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& INVESTMENT REPORT

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MEDICAL DEVICES BLOOM

Li Ka Shing Foundation donates $130m to Technion

The largest ever donation to the Technion will be partly used to establish the Technion Guangdong Institute of Technology in China

The Li Ka Shing Foundation has donated $130 million to the Technion Israel Institute of Technology. The funds will be used to strengthen its home campus in Haifa and enable it to meet its commitment to establish the Technion Guangdong Institute of Technology, a joint venture with Shantou University in Guangdong Province in southern China. This is the largest ever donation to the Technion and one of the biggest in the history of Israeli higher education.

Guangdong Province and Shantou Municipal Government will set aside RMB 900 million ($147 million) to fund construction and initial operations of the Technion Guangdong Institute, and allotted 330,000 square meters for the campus.

Technion President Prof. Peretz Lavie and Shantou University Provost Prof. Gu Peihua signed the memorandum of understanding between the universities in Tel Aviv today in the presence of Li Ka Shing Foundation and Hutchison Whampoa chairman Li Ka-shing. The agreement will soon be brought for the approval of the Technion's and Chinese statutory authorities.

The Technion Guangdong Institute will begin offering undergraduate programs in civil and environmental engineering and computer sciences in the 2014 academic year. The establishment of an innovation center, connecting industries in Guangdong with Israel's technological creativity,

In this and in the next issue we will concentrate on Irsael's medical device industry

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will bridge Israeli technology into China and promote joint research and innovation. The institute's language of instruction will be in English and its faculty will be recruited from international researchers and scientists in universities around the world.

Beginning in 2014, Technion Guangdong Institute and Shantou University will conduct life sciences research based on Big Data to tackle the pressing social and livelihood issues like inadequate healthcare system and services, and improvements in clinical diagnosis procedures. By 2020, the institute will offer courses in other engineering-related fields, from mechanical to aerospace engineering.

"In this new world of fluid boundaries, the fast changing, fascinating, and transforming power of technology sometime does seem to wave like a magic wand, bringing new models and opportunities to many frontiers and generating new solutions to entrenched problems at a pace that is often hard to keep up with," said Li at the signing ceremony. "Our responsibility is to invest in reforms in education that unlock that genius and enable the continuing realization of human potential, building a knowledge rich society and securing a sustainable quality of life for all. Failing to do so amounts to a crime against the future."

The partnership between Israel and the Li Ka Shing Foundation began in 2011, after foundation executives visited the Technion and Prof. Lavie made a reciprocal visit to the foundation's headquarters in Hong Kong. That visit to Technion also resulted in an investment from Li's private investment company Horizon Ventures in Waze Ltd.. The profits from the sale of Waze to Google Inc. (Nasdaq: GOOG) became part of the donation to Technion.

Enzymotec raises $63.5m in Nasdaq IPO

The lipid-based products developer held the IPO at $14 per share, below its target of $16-18, but the share price rose 30% on

Enzymotec Ltd. (Nasdaq: ENZY) has raised a net $63.5 million in its Nasdaq IPO on Thursday, after the underwriters exercised their over-allotment options in full. The exercise of options for 661,800 shares boosted the offering to 5,073,800 shares.

Enzymotec, a developer of lipid-based products and solutions for the nutritional and healthcare markets, held the IPO at $14 per share, below its target range of $16-18, but the share price jumped 29.7% on Friday from $14.10 to $18.16.

Enzymotec will use the proceeds to meet its anticipated increased working capital requirements resulting from the expected growth in its business and for other general corporate purposes.

Enzymotec has developed a proprietary method for processing fatty acids (lipids). The nutritional supplements developed on the basis of its method are sold under leading international nutritional supplements labels, as well as under its own label. In the US, the company also sells nutritional supplements, backed by clinical trials, for special indications, such as high cholesterol, heart disease, and memory improvement.

Enzymotec was founded in 1998 at Naiot Venture Accelerator in Yokne'am, on the basis of research by Dr. Sobhi Basheer. It is now based in Migdal Ha'Emek and its CEO is

In the first half of 2013, the company had sales of $28.7 million, 84% more than in the corresponding period in 2012, and posted a net profit of $4.7 million, which compares with $845,000 for the corresponding period, and $4.8 million for 2012 as a whole.

Enzymotec is owned by Galam Group Ltd.

(Kibbutz Ma'anit), XT Investments Ltd. (formerly Ofer Hi-Tech), GlenRock Israel, Millennium Material Technologies Fund, and Mexico's Arancia Industrial SA de CV.

Medical Device Sector Continues Strong Growth

Israel has emerged as one of the world's leading centers for the development of innovative medical devices. The country has by far the highest proportion of any country of new patents in this sector per head of the population. Nearly 300 companies in this field in Israel, about half of the country's Life Sciences sector, encompass a diverse range of medical disciplines including therapeutics, diagnostics, implants, disposables and medical equipment.

Medical devices sector constitutes a fast growing global market with innovative devices providing breakthroughs in earlier and better diagnoses and medical treatments that bring clinical benefits to patients at a cost savings to the healthcare system and the individual patients.

Israel's strength in this sector stems from inter-disciplinary capabilities, which bring together medicine, clinical expertise, materials science, electronics, software expertise and engineering know-how. Some of the world's leading universities with renowned R&D faculties, leading edge medical centers, the world's highest per-capita number of physicians, and a flourishing high-tech sector combined with a spirit of entrepreneurship have all contributed to the country's dynamic growth in medical devices.

Israel's best-known medical device firm is Given Imaging, which is redefining gastrointestinal diagnosis by developing, producing and marketing innovative, patient-friendly products for detecting gastrointestinal disorders. The company's flagship technology, the Given Diagnostic System features the naturally ingested PillCam(TM) video capsules endoscopes. PillCam™ SB for the small bowel and PillCam ESO for the esophagus, both cleared by the FDA. PillCam capsules for the stomach and the colon are under development. Established in 1998, Given Imaging is listed on the NASDAQ.

Israel's medical device sector evolved from the country's highly successful medical equipment industry, which was pioneered in the 1980's and 1990's by Elbit, which developed diagnostic imaging technology including innovative nuclear and magnetic resonance imaging and ultra-sound equipment. Elbit eventually sold its diagnostic medical imaging using computer tomography to General Electrics Marconi division, which in its turn was acquired by Philips Medical Systems. Similarly, Elbit's diagnostic ultrasound and nuclear and magnetic resonance imaging were sold to GE Healthcare.

Elbit and GE Healthcare's partnership has spawned one of the country's most promising medical device firms – InsighTec. Established in 1999 by Elbit and General Electric, ExAblate 2000, InSightec's first product, is FDA approved, and integrates focused ultrasound thermal ablation with magnetic resonance imaging capabilities to provide a non-invasive method for destroying or ablating targeted tumor tissues. InsighTec plans a summer IPO on the NAS-

DAQ market.

Another veteran Israeli medical device company is Lumenis, initially established in 1991 as ESC Medical Systems and formed several years later following a merger with Coherent Medical Group. Lumenis develops, manufactures, and markets state-of-the-art proprietary laser and intense pulsed light devices for dermatology and aesthetics. Traded on the US NASDAQ market, Lumenis is Israel's largest medical devices company.

In recent years Israel's medical device sector is attracting increasing amounts of foreign investment. This is achieved through VC funds, IPOs and direct investments from major US and international companies like Johnson & Johnson, Boston Scientific, Medtronic and Guidant.

Johnson & Johnson acquired Israeli medical device firm Biosense through its Cordis Division. Biosense provides solutions for endocardial diagnosis and therapy. Johnson & Johnson has also invested in Contec Medical, which develops multimedia information solutions for point of care applications and NESS (Neuromuscular Electrical Stimulation Systems), which provides technological solutions for patients suffering from paralysis due to neurological disorders. The company has also made an investment in Impulse Dynamics- a developer of an active implant to treat chronic heart failure.

Boston Scientific acquired Mel – Medical Enterprises Group, which develops minimally invasive therapies for the treatment of cancer with a flagship product that induces remission and reduces recurrences of cancer of the bladder. Boston Scientific has also invested in Sightline, which specializes in the design and development of medical endoscopic systems,. In addition, Boston Scientific invested in BrainsGate that is developing an implantable neuromodulator to treat brain tumors and other neurological disorders and in VisionCare Ophthalmic that has developed an implantable telescope to treat the dry form of Age Related Macular Degeneration.

Guidant Technologies acquired X-Technologies in 2003 for about $150 million. X-Technologies, founded in 1999, has developed a pull wire for use with catheters in balloon angioplasty, which effectively treats artery narrowing. Kodak Health acquired OreComputed Radiography . Orex is developing, manufacturing and marketing low cost computerized radiography products, based on innovative phosphor plates. The technology captures X-ray images digitally, eliminating the need for film development processing

Examples of IPOs in addition to Given Imaging include Card Guard, traded on the Swiss Stock Exchange, which has developed advanced telemedicine software and monitoring equipment for high-risk and chronically ill patients, and Oridion Medcial, also traded on the Swiss Stock Exchange, develops and manufactures breath-test analyzers, which can detect cancers and ulcers.

Israel is a world leader in medical IT and Aerotel is a world leader in modular, mobile telemedicine devices, while Neurotrax Israel has developed Mindstreams which provides physicians with real-time objective measurement of cognitive functioning.

Tadiran LifeCare, a business unit of Israeli-based wireless communications company Tadiran Spectralink, has developed a series of cellular-based wrist-wearable mobile monitoring devices.

Promising young companies include Bio-Control, which was founded in 1999, and has developed active implantable muscle stimulator to treat incontinence of all types and an implantable device to treat chronic heart failure. Versamed, established in 1999, is a leading provider of software-based 'smart' medical ventilators, while MediSpec is dedicated to making the most efficient and minimally-invasive medical treatments in such areas as orthopedics, cardiology, oncology and relief from kidney stones. InterCure, a medical device company has developed and patented a technology platform for respiratory-based treatment of cardiovascular and pulmonary diseases.

Quantomix develops innovative products for rapid, high resolution imaging of wet samples, while Impliant has developed a new orthopedic technology, which replaces polyethylene and metal used in hemiathroplasty and spine implants with patented polyurethane. Medingo Ltd., which was established by RDC (owned by Elron and RAFAEL) at the end of 2005, is developing a miniature disposable insulin dispenser.

Another successful drug delivery company is WaisMed, which has developed advanced intraosseous infusion (IOI) devices, designed to offer safe and highly effective solutions whenever traditional intravascular access is not possible. Microjet-Tech is developing a high precision micro syringe.

TopSpin Medical has developed a unique and novel technology for local high-resolution MR imaging using a miniature handheld probe incorporating all magnetic field sources and eliminating the need for external magnets and a bulky and expensive MRI scanner. Another imaging company is Cadent, which develops and manufactures digital imaging solutions for the dental industry, while Odin Medical Technologies develops, manufactures and commercializes Intraoperative MRI systems designed for use by the neurosurgeon in standard ORs.

OrthoMediTec specializes in orthopedic trauma solutions, while GI View is engaged in the development of highly advanced endoscopic technologies for the gastrointestinal tract. HDH Medical is developing devices for suture-less vascular anastomosis and Or-Sense is developing non-invasive glucose monitoring systems for diabetes sufferers. TavTech's skin rejuvenation products are based on jet aviation principles, while Cardiosol is developing innovative technology for interpreting the electrical activity of the heart. Nanomedica is developing innovative scanning Doppler ultrasound technology.

In the area of therapeutics Galil Medical specializes in the development, manufacture and marketing of minimally invasive cryo medical devices and systems. Incorporating advanced hyper-cooling technology, the Galil Medical system allows extremely fast, high-resolution and controlled tissue ablation, including cancerous tissue. Medinol is a global leader in minimally invasive cardiovascular stent technology. Dune Medical Devices is developing surgical devices and techniques for real-time, intra-operative optimization

of surgical oncology procedures. Dune's groundbreaking technology for intra-operative tumor margin assessment will eliminate the need for painful and costly repeat surgical oncology procedures.

Leading start-ups include NeuroSonix, which is developing non-invasive technology for protecting the brain from embolisms during open-heart surgery and other cardiologic procedures and angiographies. E-Pill Pharma is developing an oral drug delivery platform enabling large molecule drugs to be administered orally, while ETView's flagship product is an endotracheal tube (ETT) with an embedded video camera at its tip, which provides for a clear view and continuous monitoring of the upper airways and trachea during intubation.

At present the medical devices sector in Israel is dominated, in terms of numbers, by young start-up and early stage companies each with fewer than 20 employees. About 50% of the companies in this sector were established in the past decade.

