21 August 2015].

[48] Dyrda, Spine & Orthopedic Device Company M&A: 6 Key Trends. May 2014.

Exhibit 1

Mazor's Revenue Model



Source: *Mazor archival report*

Exhibit 2

Medical Devices Market by Segments

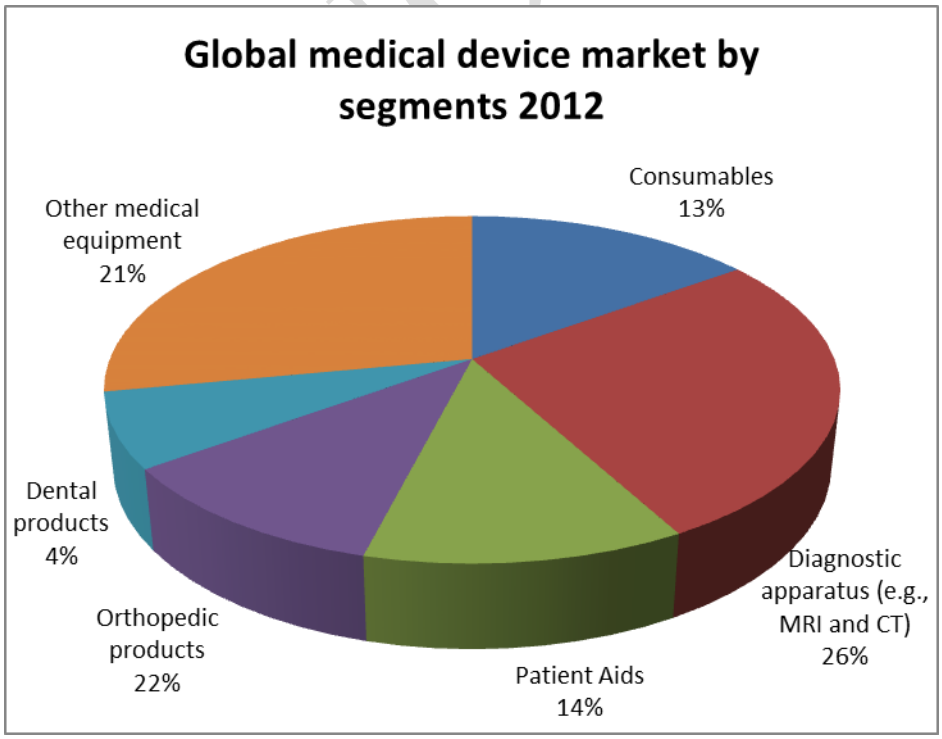


Exhibit 3

*Table of Leading Medical Devices Markets by Sales Revenue**

Rank	**Country**	**Estimated sales revenue (US$ billion)**	**Market share (%)**
1	United States	118.9	36.3
2	Japan	32.4	9.9
3	Germany	23.1	7.0
4	China	14.1	4.3
5	France	13.5	4.1
6	United Kingdom	9.9	3.0
7	Italy	8.6	2.6
8	Russia	6.8	2.1
9	Canada	6.8	2.1
10	Brazil	5.3	1.6
World total (67 countries)		**327.7**	**100**

* Excluding in-vitro diagnostic sales
Source: *Espicom, The World Medical Market Book 2013.*

Exhibit 4

2000 Worldwide Orthopedic Market

	In US$ Billions	% Growth
Hips	2.2	7
Knees	2.0	8
Trauma	2.0	9
Spine	1.4	22
Arthroscopy	1.3	10
Instruments	0.7	4
Bone Grafts	0.3	10
Bone Cement	0.3	4
Other	2.0	7
Total	12.3	9

Source: *Company's archival records; ABN AMRO*

Renaissance

From Art to State of the Art

Three Building Blocks

1. *Workstation*
2. *Planning Software*
3. *Robotic Device*

Exhibit 5.1
Mazor Financials 2005 – 2014 (USD)

