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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.
KEY FINDINGS

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.

In 2011 Israeli medical devices companies 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 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.

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.

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.
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 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.

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.

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

![Value of the Medical Devices Global Market (2009-2011)](image)

*Source: Kalorama Information estimates*

### 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 21st 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.
Mile Stones

1962  
**Mego Afek AC**, the first medical devices company in Israel, was established.

1972  
First Israeli IPO (initial public offering) on NASDAQ. **Elscent**, a medical devices company specializing in imaging technology, was the first Israeli company traded on NASDAQ.

1997  
**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.

1998  
**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, **Elscent**’s NM and MRI divisions and **Versamed**.

2004 MAR  
**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.

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

Source: IVC Research Center
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.

<table>
<thead>
<tr>
<th>Industry</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td>60%</td>
</tr>
<tr>
<td>Pharmaceuticals &amp; Biotechnology</td>
<td>23%</td>
</tr>
<tr>
<td>Healthcare IT</td>
<td>8%</td>
</tr>
<tr>
<td>Biologicls</td>
<td>3%</td>
</tr>
<tr>
<td>Agrobiotech</td>
<td>2%</td>
</tr>
<tr>
<td>Industrial</td>
<td>3%</td>
</tr>
<tr>
<td>Bioinformatics</td>
<td>1%</td>
</tr>
</tbody>
</table>

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 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.

![Number of Employees in Israeli Medical Devices Companies](image)

**Business Stages**

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

- **Seed**
  - A startup company, which is in its early days of product development and fund raising.

- **R&D**
  - A company that has past the seed stage but is still developing its product/s or is in the process of applying for marketing permission.

- **Initial Revenues**
  - A company whose yearly revenues do not exceed $10 million dollars
  - These companies may still be developing new products or improving existing products.

- **Revenue Growth**
  - A company whose yearly revenues exceed $10 million dollars.
  - These companies may still be developing new products or improving existing products.
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](image)

**Source:** IVC
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.

Medical Device Market Domestic Value (2011)

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Value (US$ Millions)</td>
<td>$913M</td>
</tr>
<tr>
<td>Growth rate (%)</td>
<td>3.7%</td>
</tr>
<tr>
<td>As % of Total Health Expenditure</td>
<td>4.8%</td>
</tr>
<tr>
<td>As % of World Market</td>
<td>0.3%</td>
</tr>
<tr>
<td>Supplied by Imports (%)</td>
<td>78.8%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Market (US$ millions)</td>
<td>922.2</td>
<td>957.4</td>
<td>1,016.3</td>
<td>1,080.1</td>
<td>1,096.8</td>
</tr>
<tr>
<td>Growth (%)</td>
<td>1.05</td>
<td>3.82</td>
<td>6.15</td>
<td>6.28</td>
<td>1.55</td>
</tr>
<tr>
<td>As % of health expenditure</td>
<td>4.7</td>
<td>4.7</td>
<td>4.6</td>
<td>4.5</td>
<td>4.3</td>
</tr>
</tbody>
</table>

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.

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![Graph](image.png)

*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.
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.
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 itself. 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.

![Segmentation of Chief Scientist Grants by Technological Sectors (2011)](image)

Source: The Office of the Chief Scientist
SWOT Analysis - Israeli Medical Devices Industry

Strengths
- Professional inter-disciplinarity: High expertise in the many fields relevant for medical devices (medicine, electronics, software)
- Highest patent ratio per capita in the world in the field of medical devices
- High flexibility of the industry enables it to accommodate changes
- Strong imaging sub-sector

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

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) expected to invest large amounts in medical devices companies

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
government grants and angel investors. 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.

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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 access 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 responsible 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).
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 Regulatory Process**

- **Device Classification**
  - **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 breast implants, pacemakers. PMA approval.
  - Certain dental implants, metal-on-metal hip joints. 510(k) clearance.

Source: Congressional Research Service
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 lengthy 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 drags on for 27.1 months (over 2 years).