Israel Information Technology Report

IT spending is expected to reach ILS22.6bn in 2013, with relatively stronger growth in software and services, compared to hardware as the market matures. Although vendors reported a seasonal dip in new projects in Q113, BMI believes IT spending will remain on a positive trajectory this year. The market will increasingly be driven by software and services in key sectors such as government, defence and financial services - resulting in IT services accounting for 36.4% of the overall market spending by 2017.

Headline Expenditure Projections

Computer Hardware Sales: ILS9.56bn in 2012 to ILS9.55bn in 2013, down 0.1% in local currency terms. The slowdown is primarily the result of macroeconomic factors, but Israeli businesses are investing more to facilitate expansion and development and sales growth should strengthen from 2014.

Software Sales: ILS5.0bn in 2012 to ILS5.1bn in 2013, an increase of 2.3% y-o-y. Device and data proliferation will drive spending on customer relationship management (CRM), databases and business intelligence.

IT Services Sales: We expect IT services sales will outperform the rest of the IT market, increasing from ILS7.73bn in 2012 to ILS7.90bnin 2013. Stable sectors such as government and defence offer continued revenue opportunities, while growth will be derived from cyber and data security, cloud computing and outsourcing.

Key Trends & Developments

The IT market in Israel continues to be held back by the wider economic environment, underpinning our view of weak IT market sales growth in 2013. Despite a domestic slowdown and global economic headwinds, a significant number of opportunities remain. The launch of Windows 8 operating system and an expected increase in tablet sales will offset some of the economic slowdown in the retail hardware market, as will the development of multi-use hybrid notebooks by Windows vendors in 2013 and 2014.

The IT services market will also fare better than either software or hardware, with sales driven by cloud computing, outsourcing and security. As a wider range of cloud

computing products are released, and increased competition between vendors lowers prices, uptake will increase among enterprises and government. Particular areas of opportunity for cloud computing include banking and retailing as organisations in those fields looking to save money on hardware investments. Businesses will not only seek to make cost savings, but will look to boost efficiency and increase flexibility of response to customer needs.

BMI also highlights the potential for of continued financial sector spending in Israel as a result of a number regulatory changes introduced in the wake of the economic crisis of 2008-2009.Israeli financial services regulatory body the Israeli Security Authority has increased supervision of companies offering advice with respect to pensions, insurance and other financial products. This, in turn, has generated additional IT spending, with banks and other organisations often needing to implement solutions to ensure compliance within a set time.

Israeli Security System to be Used in NYC Housing Projects

A security system developed in Israes being used in NYC housing projects

An apartment security system developed in Israel will be used in housing projects in New York, according to a report in the New York Post.

The system does not use keys but is rather based on face and voice recognition. A low-income project in Harlem and a new luxury condominium will be getting the high-tech security system, reported the New York Post.

A one-building pilot project at the 1,600-unit Knickerbocker Village has been using the SafeRise program from the Israeli-based FST21 that is now rolling out to all dozen buildings.

The company is headed by retired IDF Major General Aharon Zeevi Farkash, formerly the head of Israeli Military Intelligence. He said the system is the ultimate answer to lost ID cards and security guards who don't really examine IDs.

"Everyone who tried the system, was, 'Yes I want it,'" Farkash told the newspaper. "This is the best way to introduce new technology."

In a typical installation process, residents of a building or students in a dorm or workers in an office get a facial scan during a fast enrollment process that also looks at other body measurements and movements.

After that, the individuals can simply stroll in and look at the camera to be cleared.

"We don't do traditional face [scans]," according to Daniel Peled, the company's vice president of sales and marketing.

"It is a fusion of identify technologies — one is facial recognition [but] there are behavior analytics and other items that are part of our patented technology," he explained.

These also include voice recognition, where the system speaks to and screens visitors in either a man's or woman's voice. It can dial any predetermined phone, so one can speak to visitors and/or see them, decide to let them in, or shut them out. Visitors can also speak with a central monitoring station, a building's concierge or security desk.

At Knickerbocker Village, the system speaks both English and Cantonese — while Mandarin is being added. Other languages are also available.

The cameras, which can also read license plates for entry into garages, are also specially designed to be vandal-resistant.

The company is now beginning pilot proj-

ects at 50 other private buildings, including the four 35-story Taino Towers in Harlem, according to the New York Post.

Broker Efraim Tessler of Keller Williams, whose father Yitzchak Tessler, developed the project, told the newspaper, "It's also a smart doorbell that gets you around the world on your phone. And if you have a visitor staying for a week, you can give them a QR bar code."

Several commercial buildings are also set to begin pilot programs soon, Farkash told the New York Post.

BioLineRX obtains FDA orphan drug status for leukemia drug

The company has obtained orphan drugs designation for BL-8040 as a therapeutic for the treatment of acute myeloid leukemia.

EXECUTIVE SUMMARY

Israel is well known for its innovative medical devices industry and despite the unfavorable global economic climate this sector has been steadily growing. As of August 2012, there are 656 medical devices companies in Israel which constitute around 60% of the entire life sciences industry. It should be noted, however, that medical devices companies are typically very small and in Israel over 50% of all companies are based on only 5 employees or less. Only 19 companies employ over 100 workers. Most of the companies, almost 70%, have not yet reached the commercial stage and are still at various stages of their product development.

The Israeli medical devices sector consists of 9 sub-sectors, the biggest of which is therapeutics (225 companies) followed by the monitoring & diagnostics sub-sector (141 companies). The most dominant sub-sector in terms of successful companies and advanced stage companies is the imaging sub-sector. This sector includes one of Israel's well-known and successful medical devices company – Given Imaging. The telemedicine sub-sector, while young, holds a great promise as will be further explained in this research.

After a sharp drop in exports following the economic downturn in 2008, exports of medical devices has been steadily growing during the last years. In 2011 Israel exported over $1.6 billion worth of medical devices mainly to the US, Japan, China and Europe.

The medical devices sector has always held a high risk for investors. Lately, this risk has grown due to uncertainty as to the future economic climate, more stringent regulation (by the FDA) and price pressures. Due to the fact that the US is the largest market for medical devices, FDA marketing approval is vitally important for medical devices companies. The fact that these approvals have become more difficult to obtain, deters some investors from investing before a company overcomes the regulatory hurdle. Generally, these risks are making investors more cautious and less likely to invest in early stage companies. This means that many companies will not make it to the finish line, not necessarily because their products are not good enough but because they do not have enough funds to see it through. Israel Medical Devices Industry –

Strong imaging sub-sector in terms of successful companies (7 of which had been acquired by multinational giants) and the number of advanced stages companies.

The global medical devices market was estimated at $322 billion in 2011. The production revenue (export and local sales) of

the Israeli medical devices industry in 2011 was $1.8 billion.

Israel is considered a leading country in the field of medical devices. The total number of granted patents in the medical devices area positions Israel in the first place in patents per capita in the world and in the fourth place in absolute number of patents.

656 medical devices companies are active in Israel. Over 50% of the companies are based on 5 employees or less, while only 3% have over 100 employees. Over 65 % of the companies have not yet reached the commercial stage and are still in the seed or R&D stages of development.

In 2011 the Israeli life science industry raised $385 million (not including Government funds). Over 55%, $218 million, were invested in the medical devices sector.

The amount raised by the life sciences industry in 2011 was bigger, in absolute numbers, than that raised in 2010, but the weight of life sciences investments decreased from 28% of all hi-tech investments in 2010 to 18% of all investments in 2011.

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THE FIELD OF MEDICAL DEVICES

The biomedical industry is based on 3 main sub-industries: medical devices, pharma and biotechnology. According to the FDA, a medical device is an instrument, apparatus or implant intended for the use in the diagnosis, cure, treatment or prevention of disease in man or animals. Medical devices differ from drugs in that they do not affect the human body by chemical, metabolic or immunological means but by physical mechanisms. Some products may be composed of a combination of a drug and a device and in such cases the product's classification will be defined by the primary mechanism of its action.1 Medical devices can range from simple tools such as bandages or incision blades to complex or life-saving equipment such as pacemakers and dialysis machines. Medical devices are used in healthcare facilities and at home.

1 The classification of a product is important for regulatory purposes (see "Regulation of Medical Devices" Chapter).

The Global Context

The global industry for medical devices includes thousands of companies, most of which are small enterprises with less than 50 employees. Startup companies, mostly supported by venture capital and other investments, are viewed as the drivers of innovation in the medical device industry. Many startup medical-device companies generate little or no sales revenue during the development phase before they receive permission to commercialize a device, and the funds invested in these companies by venture capitals and other investors must sustain the companies until regulatory approval or clearance. Another potential barrier to the economic viability of both small and large companies is supportive insurance for coverage, payment, and reimbursement. In general, for nearly all device-based therapies and many diagnostic tests, a device must be cleared or approved before an insurer or payer will consider covering the service.

The US is the largest consumer and producer of medical devices in the world, with about half of the world market. Japan, The European Union (EU), Canada, and Australia also have large, stable medical-device markets. Overall, the developed world is rapidly increasing both its consumption

and its production of medical devices.
Israel Medical Devices Industry – Market OThe value of the global market for medical devices is growing steadily due to emerging markets in developing countries and extending life expectancy in developed countries, among other factors.

THE ISRAELI MEDICAL DEVICES INDUSTRY

Background

The medical devices sector is the largest sector within the local life science industry. In the global context, Israel is considered to be one of the leading countries in the field of medical devices: The total number of granted patents in the medical device area positions Israel in the first place in patents per capita and in the fourth place in absolute number of patents.

The Israeli medical device industry has been growing rapidly in the past 20 years. The first medical devices company established in Israel was Mego Afek AC (still active today). During the 1990's, inter alia, due to the major immigration of academics from Russia, the number of medical devices companies established in Israel increased significantly, with 269 new companies emerging during that decade. But it wasn't until the first decade of the 21th century that the medical devices industry in Israel became the major industry that it constitutes today. Between the years 2001-2010 632 new medical devices companies were established in Israel. Israel Medi

Number of Medical Devices Companies Established in Israel Since 1960 totals 971 (not all active today)

Note: The last column represents only 2 years of a decade and therefore is small.

Source: IVC Research Center

Mile Stones

Mego Afek AC, the first medical devices company in Israel, was established.

First Israeli IPO (initial public offering) on NASDAQ. Elscint, a medical devices company specializing in imaging technology, was the first Israeli company traded on NASDAQ.

Johnson & Johnson acquired Biosense, a company established by Shlomo Ben-Haim, and merged it with Webster Laboratories creating Biosense Webster in a $400 million deal, the biggest purchase of an Israeli medical devices company. Biosense Webster Israel is a R&D center specializing in cardiac imaging technologies.

GE Healthcare, of the giant General Electric Company, founded GE Healthcare Israel through the purchase of existing operations of Israeli medical systems businesses, including Elbit Medical Imaging's Ultrasound division, Elscint's NM and MRI divisions and Versamed.

Given Imaging was the first medical devices company to be traded in the Tel Aviv Stock Exchange. In 2001 the company launched its first IPO on NASDAQ and on March 2004 was dual listed on TASE.

Market OvHealthcare IT 8Israel's Life Science Industry Segmentation

MediGuide, an imaging solution company, was acquired by St. Jude Medical for $300 million.

Ventor Technologies, today, Medtronic Ventor, was acquired by Medtronic for $325 million.

The Biomed index is launched on TASE. The biomed index was originally comprised of 25 Israeli biomed companies, medical devices companies among them. Today the index holds 23 companies.

superDimension, specializing in lung cancer diagnosis and treatment was acquired by Covidien for $300 million.

The Israeli Medical Devices Industry Today

As of August 2012, 1,086 life science companies are active in Israel. Over half of these companies, 656 companies, are medical device companies. Of the 656 companies, 18 are owned by foreign companies and operate an R&D center in Israel.

35 Israeli medical devices companies are publicly traded, most of them – 22, on the Tel Aviv Stock Exchange (TASE). 2 Companies are traded on NASDAQ – Given Imaging (who is also traded on TASE) and Syneron

Over 100 3%

Number of Employees in Israeli Medical Devices Companies

The majority of medical devices companies in Israel are typically very small. As can be seen in the chart below, over 50% of the companies are based on 5 employees or less, while only 19 companies, 3%, have over 100 employees. The 3 largest companies are Shamir Optical Industry (1400 employees), Lumenis (903 employees) and Given Imaging (760). All 3 companies are based in Israel and have branches throughout the world.