P&L's

(in US$ thousands)	2005 *	2006 *	2007 *	2008 *	2009 *	2010	2011	2012	2013	2014 9M	CAGR 05-13
Revenue	527	123	275	552	1,404	3,973	5,904	12,175	19,983	15,463	58%
Cost of revenue	486	758	349	410	490	961	1,879	2,893	4,280	3,153	31%
Gross profit	41	-635	-74	142	915	3,012	4,025	9,282	15,703	12,310	110%
Research and development	1,569	1,571	1,969	1,815	1,359	2,292	3,062	2,760	4,174	4,526	13%
Selling and Marketing	918	2,291	2,403	2,453	2,422	4,592	6,990	8,887	15,692	15,828	43%
General and administrative	748	874	1,119	1,365	1,426	1,424	1,639	1,845	2,766	3,181	18%
Operating Income (Loss)	-3,193	-5,372	-5,565	-5,491	-4,292	-5,296	-7,666	-4,210	-6,929	-11,225	10%
Financing income (expenses)	26	-495	-86	310	-204	-469	-184	-2,831	-13,433	-225	
Loss before taxes on income	-3,168	-5,867	-5,651	-5,181	-4,496	-5,765	-7,850	-7,041	-20,362	-11,450	26%
Taxes on income	2	3	3	1	5	8	-68	23	167	157	79%
Net loss	-3,169	-5,870	-5,655	-5,182	-4,501	-5,773	-7,782	-7,064	-20,529	-11,607	26%
Other expenses	-	-	-	-	-	999	-950	-281	-	-	
Overall Net loss (inc. Other)	-3,169	-5,870	-5,655	-5,182	-4,501	-4,774	-8,732	-7,345	-20,529	-11,607	26%
Net loss per share	-0.57	-0.64	-0.53	-0.37	-0.30	-0.29	-0.36	-0.29	-0.57	-0.28	0%
#shares – Basic and diluted in mi	5.6	9.2	10.6	14.2	15.2	16.5	24.3	25.3	36.0	41.7	26%
Gross Margin	7.8%	Loss	Loss	25.7%	65.1%	75.8%	68.2%	76.2%	78.6%	79.6%	
R&D %	297.5%	1279.2%	716.5%	328.7%	96.7%	57.7%	51.9%	22.7%	20.9%	29.3%	
S&M %	174.0%	1865.3%	874.5%	444.1%	172.5%	115.6%	118.4%	73.0%	78.5%	102.4%	
G&A %	141.8%	711.4%	407.2%	247.2%	101.6%	35.8%	27.8%	15.2%	13.8%	20.6%	

Exhibit 5.2
Mazor Financials 2009-2014 (USD)

Balance Sheet

(in US$ thousands)	2009 *	2010 *	2011	2012	2013	2014 9M
Current Assets						
Cash and cash equivalents	3,537	4,802	1,655	12,797	19,803	24,014
Short Time Investments	6,817	-	1,859	-	-	
Investments in marketable securities	11,602	13,335	12,596	4,156	45,014	22,952
Trade receivables	335	841	1,356	1,147	1,974	3,970
Other accounts receivable	134	280	268	680	655	1,756
Tax Current Assets	20	-	-	-	-	-
Inventory	278	1,167	1,326	1,257	2,480	2,946
Total Current Assets	22,723	20,424	19,060	20,037	69,926	55,638
Total Non-Current Assets	1,213	1,348	1,364	1,297	963	8,604
Total assets	**23,936**	**21,772**	**20,424**	**21,334**	**70,889**	**64,242**
Current liabilities						
Total current liabilities	1,013	2,394	6,324	4,024	6,464	7,040
Total Non-Current liabilities	3,574	4,233	616	4,490	332	351
Total liabilities	4,586	6,627	6,940	8,514	6,796	7,391
Equity						
Share capital	52	56	55	73	106	110
Share premium	47,895	51,052	51,122	58,910	130,472	135,013
Amounts allocated to share options	3,017	3,209	1,267	554	77	77
Amounts allocated to share options (	817	869	795	-	-	-
Capital reserve for share-based payr	1,827	2,465	2,787	3,170	3,854	3,674
Foreign currency translation reserve	-	-	2,400	2,119	2,119	2,119
Accumulated loss	-34,259	-42,505	-44,942	-52,006	-72,535	-84,142
Total equity	19,350	15,145	13,484	12,820	64,093	56,851
Total liabilities and equity	**23,936**	**21,772**	**20,424**	**21,334**	**70,889**	**64,242**
Equity / Balance Sheet > 50%	81%	70%	66%	60%	90%	88%

* 2009 estimation (was presented originally in NIS)

Exhibit 5.3
Mazor Stock Price & Market Value 2007-2015 (USD)