Among other things, Dr. Radnisky learned that floods taking place closely following a drought were a preliminary sign of an outbreak of cholera. Today she is involved in an organization that is active against genocide, as well as with medical organizations, in order to implement lessons learned from her research. Research carried out by Dr. Radinsky has earned her awards and recognition from several organizations and bodies, among them Google, Yahoo and Facebook.

"Over the years, we have succeeded in selecting men and women whose innovations, and the companies they established, deeply influenced different fields and humanity," explained Jason Pontin, the editor-in-chief and publisher of the MIT Technology Review.

"It is a big honor to be included in the MIT list of the young innovators. This is one of the most prestigious prizes that someone my age can receive," Radinsky said Thursday. "I really hope my win will encourage other young people to go into research, and that they will chose to do things that will influence all of our lives."

Three Israeli universities in top 100 world rankings

Hebrew University of Jerusalem,

Weizmann Institute of Science and Technion – Israel Institute of Technology listed in the annual ARWU global survey.

Three Israeli academic institutions are included in the 2013 Academic Ranking of World Universities (ARWU), an annual survey published by the Center for World-Class Universities at Shanghai Jiao Tong University. The three universities — Hebrew University of Jerusalem, Weizmann Institute of Science and Technion – Israel Institute of Technology — were also included on last year's prestigious list.

This year's rankings put the Hebrew University of Jerusalem in 59th place, followed by the Technion in Haifa at 77th and the Weizmann Institute at the 92nd place. Both the Technion and Weizmann Institute moved up one place from last year's poll.

The Hebrew University has appeared on the Top 100 list since the ARWU first appeared in 2003.

"I'm proud to see the prominent positions of Israeli research universities in these important international rankings, and I'm pleased that once again the Hebrew University has been recognized as Israel's leading university. The fact that the Hebrew University continues to achieve such high ratings is a testament to the hard work of our faculty and the university community, and their continuing quest for uncompromising academic and research excellence," said Hebrew University's President, Prof. Menahem Ben-Sasson.

Once again, American universities dominated the Top 20. And, as it has placed since 2003 when the survey began, Harvard repeated its top spot placing.

The ARWU's Top 100 university ranking is actually part of a larger Top 500 university survey. Four other Israeli institutions were included in the longer list: Tel Aviv University (101-150th place); Bar-Ilan University and Ben-Gurion University of the Negev (301-400th place); and University of Haifa (401-500th place).

According to the ReWalk website, the device "uses patented technology with motorized legs that power knee and hip movement. It controls movement using subtle changes in center of gravity, mimics natural gait and provides functional walking speed. A forward tilt of the upper body is sensed by the system, which triggers the first step. Repeated body shifting generates a sequence of steps, which allows natural and efficient walking." The technology was also demonstrated for U.S. President Barack Obama in Jerusalem this past March, and is being used in homes in Europe, especially Germany. The technology is awaiting Food and Drug Administration approval in the U.S.

Pezaro demonstrated her ease of movement to the many guests.including Université de Montréal vice-rector of studies and psychology pro

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OVERVIEW

THE FIELD OF MEDICAL DEVICES

The biomedical industry is based on 3 main sub-industries: medical devices, pharma and biotechnology. According to the FDA, a medical device is an instrument, apparatus or implant intended for the use in the diagnosis, cure, treatment or prevention of disease in man or animals. Medical devices differ from drugs in that they do not affect the human body by chemical, metabolic or immunological means but by physical mechanisms. Some products may be com-

posed of a combination of a drug and a device and in such cases the product's classification will be defined by the primary mechanism of its action.1 Medical devices can range from simple tools such as bandages or incision blades to complex or life-saving equipment such as pacemakers and dialysis machines. Medical devices are used in healthcare facilities and at home.

The global industry for medical devices includes thousands of companies, most of which are small enterprises with less than 50 employees. Startup companies, mostly supported by venture capital and other investments, are viewed as the drivers of innovation in the medical device industry. Many startup medical-device companies generate little or no sales revenue during the development phase before they receive permission to commercialize a device, and the funds invested in these companies by venture capitals and other investors must sustain the companies until regulatory approval or clearance. Another potential barrier to the economic viability of both small and large companies is supportive insurance for coverage, payment, and reimbursement. In general, for nearly all device-based therapies and many diagnostic tests, a device must be cleared or approved before an insurer or payer will consider covering the service.The US is the largest consumer and producer of medical devices in the world, with about half of the world market. Japan, The European Union (EU), Canada, and Australia also have large, stable medical-device markets. Overall, the developed world is rapidly increasing both its consumption and its production of medical devices.

The classification of a product is imp for regulatory purposes (see "Regulation of Medical

The value of the global market for medical devices is growing steadily due to emerging markets in developing countries and extending life expectancy in developed countries, among other factors.

THE ISRAELI MEDICAL DEVICES INDUSTRY

Background

The medical devices sector is the largest sector within the local life science industry. In the global context, Israel is considered to be one of the leading countries in the field of medical devices: The total number of granted patents in the medical device arepositions Israel in the first place in patents per capita and in the fourth place in absolute number of patents.

The Israeli medical device industry has been growing rapidly in the past 2 0 years. The first medical devices company established in Israel was Mego Afek AC (still active today). During the 1990's, inter alia, due to the major immigration of academics from Russia, the number of medical devices companies established in Israel increased significantly, with269 new companies emerging during that decade. But it wasn't until the first decade of the 21th century that the medical devices industry in Israel became the major industry that it constitutes today. Between the years 2001-2010 632 new medical devicescompanies were established

Mile Stones

Mego Afek AC, the first medical devices

company in Israel, was established.

First Israeli IPO (initial public offering) on NASDAQ. Elscint, a medical devices company specializing in imaging technology, was the first Israeli company traded on NASDAQ.

Johnson & Johnson acquired Biosense, a company established by Shlomo Ben-Haim, and merged it with Webster Laboratories creating Biosense Webster in a $400 million deal, the biggest purchase of an Israeli medical devices company. Biosense Webster Israel is a R&D center specializing in cardiac imaging technologies.

GE Healthcare, of the giant General Electric Company, founded GE Healthcare Israel through the purchase of existing operations of Israeli medical systems businesses, including Elbit Medical Imaging's Ultrasound division, Elscint's NM and MRI divisions and Versamed.

Given Imaging was the first medical devices company to be traded in the Tel Aviv Stock Exchange. In 2001 the company launched its first IPO on NASDAQ and on March 2004 was dual listed on TASE.

MediGuide, an imaging solution company, was acquired by St. Jude Medical for $300 million.

Ventor Technologies, today, Medtronic Ventor, was acquired by Medtronic

for $325 million.

The Biomed index is launched on TASE. The biomed index was originally comprised of 25 Israeli biomed companies, medical devices companies among them. Today the index holds 23 companies.

superDimension, specializing in lung cancer diagnosis and treatment was acquired by Covidien for $300 million.

The Israeli Medical Devices Industry Today

1,086 life science companies are active in Israel. Over half of these companies, 656 companies, are medical device companies. Of the 656 companies, 18 are owned by foreign companies and operate an R&D center in Israel.

Israel's Life Science Industry Segmentation

Agrobiotech
2% Bioinformatics
Industrial 1%
3%

Biologicals
3%
Healthcare IT
8%
Medical Devices
60%
Pharmaceuticals
& Biotechnology
23%
Source: IVC

35 Israeli medical devices companies are publicly traded, most of them – 22, on the Tel

Aviv Stock Exchange (TASE). 2 Companies are traded on NASDAQ – Given Imaging (who is also traded on TASE) and Syneron Medical.

The majority of medical devices compa-

nies in Israel are typically very small. As can be seen in the chart below, over 50% of the companies are based on 5 employees or less, while only 19 companies, 3%, have over 100 employees. The 3 largest companies are Shamir Optical Industry (1400 employees), Lumenis (903 employees) and Given Imaging

(760). All 3 companies are based in Israel and have branches throughout the world.

Business Stages

The 656 medical devices companies are each at different stages of development: seed, R&D, initial revenues or Revenue Growth.

It is important to note that all medical devices companies engage in R&D (research and development) throughout most of their existence. The business stage named R&D will signify throughout this paper the stage when a company is no longer a seed company and is already in advanced stages of the development of its product/s but has not yet finished the development of the product or is still ongoing clinical trials and other requirements in order to gain marketing permission.

Over 65 % of the companies have not yet reached the commercial stage and are still in the seed or R&D stages of development. Of the 195 companies that are already selling their products only 30 have been showing revenues of over $10 million dollars.

Segmentation of Companies by Business Stage

Revenue

Growth

5%

Initial

Revenues

26%

R&D

35%

Seed

34%

MEDICAL DEVICES MARKET DOMESTIC VALUE

Israel has the second largest medical devices domestic market in the Middle East, second only to Saudi-Arabia. Most of the products, almost 80% are supplied by imports. According to Espicom Business Intelligence, in 2011 the Israeli domestic medical devices market value was estimated at $913 million. This figure represents the value of medical devices purchased by Israel (from both Israeli and foreign companies) during 2011, and represents a growth rate of 3.7% compared to the previous year.

Courtesy: IVC

Medical Device Market Domestic Value)

2011
Market Value (US$ Millions)

913M$
Growth rate (%)

3.7%
As % of Total Health Expenditure

4.8%
As % of World Market

0.3%
Supplied by Imports (%)

78.8%
Source: Espicom Business Intelligence estimates

Espicom's forecast predicts a steady growth of the domestic market over the next five

years.

Domestic market value 5 year forecast

2012
2013
2014
2015
2016
Medical Device Market (US$

millions)
922.2

957.4

1,016.3

1,080.1

1,096.8
Growth (%)

1.05 3.82 6.15 6.28 1.55
As % of health expenditure

4.7
4.7
4.6
4.5
4.3
Source: Espicom Business Intelligence estimates

PRODUCTION REVENUE OF THE INDUSTRY

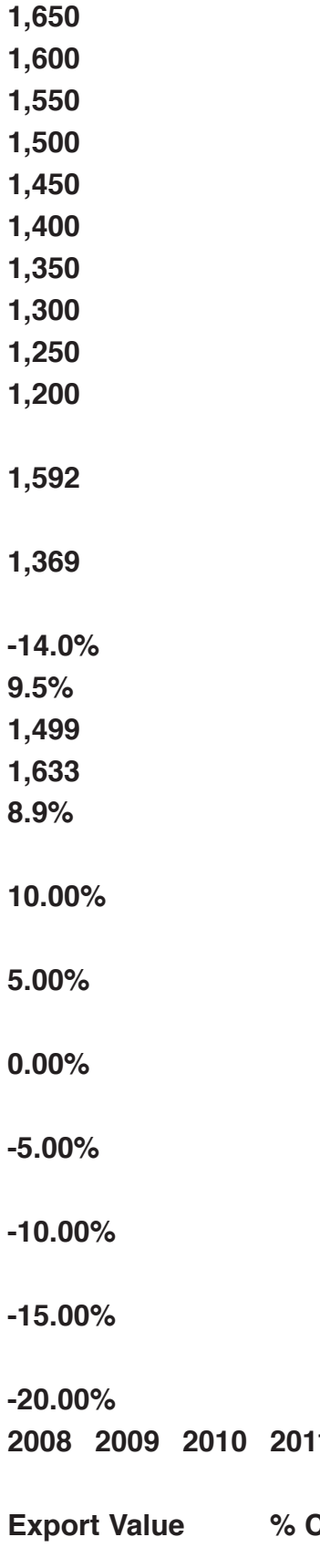
The overall production revenue (exports and local sales) of the Israeli medical devices industry in 2011 was estimated at $200 million. This amount stands for over 20% of all medical devices sales in Israel.

INTERNATIONAL EXPORT VALUE OF THE INDUSTRY

In 2011 Israel exported over $1.6 billion worth of medical devices. Following the sharp drop in exports due to the economic crisis in 2008, exports of medical devices have been steadily growing since then.

1,700
Israeli Companies Export of Medical Devices and Y-o-Y Change
(2008-2011)

15.00%



Source: Central Bureau of Statistics (CBS)

About a third of medical devices exported from Israel are shipped to the US, the largest medical devices market in the world. Other leading export destinations are the EU, China and Japan.

Leading Export Destinations (2011)

Source: CBS

GOVERNMENT SUPPORT PROGRAMS

It is evident that the Israeli government has long recognized, along the past years, the economic promise and value of the biomedical industry. Such government financial involvement in pre-seed and seed stages of a life science start-ups is most significant, as venture capital funds and other investors usually find it too risky to invest at such an early stage. The global economic crisis has made risky investments even riskier, increasing the significance of government support and incentives for the life science industry.

Over the last 30 years, the government has established a policy of incentives to encourage and support investments in technology oriented companies and projects, mainly through the Office of the Chief Scientist. It should be noted, though, that

government support decreased significantly over the past decade.

Source: The Office if the Chief Scientist

Of the many programs that the government implements one program is dedicated exclusively to the life science industry. In 2009 the government released a tender for a government sponsored venture capital

fund dedicated to the life science industry in Israel. OrbiMed, a leading global investment management firm, won the tender and set- up a $222 million fund, which includes a $50 million anchor investment by the Government its self. The fund has made a few investments already and has plans to invest in medical devices companies.

Other government support programs are not restricted to the life science industries but many life science companies, and many medical devices companies among them, benefit from them greatly:

The R&D Fund – The R&D fund is the main support program offered by the Chief Scientist for innovative R&D. Grants that are approved cover up to 50% of R&D expenditures and may reach tens of millions of shekels. These grants are conditional grants meaning that the company is not required to pay it back should the R&D project fail. Grants of projects that are successful have to be paid back – but under very easy terms.

Technological Incubators – A company or facility designed to foster entrepreneurship and help startup companies, usually technology-related, to grow through the use of shared resources and intellectual capital. The program provides R&D grants, logistical support and legal and business development services for the first two years of

company life when risk is the highest and private funding is scarce. The government funds 85% of the initial investment required by the incubator company, some

$600,000, during those first two years. The remaining 15% is invested by the incubator.

Currently 26 incubators are active throughout Israel containing about 200 start-up companies. Although the incubator program was not designed exclusively for the medical devices industry, around 40% of incubated companies are medical devices companies.

Tnufa – This program assists start-up companies by evaluating the technology and the economics of a new idea, the preparation of the patent proposal, construction of a prototype, preparation of a business plan, establishing contact with industry representatives, attracting investors and finally, with direct support of up to $ 250,000

for each project.

Overall, medical devices companies received 11.2% of the Chief Scientist grants in 2011.

SWOT ANALYSIS -ISRAELI MEDICAL DEVICES

INDUSTRY

Strengths

- ProfessionalInter-disciplinarity: High expertise in the many fields rele vant for medical devices (medicine,electronics,software)

-Highest patent ratio per capita in the world in the field of medicaldevices

-High flexibility of the industry enables it to accommodate changes

- Strong imagingsub-sector

Opportunities

-Emergence of new markets

(China,India)for medical devices

- Growth potential:Hundreds of companies in seed and R&D stages with growth potential

-New life sciences VC fund (Orbimed,$222m) e xpected to invest large amounts in medical devices companies

Weaknesses

-Weakness on stock markets- Most companies are still struggling on TASE;only 2 companies listed on NASDAQ

-Early and under valued ‘’Exits”, both through M&A and IPOs

-High risk profile,unattractive for investors

Threats

- Regulatory hurdles:possibly even more stringent FDA marketing permission process is expected in the future

- Valley of death:Harder to raise money for early stages companies

- Payer pressures- demand for better devices for a lower price

COMPANY LIFECYCLE AND ECOSYSTEM

COMPANY LIFECYCLE

The average lifecycle of a medical devices company ranges between 3 to 5 years. Naturally, not all companies will reach that stage for many reasons (lack of funding, failure in the development of the device, failure in obtaining marketing permission, etc.). As a company advances in its lifecycle, more financing is required in order to achieve the next milestones (for and expansion on company financing see “Economic Climate” chapter).

COMPANY’S ECOSYSTEM

Each medical devices company is surrounded by an ecosystem that follows the company throughout its lifecycle. The ecosystem begins even before the company is established with institutions such as universities and research centers supplying ideas and patents to business entrepreneurs. Israeli universities have technology transfer companies whose objective is to sell academic ideas and inventions.

Medical devices companies, like most hi-tech companies, require investment throughout their entire lifecycle. The nature of these investments changes as the company develops. Companies at very early stages of development usually rely on investments from

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government grants and angel investors2. Traditionally, venture capital firms also start investing at a relatively early stage but due to the economic climate even VC firms are growing averse to the risks associated with seed financing. Private equity investors will come into the picture when the company is already quite mature and stable.

Once a company has reached marketing stage, it starts interacting with potential payers for its devices – governments, hospitals, insurance companies and individual consumers.

Also, parts of the ecosystem are the company’s competitors and other companies which are searching for promising companies to purchase.

2 Angel investor - An investor who provides financial backing for small startups or entrepreneurs. Angel investors are usually found among an entrepreneur’s family and friends.

REGULATION OF MEDICAL DEVICES

Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices. The act of regulation attempts to balance between the goals of allowing consumers to have quick acess to new and improved medical devices and preventing devices that are not safe and effective from entering the market.

The decision to develop and manufacture a medical device depends mainly on it being cost effective. Harsh regulatory measures may increase the cost of the development in a manner that would make the development not worthwhile or increase the price of already expensive devices. On the other hand, if the regulation of devices is not stringent enough, unsafe or ineffective products may be introduced to the market and cause harm to consumers.

This following chapter will describe the regulatory process in the 3 biggest medical devices markets.

UNITED STATES

The Food and Drug Administration (FDA) is the agency responible in the US for protecting the public's health by overseeing medical products, including devices. As the USA is the largest medical devices market today, FDA approval for medical devices is extremely important to all medical devices companies. The FDA regulates the safety and efficiency of medical devices through the Center of Devices and Radiological Health (CDRH).

The FDA classifies devices according to the risk they pose to consumers. Low risk devices (Class I) such as plastic bandages pose only minimal risk to consumer and can be legally marketed upon registration alone. Moderate (Class II) and high risk devices (Class III), on the other hand, must obtain the FDA's premission prior to marketing. There are 2 paths that can be used in order to gain this permission: premarket approval (PMA) or premarket notification – 510(k).

Device Classification	Examples	Required Submission
Class I	Elastic bandages, plastic gloves, hand-held surgical instruments	Registration only unless 510(k) is specifically required
Class II	Powered wheelchairs, infusion pumps, surgical drapes	510(k) clearance unless exempt
Class III	Heart valves, silicon breat implants, pacemakers	PMA approval
	Certain dental implants, metal-on-metal hip joints	510(k) clearance

Source: Congressional Research Service

The PMA path is the most stringent regulatory category for medical devices. It consists of conducting clinical trials and requires scientific evidence to assure that the device is safe and effective for its intended use. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, "substantially equivalent", to a legally marketed device that is not subject to PMA. The PMA process is generally used for novel and high-risk devices and is typically lengthy and expensive. The permissions for a PMA and 510(k) regulated devices are called approval and clearance, respectively.

Summary of Medical Devices FDA Regula-

tory Process

Whereas once medical devices were considered to have lower regulatory hurdles than pharmaceutical in the USA, today marketing permission times have lengthened significantly, especially for the already lenghty PMA process. Clearance times for 510(k) have gone up by 45%, from an average of 3.1 months to 4.5. Approval times for PMA have increased by 75% and the process which once lasted 15.5 months (just over a year) now

dragges on for 27.1 months (over 2 years).

Average 510(k) Clearance

Times (months)

Average PMA Approval

Times (months)

27.1

+45%

3.1 4.5

15.5

+75%

2003-07 2010

2003-07 2010

Source: Ernst & Young, Pulse of the Industry

It's worth mentioning that the longer process is not the only setback for medical devices companies. In addition to the longer regulatory process, the number of product marketing permissions by the FDA has decreased for both lanes:

Source: Ernst & Young, Pulse of the Industry

Moreover, there has been much criticism in the USA over the hurried 510(k) path and questions of the safety of devices cleared in this process have arised. Consequently, a great uncertainty covers the future of this rapid process and it is possible that in the near future this path will be cancelled and replaced by a longer and more complicated path.

The results of this trend are that some device companies, Israeli companies among them, launch new products in Europe instead of waiting for an FDA approval. This regulatory trend also has great financial implications for companies which will be expanded on in the next chapter.

EUROPEAN UNION

Until the 1990's each European country had its own approach to medical devices evaluation. Today 3 directives regulate the medical devices industry in Europe: the Medical Devices Directive, the Active Implantable Medical Devices Directive and the In Vitro Diagnostics Medical Devices Directive. The main purpose of these directives is to harmonize the regulation of devices in Europe in order to bring about a single market. These directives require CE (Communité European) marking of all products covered by them. This mark means that a manufacturer claims their product "satisfies the requirements essential for it to be considered safe and fit for its intended purpose". The CE mark also means that the product can be freely marketed throughout the European Union without further regulation.

Classification of devices in Europe is very similar to the US but is composed of 4 classes. Like in the US, the devices are classified by risk to the patient and in addition, 18 rules classify medical devices that require understanding and interpretation as there are no clear-cut categories.

Device

Description Requirements

Classification

Class I Low risk, mostly non- Self certified by the manufacturer invasive

Class IIa Medium risk; invasive Assessed quality systems

Class IIb Medium risk; partialy or third-party assessed quality systems completely implanted

Class III High risk Clinical trials, product certification, assesed quality system.

Source: Regulation in the Medical Devices Industry in the US and Europe

Unlike the US where the FDA performs all inspections of medical devices, the European system relies on Notified Bodies. These bodies are commercial certification companies who have been 'notified' or approved by the respective Competent Authority (CA) in each EU country.

Overall, the regulatory process in Europe is less stringent and faster than the FDA process, and therefore patients in the EU have access to some new, complex technologies earlier than patients in the USA (up to several years earlier). Thus, many Isaeli medical devices companies seek the CE mark before approaching the FDA, in order to start selling their product as soon as possible.

JAPAN

The regulatory process for medical devices in Japan, the second largest market for medical devices, is considered to be one of the most difficult in the world. Many devices that have been approved and are widely in use in other countries have not yet been approved in Japan, and in some cases, only devices from two or three device-generations ago are available. But in recent year the Japanese are making efforts to change the situation. In 2004 the Pharmaceuticals and Medical Devices Agency (PMDA) was established and has improved the efficiency of the review system by delegating the review and certification processes to external organizations.

The Japanese classify medical devices into 5 classes according to the type of medical device and the degree of risk presented to the human body.

THE GLOBAL HARMONIZATION TASK FORCE (GHTF)

With the rapid growth of the global medical devices market governments have recognized a need to harmonize national standards in order to minimize regulatory barriers, encourage trade and improve access to new technologies. The Global Harmonization Task Force (GHTF) was founded in 1993 by the governments and industry representatives of the USA, EU, Japan, Canada and Ausralia.

THE ECONOMIC CLIMATE

Medical devices companies are facing an unfriendly financial environment since the beginning of the global economic criss in 2008. The medical devices industry has always held a big financial risk to all those involved –companies and investors – but in the last few years the existing risks have increased and new ones emerged. This chapter will point the financial risks in the industry in the years following the economic crisis and will then describe the financial ramifications of these risks for the industry.

INCREASING FINANCIAL RISKS IN THE MEDICAL DEVICES

INDUSTRY

More stringent regulatory environment - As described in the previous chapter, the already difficult to obtain FDA marketing

permission is becoming even more difficult to obtain. This has to do with internal USA policy but also with the uncertain economic future compelling the FDA to guarantee that new devices justify their cost in terms of effectiveness and outcomes. Much of the attraction that the medical devices market held for investors over the pharmaceuticals industry derived from the much faster pace of innovation and the cheaper process. The uncertainty of the future of the regulatory process poses a threat for investors.

Payer pressures – Public and private payers for health products (governments, hospitals etc.) have seen their budgets squeezed over the past years and are, in turn, pressuring medical devices companies to prove that their products will improve health outcomes. Israeli medical devices are discovering that passing the FDA hurdle does not guarantee immediate sales of the devices. In todays economic climate it is much more difficult to convince surgeons and other physicians to purchase a new device. Here too, like in the case of FDA premissions, hospitals and doctors wish to see proof of the supriority of a new device to cheaper devices or to devices that are already owned by them.

In addition, the medical doctor's freedom to pick the device they preferred is now restricted, as hospitals limit the numbers of options in each product category or

impose price caps.

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USA President Obama's health care reform – The implications of Obama's "Patient Protection and Affordable Care Act" (passed in 2010) for individuals and employers have been much discussed in recent years. However, not many are aware of the bill's implications for the medical devices industry. One of the funding sources for the health care reform will be a 2.3% excise tax based on the sale price of certain[3] medical devices sold in the US by the manufacturer, producer or importer of the device. The tax will go into effect on sales made after December 31, 2012. This excise tax is introduces further price pressures on the medical devices industry. Note that excise taxes are taken as a percentage of a manufacturer's revenue. Therefore regardless of whether a company generates profits, the tax is enforced at the same rate.

Weak economy – The global economy has not yet recovered form the 2008 financial dowturn and the gloomy future of the European economy has left

investors very cautious.

Overall, 2011 was a year of recovery for Israel's hi-tech investments. $2.1 billion were invested by local and foreign investors, a 70% increase to the $1.26 billion raised in 2010. Although a smaller percentage of overall investments went to the lifescience industry, the industry raised $385 million, an increase of 13% from 2010. As can be seen in the chart below, investments in the life sciences industry dropped from 28% of overall investments in 2010 to only 18% of over all investments in 2011.

Of the $385 million raised by the life science industry in 2011, the medical devices industry raised $218 million, over 55% of the amount raised by the entire life sciences industry, and

10% of total capital raised by all sectors.

3 Consumer devices like hearing aids, eyeglasses, contact lenses and devices which are generally purchased by the general public at retail for individual use will likely be exempt.

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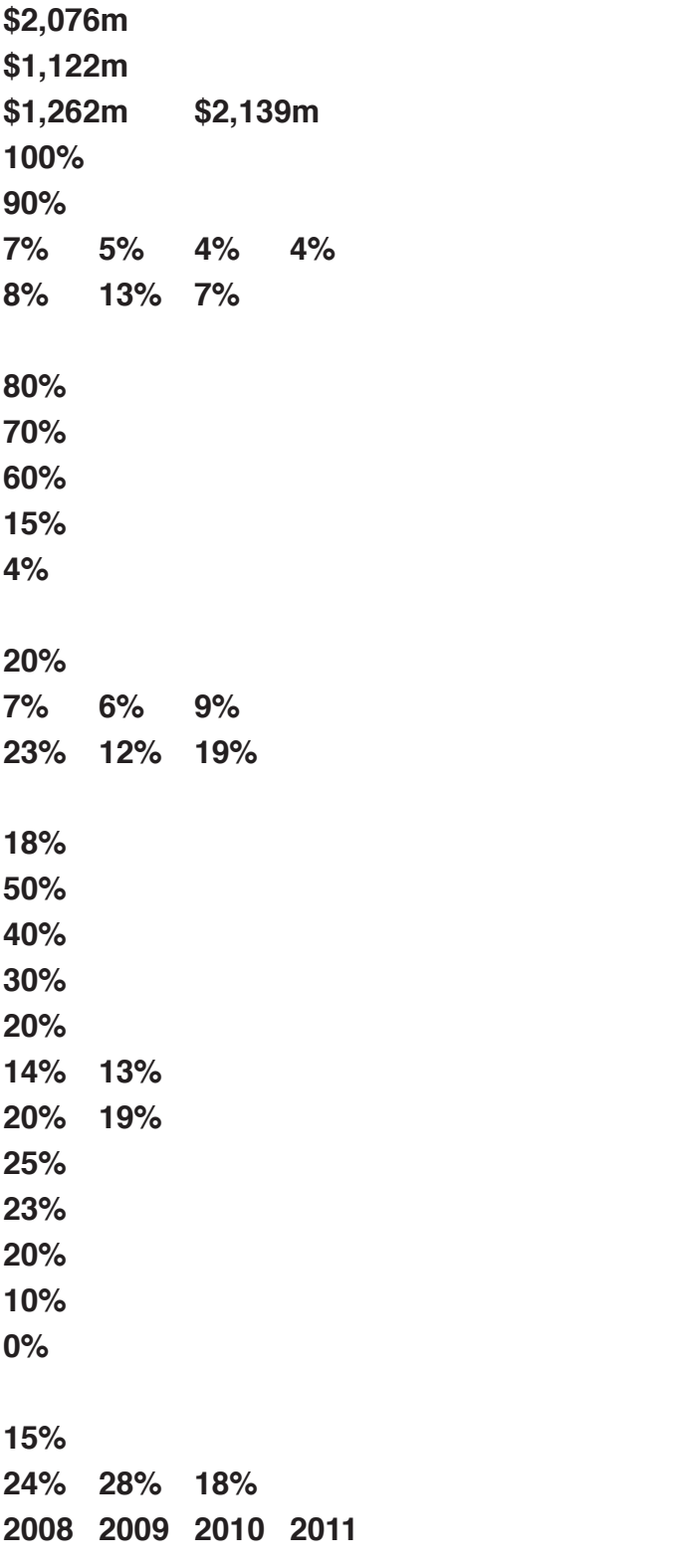
Capital Raised by Israeli High-tech Companies by Industry



Source: IVC Yearbook 2012

Although investments have gone up, their nature has been changing in the last years due to the increasing risks described above.

Investments shift from small companies to mature companies – According to Ernst & Young, while the overall funding of medical devices in USA and Europe (including Israel) has increased in the last 2 years, most of the money has gone to a small number of large commercial companies (companies with revenues in excess of $1 billlion). Since the beginning of the financial criss, the share of funds

raised by these companies has steadily increased, to reach a high of 73% in 2010.

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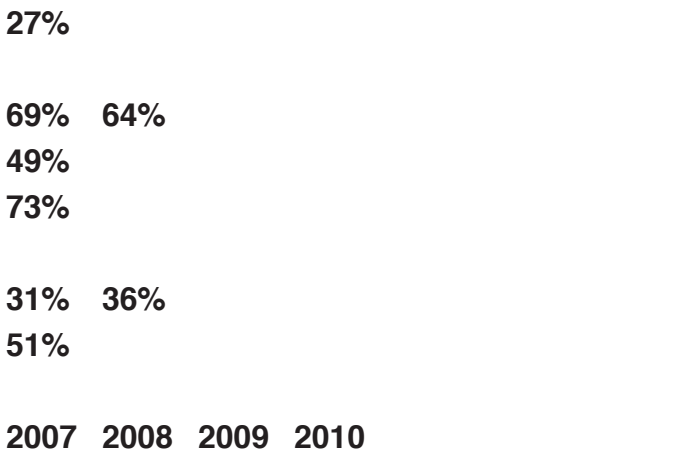
Large Medical Devices companies' Share of Total Capital

Raised has Grown Dramatically (USA and Europe)



Commercial Leaders Small Companies

Source: Ernst & Young, Pulse of the Industry

Although overall investments in Israeli hi tech companies reached a high of $2.1 billion in

2011, according to IVC, seed companies in Israel (including medical devices companies) are still raising money in smaller amounts than prior to the 2008 economy crisis.

Milestones – Conglomerats acquiring medical devices companies are increasingly relying on milestone payments and structured earn-outs in order to pass some of the acquisition risk to the seller.

Weak activity on stock markets – According to financial analysts, Israeli life science companies reach the public markets too early, and cannot maintain a suitable liquid and valuable share price. This is evident as many public medical devices companies have serious liquidity problems and some of them are looking for elegant ways to exit the market.

As of August 2012, 22 of the medical devices companies are traded on TASE, 6 of them are included in the biomed index.The total market cap of these companies is estimated at 2.07 billion NIS. All traded companies except one – Given Imaging

– are operating at a loss.

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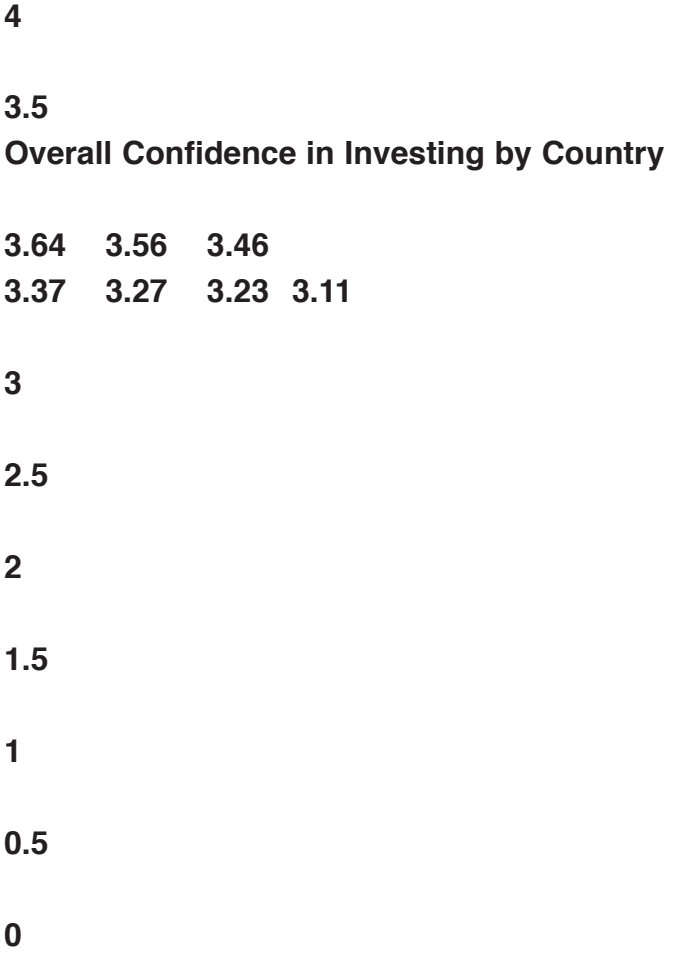
SPOTLIGHT ON VENTURE CAPITAL INVESTMENTS

Venture investments allow small startup life science companies to develop these technologies and commercialize them. The monetary support and expert business councel provided by venture capitals speed the time it takes to move novel medical therapies and technologies from the lab to the patient. Due to the high risk, uncertainty of outcomes, and the long-term nature of life sciences commercialization, venture investment is often the only funding option for these small companies.

A recent survey conducted by Deloitte and the National Venture Capital Association (NVCA) revealed the global and local trends in venture capital. The key finding of the survey was that in today's economic environment, venture capitals are more confident investing domestically than globally. This means that raising venture capital for the medical devices industry in Israel from foreign venture capital funds is more difficult. Having said that, overall, venture capital funds from around the world have high

confidence investing in Israel relatively to other leading economies.



3.08 3.03 2.97 2.91

2.7

2.51 2.34

Note: Confidence levels were measured on a scale of 1 to 5 (5 representing the highest).

Source: Global Trends in Venture Capital, Deloitte and National Venture Capital Association

The chart above demonstrates the confidence that venture capital funds have in investing in Israel over other countries. While the US, Brazil and Ch ina arouse more confidence than Israel, the investors confidence in Israel is larger than their confidence in

strong economies like Germany, the UK and Japan.

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As can be seen in the chart below, the venture capital funds that expressed the highest confidence investing in Israel were Israeli funds (as indicated by the key finding). Following them, high confidence was expressed by Brazilian and Dutch venture capital funds. The confidence expressed by US funds in lower but is still relatively high in

comparison to most other countries.

4.5

4

3.5

3

2.5

2

1.5

1

0.5

0

Confidence in Investing in Israel by Venture Capitals

4.27

Source: Global Trends in Venture Capital, Deloitte and National Venture Capital Association

The sector that enjoys the most confidence of venture capital funds is the cloud computing sector. The medical devices sector is only 6th after such sectors as health IT

and software but before pharmaceuticals.

4.5

4

3.5

3

2.5

2

1.5

1

0.5

0

Confidence in Venture Capital Investing by Sector

3.92 3.8 3.72 3.7

3.4 3.36 3.15 3.08 3.07

2.92

2.52

Source: Global Trends in Venture Capital, Deloitte and National Venture Capital Association

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The chart below indicates that confidence of North American VC funds (US and Canda) is

especially low when it comes to investing in the medical devices sector.

Confidence in VC Investing in the Medical Devices Sector

4

3.5

3.57

3.88

2.4

4 3.8 3.77

3.33

3.61

3.83

3.57

3.29

2.92

2

1.5

1

0.5

0

Source: Global Trends in Venture Capital, Deloitte and National Venture Capital Association

In conclusion, although VC investments in the medical devices sector are not as popular as investments in cloud computing and other computer related sectors, it seems that when investing in medical devices, the Israeli medical devices sector is one of the most

attractive for VC investors.

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INDUSTRY STRUCTURE

The Israeli medical devices industry can be divided into 9 sub-sectors, some very large like the therapeutic devices sector (222 companies) and some small like the robotics sector (11 companies). In addition to these 9 separate sectors, a group of 9 companies, mostly well- established and large companies, are active in more than one sector. These companies were placed in a category of their own in order to prevent a repetition of a company in more than one category. 15 companies are currently operating in stealth mode or have not yet clarified their intentions and were, therefore, not placed in any of the sectors.

The following chapter will analyze each of the sectors and point out important insights on these sub-sectors.

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SECTORS OVERVIEW

The chart below displays the size of each of the sectors in the medical devices industry. As can be seen, the therapeutic devices sector is the largest and constitutes of about a third of the entire industry. The monitoring and diagnostics sector follows with 22% of the industry. Together these 2 sectors amount to over half of the industry. The rest of the sectors are smaller with less than 100 companies, some with even less than 20.

Sectors of the Medical Devices Industry

11 9 3

15

Therapeutic Devices 16

Monitoring & Diagnostics

Implants and Prosthetics Medical Equip-

ment Imaging
Drug Delivery Telemedicine N/A
Robotics

Multi-sector
38

55

68

74,
141
225
Source: Meidata

The following chart compares between the business stages of the medical devices companies by sectors. Note that each sector is of a different size – the larger sectors were placed at the bottom of the chart.

The chart indicates that 2 of the strongest sectors in the Israeli medical devices industry are the imaging and telemedicine sectors. In the telemedicine sector over 50% of the companies are already selling their products and so do 40% of imaging companies. Although in absolute numbers the therapeutic devices sector has the most commercial companies, they stand for less than 35% of the whole sector.

Most of the companies in all sectors are still in seed or R&D stages and naturally, not all companies will manage to market their product and will close without success.

Israel Medical Devices Industry – Market Overview // Aug. 2012
Segmentation of Sectors by Business Stage

Research & Education 1

Multi-sector 2 3

Robotics 0 1 5

Telemedicine 2 6

Drug Delivery 1 12

Imaging 4 16
2

3

5

2 5

18 7

19 10

Medical Equipment 3 21 21
22

Implants & Prosthetics 2 13 26
29

Monitoring & Diagnostics 7 29
50 54

Therapeutic Devices 8 65 78
70

0% 20% 40% 60% 80% 100%

Revenue Growth Initial Revenues R&D
Seed

Note: The chart does not include companies that are based in Israel but are branches of

foreign companies.

Source: Raw data IVC; Meidata analysis

THERAPEUTIC DEVICES

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

225

Cardiovascular Seed: 70 1-5: 128

Dermatology & Aesthetics R&D: 78 6-10: 44

Orthopedics Initial Revenues: 63 11-20: 22

Revenue Growth: 8 21-50: 20

51-100: 6

Over 100: 3

Public Companies

12

Companies Incubated

(Now or in the past)

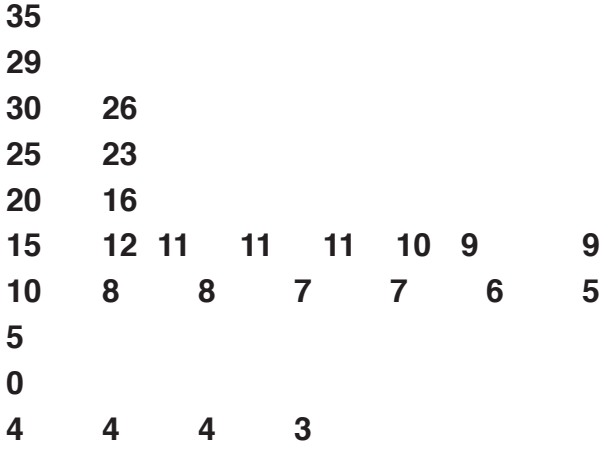
44

- Largest medical devices sub-sector in Israel.
- Israeli aesthetic devices companies among leading aesthetic devices companies in the world.

The therapeutic devices sub-sector is the largest in the medical devices industry in Israel. This sub-sector consists of companies that manufacture medical devices intended for treatment of a disease, pain and injury. This sub-sector also includes companies manufacturing devices for aesthetic treatments.

Note: Implantable medical devices with therapeutic effects are categorized as an independent sector.

Segmentation of Therapeutic Companies by Medical Field



Source: Meidata

As can be seen from the chart above, the local therapeutic devices sector is largely composed of companies in the fields of cardio, dermatology & aesthetics and orthopedics. The fact that cardiovascular diseases receive the most attention from the Israeli therapeutic devices market is not surprising as these diseases are the number one cause of death in the modern world, and are even more common in high-income

countries (WHO).

The global market for aesthetic medical devices is continuing to grow despite the economic slowdown. According to GBI Research, this market was valued at $1.8 billion in

2009 and is estimated to reach $2.9 billion

by 2012 with a CAGR of 7%. Israel is considered to be a dominant country in the global aesthetic devices market with 3 local companies, Lumenis (which also develops products for the ophthalmic and surgical markets), Syneron Medical and Alma Lasers, among the leading aesthetic devices companies in the world.

Company	Estimated Revenues	No. of Employees	Established
Lumenis	$247M (2011)	903	1991
Syneron Medical	$228.3M (2011)	605	2000
Alma Lasers	$100M (2009)	150	2005

Segmentation of Therapeutic Devices Companies by

Number of Employees

21-50	20
51-100	6
-20	22
1-5	Over 100
3	
6-10	44
128	

Source: IVC

A relatively large number of therapeutic devices companies, 32%, are already selling their

products.

Segmentation of Therapeutic Devices Companies by

Business Stage OCTOBER 2013

Revenue Growth	8
Initial Revenues	63
R&D	78
Seed	70

Note: Does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

Therapeutic Devices Companies with revenues of over $10 million

Company	Medical Field	Revenues	No. of Employees	Established	Ownership
Dermatology					
Estimated					
Alma Lasers & Aesthetics		$100m	150	2005	Private
AngioScore	Cardiovascular	N/A	30	2003	Private
Galil Medical	Urology	N/A	97	1997	Private

Home Dermatology
$40m 40 2006 Private
Skinovations & Aesthetics
Impulse
Cardiovascular N/A 60 1996 Private
Dynamics
Lumenis Multi-field $247m 903 1991 Private
Medispec Multi-field N/A 70 1991 Private
Syneron Dermatology
$228.3m 605 2000 Public(NASDAQ)
Medical & Aesthetics

Note: Companies are listed in alphabetical order.

As can be noticed from the table above, the medical fields of cardiology and aesthetics

are also dominant among the leading therapeutic devices companies.

Incubation of Therapeutic Devices Companies

Incubated in the
Past
48
Incubated
40
Never Incubated
137
Source: IVC

MONITORING & DIAGNOSTICS

At a Glance

No. of Companies
Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

141 OCTOBER 2013
General Health Seed: 54 1-5: 78

Cardiovascular R&D: 50 6-10: 24

Orthopedics Initial Revenues: 29
11-20: 18

Revenue Growth: 7 21-50: 17

51-100: 2

Over 100: 3
Public Companies

10

Companies Incubated
(Now or in the past)

44

- Almost 75% of monitoring & diagnostics companies are still in the Seed and R&D stages.

The Monitoring & Diagnostics sub-sector is the second largest in the Israeli medical devices industry with 141 companies. The rational for the basis of this sub-sector is as follows: Usually a doctor cannot diagnose a disease or a medical condition without the aid of a device. These diagnostic devices range from simple stethoscopes to complex invasive biopsy devices. The great majority of these devices can monitor a patient's condition in addition to assisting the doctor in the diagnosis and hence monitoring and

diagnostics constitute a single sub-sector.

Segmentation of Monitoring & Diagnostics Companies by Medical

Field

20 19 18 17

18

16

14

12

10

8

6

4

2

0

11 11 10 9 9

6 6 5 5 5 4

2 1 1 1 1

Source: Meidata

19 companies develop devices for the general health field. These companies usually offer better solutions for the examination of basic body functions like blood pressure, heart rate and body temperature. It is important to note that these devices can usual ly be used in other fields as well. Cardiac monitoring & diagnostics companies are also dominant in

this sector due to the prevalence of cardiac diseases.

Segmentation of Monitoring & Diagnostics by Number of Employees

50-100

2

Over 100

3

21-50

17

11-20

6-10

24

1-5

78

Source: IVC

55% of the companies employ five or less workers (similar to the industry average) and the number of companies with over 50 employees is small relatively to the sector's size. Only 2 companies (1%) employ between 50 and 100 workers while 3 companies (2%)

employ over 100.

Segmentation of Monitoring & Diagnostics Companies by

Business Stage

Revenue

Growth

7

Initial

Revenu s

29

Seed

R&D

50

Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

Almost 75% of monitoring & diagnostics companies are still in the Seed and R&D stages.

Incubation of Monitoring & Diagnostics Companies

Incubated Today (21, 15%)

Incubated the Past (23, 16%)

Never Incubated (97, 69%)

Source: IVC

Only 31% percent of the companies, 44 companies, have been incubated, a relative low number compared to the industry as a whole and to other sub-sectors.

One of the promising monitoring and diagnostics companies is Itamar Medical which develops and sells a non-invasive monitoring and diagnostic tool of the cardiovascular system. The company,

founded in 1997, is a public company (TASE) with revenues of 46 million shekels in 2011.

IMPLANTS & PROSTHETICS

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

74

Cardiovascular Seed: 29 1-5: 45

Orthopedics R&D: 26 6-10: 12

Oral & Dental Initial Revenues: 13
11-20: 7

Revenue Growth: 2 21-50: 5

51-100: 2

Over 100: 3

Public Companies

2

Companies Incubated OCTOBER 2013
(Now or in the past)

28

- Only 2 implants & prosthetic companies have annual sales of over $10 million.
- Of the 4 largest companies, 3 develop dental implants.

The devices in this sub-sector are devices which are implanted in the body or attached to the body for medical reasons, and which are intended to remain in the body after the procedure . Medical implantable devices may be divided into 2 main groups:

Segmentation of Implants & Prosthetics Devices by Medical Field

16 15

14

12

10

8

6

4

2

0

12 12

8

7

4

3 3
2 2

1 1 1 1 1 1

Source: Meidata

In the global market for implantable and prosthetic devices, the most common devices are intended for the fields of Cardiology and Orthopedics. Accordingly, of the 72 implantable devices companies active in Israel, 27 companies (over 33%) develop products

for these medical fields, as can be seen in the chart above.

Segmentation of Implants & Prosthesis Companies by Number

of Employees

51-100
2

Over 100
3

21-50
5

11-20
7

6-10
12

1-5
45

Source: IVC

Over 75% of the companies are based on 10 workers or less, the majority of which – 61% of the companies - with 5 workers or less. Of the 4 largest implants & prostherics companies, 3 develop dental implants.

Dominant Implants & Prosthetics Companies Active in Israel

	Year of Establishment	No. of Employees	Product Notes
Medinol	1992	200	Stents
MIS	1998	200	Dental implants
Foreign R&D Center			
Alpha Bio	2008	125	Dental implants
AB Dental Devices	1990	100	Dental implants
Medtronic Foreign R&D Center			
Ventor Technologies	2009	55	Heart valve

Segmentation of Implants & Prosthesis Companies by Business

Stage

Revenue

Growth
2

Initial
Revenues
13

Seed
29

R&D
26

Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

Of the companies not owned by foreign conglomerates, only 2 have revenues of over $10 million – Medinol and MIS. 13 additional companies sell their products with revenues under $10 million, while the rest of the companies, 55 (78%), are still in the seed and R&D

stages.

Incubation of Implants & Prosthetics Companies

Incubated in the Past

13

Incubated

15

Never

Incubated

46

Source: IVC

38% of the companies (28 companies) have been incubated, similarly to the numbers representing the industry as a whole.

MEDICAL EQUIPMENT

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

68

Surgery Seed: 22 1-5: 41

General Health R&D: 21 6-10: 12

Cardiovascular Initial Revenues: 22 11-20: 10

Revenue Growth: 3 21-50: 3

51-100: 2

Over 100: 1 OCTOBER 2013

Public Companies

2

Companies Incubated

(Now or in the past)

37

 Large number of commercial stage companies.

The medical equipment sub-sector is composed of devices that aid the doctor in treatment or diagnosis but do not themselves treat or diagnose the patient. Examples for such devices are sutures, surgical blades, catheters, surgical drillers and other devices that guide the doctor through a procedure. The sub-sector medical equipment will also include rehabilitation devices that do not treat a medical condition or a disability but assist in managing it like wheelchairs, hearing aides and eyeglasses.

16 15

14

12

10

Segmentation of Medical Equipment Companies by Medical Field

9

8

8 6 6

6 4

4 3 3

2

0

2 2 2 2 2 2

1 1 1

Source: Meidata

15 companies develop devices intended for surgical procedures.

Segmentation of Medical Equipment Companies by

Number of Employees

51-100

2

Over 100

1

21-50

3

11-

10

6-10

12

1-5

41

Source: IVC

Only 1 company, Shamir Optical Industry, employs over 100 workers. Shamir Optical Industry is actually the largest medical devices company in Israel. The company which produces eyeglasses and other optimetrical products employs 1400 workers. According to IVC, the company's annual sales for 2010 were estimated at $156 miliion. Shamir, which was once traded on NASDAQ and TASE is now a private company.

Segmentation of Medical Equipment Companies by Business

Stage

Revenue

Growth

3

R&D

21

Initial

Revenues

22

Seed

22

Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

The medical equipment sub-sector is the only sub-sector in which the number of commercial stage companies (intial revenues and revenue growth) is bigger than the number of seed stage companies. 25 companies (37%) are already selling their product while 22 companies (32%) are still in the seed stage. This points to the advanced state of

this sub-sector.

Incubation of Medical Equipment Companies

Incubated

18

Never

Incubated

31

Incubated in the Past

19

Source: IVC

54% of medical equipment companies, 30 companies, have been incubated. This percentage is relatively high to the industry as a whole where the percentage of

companies incubated is only 37%.

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IMAGING

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

55

General Health Seed: 10 1-5: 21

Multi-field R&D: 19 6-10: 9

Oncology Initial Revenues: 16 11-20: 7

Revenue Growth: 4 21-50: 10

51-100: 3

Over 100: 6

Public Companies

3

Companies Incubated

(Now or in the past)

12

- **Strongest Israeli medical devices sub-sector.**
- **Given Imaging among global imaging leading companies.**

Medical imaging is the technique and process used to create images of the human body for clinical purposes or for scientific research. Many times imaging technologies are used in order to diagnose or monitor a medical condition, but they are also used for trea tment, for example, by guiding a surgeon through a procedure. Different imaging technologies

exist, each giving different information about the area of the body being studied or treated.

The role of imaging in medical diagnosis and treatment has expanded considerably but the revoloution in imaging is only at its beginning. Imaging will enable therapies to be tailored to the needs of individual patients and to be more accurately targeted. In consequence, less-invasive procedures can be used for more effective care, with fewer side effects, shorter hospitalization, and reduced morbidity.

Trends in Imaging Technologies and Israeli Companies Leading These Trends

56 medical imaging companies are active today in Israel. The biggest of those companies, and arguably the most famous Israeli medical devices company is Given Imaging (760 employees). Given Imaging developed the PillCam, the first capsule endoscopy. The PillCam is a miniature ingested camera which diagnoses and photographs abnormalities in the gastrointestinal tract. The company's annual sales for 2011 are estimated at $178 million. Given Imaging is the only Israeli medical devices companies traded both on TASE and on NASDAQ.

Following Given Imaging, the the 3 biggest imaging companies in Israel are all foreign R&D companies of multi-national conglomerates (GE Healthcare Israel, Philips Medical Technilogies & Sanmina). The fact that, overall, 7 multinational conglomerates purchased Israeli imaging companies and decided to keep an R&D center in Israel, points to the

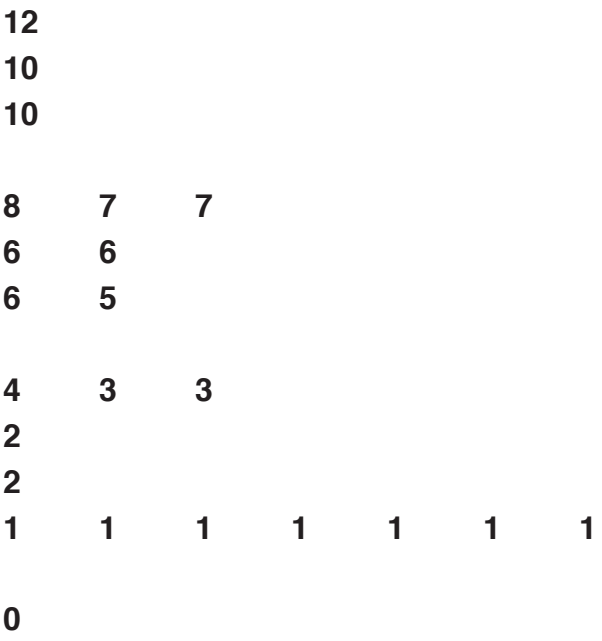
dominance of Israel in this sub-sector of medical devices.

Israel Medical Devices Industry – Market

Over all, the imaging sub-sector seems to be the strongest in the Israeli medical devices industry. The dominance of this sub-sector emerged back in the 1990s with 2 exceptionally succesful Israeli imaging companies – Elscint and Elbit's spin-off Elbit Imaging. After great commercial success, in 2000, the companies sold their imaging activities to GE Healthcare and to Picker (now Philips Medical Systems) for approxiamtely

$600m.

Segmentation of Imaging Companies by Medical Field



Source: Meidata

Most imaging devices are not restricted for use on a certain body part or for a certain medical condition and therefore, it's not surprising that many Israeli companies develop devices that can be used accross many medical fields or for general health purposes.

Israel Medical Devices Industry – Market

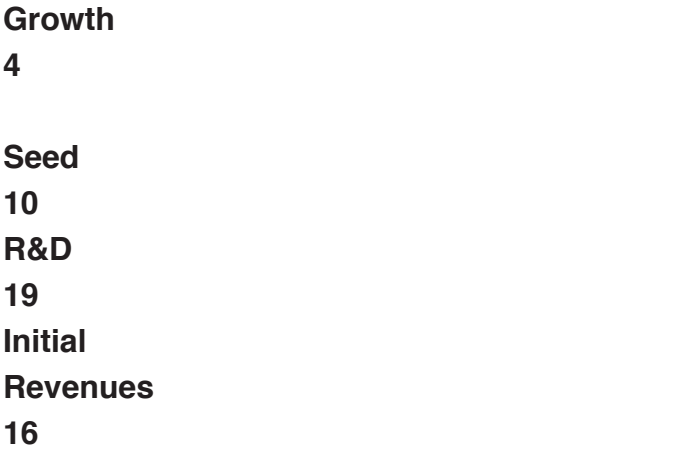
Segmentation of Imaging Companies by Number of Employees

Source: IVC

The imaging companies tend to be bigger than the average in the medical devices industry in Israel. Over 10% of the companies have over 100 employees (in contrast to 3% in the entire industry) and the number of companies with 5 or less employees is

exceptionally small (38% in contrast to the industry's 56%).

Segmentation of Imaging Companies by Business Stage



Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

The imaging companies also tend to be more established. Only 20% of the companies are at the seed stage while over 40% of the companies are already selling their products.

Incubation of Imaging Companies

Incubated in the Past (6, 11%)

Incubated

(6, 11%)

Never Incubated (44, 78%)

Source: IVC

The imaging sub-sector also stands out in the analyses of the incubation of the companies. A very small number of imaging companies, fewer 25% have been incubated. Moreover, none of the dominant companies in this sub-sector mentioned above have been incubated and their success was achieved outside of the incubators program.

DRUG DELIVERY

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

38

Diabetes & Obesity Seed: 7 1-5: 23

General Health R&D: 18 6-10: 6

Respiratory Initial Revenues 11-20: 7

Revenue Growth: 1 21-50: 1

51-100: 1

Over 100: 0

Public Companies

2

Companies Incubated

(Now or in the past)

17

 Drug delivery companies are especially small compared to the entire industry.

Many methods exist for the delivering of a drug into the human body. The most common are through the mouth by swallowing a pill or through the skin by applying an ointment.

Other conventional drug delivery methods are by an injection, by an inhaler and wit h eye drops. Yet all the above forms have their limitations:

Medical devices companies specializing in drug delivery aim to overcome these limitations by inventing devices that allow safe, controlled and targeted drug delivery.

As of July 2012, there are 38 drug delivery companies active in Israel, producing a large variety of products with applications in a wide range of medical fields

Segmentation of Drug Delivery Companies by Medical Field

Note: The chart does not include companies that haven't revealed the nature of their product.

Source: Meidata

The leading medical fields in which Israeli drug delivery companies specialize in are diabetes & obesity, general health and respiratory. In the 21st century, more people than ever are diagnosed with diabetes and according to WHO (World Health Organization), diabetes deaths will double between 2005 and 2030. Many of the diabetes patients require innovative drug delivery solutions to replace the traditional and painful daily injections of insulin. One of the most promising Israeli drug delivery companies is Insuline Medical, a public company traded on TASE. Insuline Medical is one of the 5 Israeli companies focused on finding drug delivery solutions for diabetic patients in need of insulin. Insuline is not yet commercial but is nearing FDA approval for one of her

products, the Insupatch.

Israel Medical Devices Industry – Market Overview // Aug. 2012

Segmentation of Drug Delivery Companies by Number of

Employees

Source: IVC

Like most of the industry, most of the drug delivery companies are very small. The percentage of very small companies (1-5 employees) is especially big – 61%. Only one

company employs over 100 workers.

Segmentation of Drug Delivery Companies by Business Stage

Revenue

Growth

1

Seed

7

R&D

18

Initial Revenues

12

Source: IVC

The chart above shows that 65% of the drug delivery companies are still in the seed and R&D stages. Of the 13 companies (35%) that are already selling their products, only one (Caesarea Medical Electronics) is in the revenue growth stage with annual sales of over

$10 million dollars.

Israel Medical Devices Industry – Market Overview // Aug. 2012

Incubation of Drug Delivery Companies

Currently

Incubated

2

Incubated the Past

15

Never

Incubated

21

Source: IVC

15 drug delivery companies have been incubated in the past and another 2 are currently incubated.

TELEMEDICINE

At a Glance

No. of Companies

Dominant Medical Fields Companies

by No. of Employees

Business Stage per Company
16
General Health Seed: 2 1-5: 5

R&D: 6 6-10: 0

Initial Revenues: 5 11-20: 5

Revenue Growth: 2 21-50: 3

51-100: 1

Over 100: 2
Public Companies

2

Companies Incubated
(Now or in the past)

0
2 □ of the dominant telemedicine companies are traded on SIX (Swiss
Exchange).

Telemedicine is the use of telecommunications for medical diagnosis and patient care. This practice includes transmission of test results through phone lines, video consultations, transmission of radiological images and more. Telemedicine may be as simple as two doctors discussing a case over the phone, or as complex as using satellite technology and video conferencing technology to conduct a real time consultation between specialist in different countries.

Why Telemedicine?

Segmentation of Telemedicine companies by Medical Field

General Health Cardiology & Cardiovascular

Multi-field Other Pediatrics

Source: Meidata

Currently 16 telemedicine companies are active in Israel, most of them developing products for the general health market. These companies aim at a future when visits to one's family physician will decrease significantly due to advanced communication technologies between doctor and patient and through remote monitoring of basic bodily

functions (temperature, heart rate, blood pressure etc.).

Segmentation of Telemedicine Companies by Number of

Employees

Over 100
2
50-100
1

21-50
3

-20
5

1-5
5

Source: IVC

Although the telemedicine sub-sector

consists of only 16 companies, 2 of those companies are fairly big. Both companies, LifeWatch AG and SHL Telemedicine, are public companies traded on the Swiss Exchange (SIX) and according to IVC, both have revenues of over $10 million annually.

LifeWatch AG provides remote monitoring services for high-risk and chronically ill patients. LifeWatch AG employs 510 people in Israel and

has branches in Switzerland, Hong-Kong, Brazil, Japan the US and UK.

SHL Telemedicine developed a remote monitoring device of ECG that can be monitored from any place in the world. The patient's medical data is transmitted to SHL's medical monitoring center, where it is analyzed in

order to provide the patient with speedy response. The company employs 383 people.

The 2 companies, in this sector, that are showing revenue growth (sales of over $10 million annually) are the 2 mentioned above. An additional 6 companies are also selling their product already but with revenues of under $10 million. Only 2 telemedicine companies are in the seed stage.

Segmentation of Telemedicine Companies by Business Stage

Revenue

Growth

2

Seed

2

Initial

Revenues

6

R&D

5

Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

None of the telemdicine companies are incubated or have been incubated in the past.

ROBOTICS

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage per Company

11

Rehabilitation Seed: 5 1-5: 6

Diagnostics R&D: 5 6-10: 3

Surgery Initial Revenues: 1 11-20: 2

Revenue Growth: 21-50: 0

51-100: 0

Over 100: 0

Public Companies

1

Companies Incubated

(Now or in the past)

8

 A young sub-sector – first robotics company established in 2001.

8 of the 11 companies are incubated or had been in the past.

In general, the robotics sector is a fairly new addition to the medical devices industry in the world and in Israel, in particular.

While the first medical robot was designed in the

1980's, the first Israeli medical robotics company, Mazor Robotics, was established only in

2001. Robots today are performing a large variety of medical procedures and functions which can be categorized into 3 main fields:

The Israeli robotic sector, which consists of 11 companies, engages in all of the 3 fields

mentioned above.

Segmentation of Robotics Companies by Medical Field

Surgery

2

Rehbilitation

5

Diagnostics

3

Source: Meidata

Along with the many advantages that robotic systems provide for the medical world, there are some disadvantages as well. But medical robotics is still in its infancy and many of the problems may be solved in the future.

The most dominant company in the robotics sub-sector is Mazor Robotics who, aside from being the oldest company, is the only company to be showing revenues. Mazor is also the largest robotics company with 45 employees and the only one who is publicly traded (TASE). The company's flagship, the Rennaissance surgical guiding system, is already being marketed for spinal surgery and was recently approved by the FDA for brain biopsies.

Segmentation of Robotics Companies by Source: IVC

Segmentation of Robotics Companies by Business Stage

Initial Revenue

1

Seed

5

R&D

5

Source: IVC

Of the 11 robotics companies only one, Mazor Robotics, has started to sell their product.

The rest of the companies are still in the developing stages.

Israel Medical Devices Industry – Market Overview // Aug. 2012

Incubation of Robotics Companies

Never

Incubated

3

Incubated

Incubated in the Past

4

Source: IVC

8 of the 11 robotics companies have passed through technological incubators. 4 of them are currentlly incubated. Relatively to the

sub-sectors' size, the number of companies incubated is very large and seems to indicate the attraction of the incubators' owners to this sub-sector and also the attraction of robotics companies to the many advantages of the incubators.

RESEARCH & EDUCATION

Only 3 Israeli companies specialize in medical devices for research or education. Naturally, devices developed by companies from other sub-sectors may be also used for research and educational purposes but these 3 companies focus on the benefits of their devices for research and education and not for treatment of patients. As this sector is so small, the 3 companies will be presented a table without charts.

Company	Established	Business Stage	No. of Employees	Medical Field
Simbionix	1997	Revenue Growth ($15m)	100	Cardiovascular
NAN	2003	Seed	3	Electrode Positioning Instruments
Semantic Medical	2010	Seed	6	General Health Simulations

MULTI-SECTOR COMPANIES

At a Glance

No. of Companies

Dominant Medical Fields Companies by No. of Employees

Business Stage	per Company
Multi-field	9
Seed: 3	1-5: 2
R&D: 0	6-10: 4
Initial Revenues: 3	11-20: 0
Revenue Growth: 2	21-50: 1
51-100: 1	
Over 100: 1	
Public Companies	
1	
Companies Incubated (Now or in the past)	
1	

- Elcam stands out among Multi-sector companies with 220 employees and estimated revenues of $90m in 2010.

The last sub-sector of medical devices is based on multi-sector companies. These are companies that specialize in more than one of the 9 sectors reviewed above.

Segmentation of Multi-sector Companies by Medical Field

Multi-field	Cardiology & Cardiovascular
Brain Surgery	General Surgery
Other	

Source: Meidata

Not suprisingly, companies who specialize in more than one sub sector also specialize in more than one medical field. Therefore, 5

out of 10 of the multi sector companies are multi field companies that develop solutions in more than one medical field.

Segmentation of Multi-sector

Companies by Business Stage

Segmentation of Multi-sector

Companies by Number of Employees

Revenue

Note: The chart does not include companies that are based in Israel but are branches of foreign companies.

Source: IVC

The bigger multi-sector companies are also those showing revenues. The biggest company is Elcam which employs 220 people. Elcams specializes in therapeutic devices, monitoring devices and drug delivery devices. Elcam is also one of 2 Multi-sector

companies showing revenue growth with estimated revenues of $90 million in 2010.

Incubation of Multi-sector Companies

Incubated

2

Never

Incubated

8

Source: IVC

2 multi-sector companies are currently incubated.

R&D TRENDS IN THE ISRAELI MEDICAL DEVICES

INDUSTRY

The most dominant R&D trends in the Israeli medical devices industry originate from 3 main factors that are shaping the future of the global industry:

1. Economic climate – The global economic future does not seem promising and there is a great demand for cheaper and more effective devices and for devices that will lower costs for the healthcare system.

2. Rise in life expectancy – The developed world is enjoying a steady rise in life expectancy and the population of adults aging over 65 is growing rapidly. This rise increases the health expenses for both individuals and governments. Governments, insurance agencies and hospitals are looking for innovative solutions that will help contain the expected increase in healthcare expenses.

3. Emerging markets – Markets in developing country are starting to show interest in innovative medical technologies and demand for medical devices in countries like India, China and some African countries is on the rise. These countries require effective but inexpensive devices.

The Israeli medical devices industry is well aware of these factors and R&D trends are guided by them. In the following pages these trends will be described and examples of

companies practicing these trends will be given.

R&D TRENDS

Possible Cut in R&D expenses

The economic climate expanded on previously is likely to affect R&D expenses in the medical devices industry. In the US experts estimate that the upcoming medical devices tax (see p. 25) will cut R&D investments by $2 billion per a year. We do not have data as to how the economy will affect R&D investments in Israeli medical devices companies in the future but if the ongoing cut in the Chief Scientist's R&D budget (see p. 14) is any indication, we may expect

Lowering the cost of devices and procedures

One of the common trends across all medical devices sub-sectors is their effort to lower the prices of their devices and to offer devices that will lower the overall health expenses. Medical devices companies are designing devices that achieve their intended purpose in a shorter amount of time and are trying to invent products that will cut down procedure and recovery time.

Examples:

Circ MedTech, established in 2009, develops affordable public healthcare solutions. The company's flagship product, PrePex, is a safe non- surgical adult male circumcision devices. Today, adult circumcisions require a sanitized environment and a trained doctor. The procedures are costly and require recovery time. In 2007 the connection

between circumcision and the prevention of AIDS was proved by WHO and UNAIDS. Circ MedTech tool it upon themselves to invent a device that will be cheap and enable fast and safe circumcision of millions of adult African man. The device was engineered so that a nurse could perform the procedure as there are not many doctors in African countries. The procedure does not require anasthesia, sutures or a sanitzed environment.

The product is already FDA and CE approved and costs only $20 per device. Currently PrePex is most active in Rowanda and over 4000 men have already been circumcised succesfully. By June 2013 the government hopes that half a million more men will undergo the procedure.

Circ MedTech is in the process of developing to more products that will enable safe medical procedure by a minimally trained staff.

IceCure Medical developed a fast and minimaly invasive procedure for the treatment of benign breast tumors. Cryoablation, a process which uses extreme cold to freeze and destroy diseased tissue, has been used by medical

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experts for years to treat both malignant and benign tumors, mostly in the kidneys and prostate. IceCure Medical has taken the technology into the field of breast tumors. Their system, called IceSense3, has been specifically developed to treat fibroadenomas, which are the most common type of benign breast tumors, typically seen in young women aged

15 to 30.

The system is currently being used worldwide for treatment of the benign lumps, but now also holds promise as a potential treatment option for malignant breast tumors,

after a successful clinical trial on four women in Japan.

These devices save costs for the system by shortening the procedure and recovery time. Because the procedure is so minimally invasive it also prevents the need for aesthetic breast reconscruction surgery or the treatment of scars.

Home monitoring devices and telemedicine

Another way to reduce healthcare cost is to transfer medical activities from the doctor's office to the patient's home. Many medical devices companies develop monitoring products for home use. Today, patients can monitor their health at home: from simple blood pressure and heart rate tests to more complex glucose monitoring and ECG devices. Besides the obvious way that these devices save money for the

health system (less doctor visits, less hospital beds taken) they also help save money indirectly by contributing to preventative medicine. One of the most effective ways to lower healthcare costs is by preventing diseases all together or by preventing the worsening of existing medical conditions. Once a person is taught how to monitor himself he will be able to monitor himself daily and detect problems that call for a visit to the doctor.

Telemedicine has a big role in the succes of home monitoring devices as a medical personell is usually required to study the patients monitoring results. Much of the analysis of the patient's monitoring data is performed by computers who alert the patient and his care givers if a suspicious result has come up.

Example:

Itamar Medical is one of the most succesful medical devices companies traded on TASE. The company developed the WatchPAT, a sleep related breathing

disorders diagnostic device. The device (approved by the FDA) monitors a person's breathing while he is sleeping peacefully in his home. The WatchPAT technology was selected to "The Top 10 Medical Innovations for 2010" at the annual Cleveland Clinic Medical Innovation Summit.

As can be seen in photo above, the device is worn on a patient's wrist while the signals are measured through a non-invasive fingermounted probe. The company's PAT (peripheral arterial tone) unique technology can measure levels of oxygen in the blood and identify sleep apnea events through the finger.

Robotics

Robots can have a great contribution to medicine and already medical procedures around the world are performed with the help of robots. In the past decade 11 robotics companies were established in Israel and more are expected to be established in the future. One of the world leaders in medical robotics, Moshe Shoham, is an Israeli who developed one of the robotic technologies used by the succesful Mazor Robotics. Shoham is currently developing more medical robots: a robot that can "crawl" inside the human body to perform endoscopic surgery; and the tiny Virob robot which can bring a cancer drug directly to a tumor or can be outfitted with a camera for inside -the-body diagnostic purposes.

Robots reduce procedure time and beacause they enable especially minimally invasive procedures they also reduce recovery time. Medical robots also have a great contribution to preventitive medicine as they can reach places in the human body that other wise cannot be reached.

Example:

Mazor Robotics is a world leader in robotic surgeries and offers the only robotic spinal surgery available in the world today. Mazor Robotics' flagship product, Renaissance, is a state-of-the-art surgical robotic system that enables surgeons to conduct spine surgeries in an accurate and

secure manner. Mazor Robotics systems have been successfully used in the placement of over 15,000 implants in the United States and Europe. Additionaly, the Rennaisance has

been recently approved by the FDA for brain sugery.

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SUMMARY

In 2011 the value of the global medical devices market was estimated at $322 billion and the Israeli domestic medical devices market was estimated at $913 million. The last figure represents the value of medical devices purchased in Israel (from both Israeli and foreign companies) during 2011, and represents a growth rate of 3.7% compared to the previous year. According to Espicom Business Intelligence forecast the Israeli market will be valued at $1.096 billion in 2016, an increase of 20% in comparison to 2011.

After a sharp drop in exports following the economic downturn in 2008, exports of medical devices has been steadily growing during the last years. In 2011 Israel exported over $1.6 billion worth of medical devices mainly to the US, Japan, China and Europe.

Israel is considered a leading country in the field of medical devices. The total number of granted patents in the medical devices field positions Israel in first place in patents per capita and in the fourth place in absolute number of patents. As of August 2012, 1,086 life science companies are active in Israel. Over half of these companies, 656 companies, are medical device companies. Many of these companies – over 200 – are already marketing their products throughout the world. Over 50% of the companies are based on 5 employees or less, while only 19 companies, 3%, have over 100 employees. Over 65 % of the companies have not yet reached the commercial stage and are still in the seed or R&D stages of development. Of the 195 companies that are already selling their products only

30 have been showing revenues of over $10 million dollars.

The Israeli medical devices industry can be divided into 9 sub-sectors, some very large like the therapeutic devices sub-sector (222 companies) and some small like the robotics sub- sector (11 companies). The imaging sub-sector stands out as the strongest sector in terms of success of companies (7 of which had been acquired by multinational companies) and the number of advanced stages companies.

Of the $385 million raised by the life science industry in 2011, the medical devices indus try raised $218 million, over 55% of the amount raised by the entire life sciences industry, and

10% of total capital raised by all sectors. Although the investment in the life sciences industry in 2011 was larger than that of 2010, it represents a drop from 28% of overall

investments in hi-tech in 2010 to only 18% of overall investments in 2011.

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The demand for medical devices is growing rapidly as the world population continues to age and developing countries are becoming more and more interested in moder n medicine. However, this rise in demand comes at a time when individuals, governments and insurance companies are trying to cut their investments in health due to the economic recession and the uncertain future. In order to succeed, medical devices companies have to face more challenges than ever, from the early funding stages through the regulatory process to the marketing stage.

Most of the Israeli medical devices companies are still in the early stages of development and their success depend greatly on

future of investments in this sector. Medical devices companies are considered high risk investments (in contrast with investments in the internet sector, for example) and investors are shifting some of their investments to more advanced companies at the expense of early stages companies.

Even when reaching the marketing stage, companies need to work harder than before to prove their product is effective, and they have to convince skeptical potential buyers that they should spend their dwindling amount of money on a new device.

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ABOUT MEIDATA

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