**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:

**Average 510(k) Clearance Times (months)**

<table>
<thead>
<tr>
<th>Year</th>
<th>510(k) Clearance Times (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-07</td>
<td>3.1</td>
</tr>
<tr>
<td>2010</td>
<td>4.5</td>
</tr>
</tbody>
</table>

**Average PMA Approval Times (months)**

<table>
<thead>
<tr>
<th>Year</th>
<th>PMA Approval Times (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-07</td>
<td>15.5</td>
</tr>
<tr>
<td>2010</td>
<td>27.1</td>
</tr>
</tbody>
</table>

**Source:** Ernst & Young, Pulse of the Industry

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*Meidata*

Competitive Intelligence

Israel Medical Devices Industry – Market Overview // Aug. 2012 // 22
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.

<table>
<thead>
<tr>
<th>Device Classification</th>
<th>Description</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low risk; mostly non-invasive</td>
<td>Self certified by the manufacturer</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Medium risk; invasive</td>
<td>Assessed quality systems</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Medium risk; partially or completely implanted</td>
<td>third-party assessed quality systems</td>
</tr>
<tr>
<td>Class III</td>
<td>High risk</td>
<td>Clinical trials, product certification, assessed quality system.</td>
</tr>
</tbody>
</table>

*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 Israeli 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 Australia.
THE ECONOMIC CLIMATE

Medical devices companies are facing an unfriendly financial environment since the beginning of the global economic crisis 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 today's 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 premisions, hospitals and doctors wish to see proof of the superiority 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.
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 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 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 from the 2008 financial downturn 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.

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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.
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 billion). Since the beginning of the financial crisis, the share of funds raised by these companies has steadily increased, to reach a high of 73% in 2010.
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.
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 counsel 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.

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 China arouse more confidence than Israel, the investors confidence in Israel is larger than their confidence in strong economies like Germany, the UK and Japan.
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 is lower but is still relatively high in comparison to most other countries.

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.
The chart below indicates that confidence of North American VC funds (US and Canada) is especially low when it comes to investing in the medical devices sector.

Confidence in VC Investing in the Medical Devices Sector

<table>
<thead>
<tr>
<th>Country</th>
<th>Confidence Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>3.57</td>
</tr>
<tr>
<td>Brazil</td>
<td>3.88</td>
</tr>
<tr>
<td>Canada</td>
<td>3.4</td>
</tr>
<tr>
<td>China</td>
<td>4</td>
</tr>
<tr>
<td>Germany</td>
<td>3.8</td>
</tr>
<tr>
<td>India</td>
<td>3.77</td>
</tr>
<tr>
<td>Israel</td>
<td>3.33</td>
</tr>
<tr>
<td>Japan</td>
<td>3.61</td>
</tr>
<tr>
<td>Netherlands</td>
<td>3.83</td>
</tr>
<tr>
<td>Taiwan</td>
<td>3.57</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>3.29</td>
</tr>
<tr>
<td>United States</td>
<td>2.92</td>
</tr>
</tbody>
</table>

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.
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.
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.

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.
### Segmentation of Sectors by Business Stage

<table>
<thead>
<tr>
<th>Sector</th>
<th>Revenue Growth</th>
<th>Initial Revenues</th>
<th>R&amp;D</th>
<th>Seed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research &amp; Education</td>
<td>1</td>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Multi-sector</td>
<td>2</td>
<td>3</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Robotics</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Telemedicine</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Drug Delivery</td>
<td>1</td>
<td>12</td>
<td>18</td>
<td>7</td>
</tr>
<tr>
<td>Imaging</td>
<td>4</td>
<td>16</td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td>Medical Equipment</td>
<td>3</td>
<td>21</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>Implants &amp; Prosthetics</td>
<td>3</td>
<td>26</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Monitoring &amp; Diagnostics</td>
<td>2</td>
<td>26</td>
<td>50</td>
<td>54</td>
</tr>
<tr>
<td>Therapeutic Devices</td>
<td>8</td>
<td>65</td>
<td>78</td>
<td>70</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>225</td>
<td>Cardiovascular</td>
<td>Seed: 70</td>
<td>1-5: 128</td>
</tr>
<tr>
<td></td>
<td>Dermatology &amp; Aesthetics</td>
<td>R&amp;D: 78</td>
<td>6-10: 44</td>
</tr>
<tr>
<td>12</td>
<td>Orthopedics</td>
<td>Initial Revenues: 63</td>
<td>11-20: 22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revenue Growth: 8</td>
<td>21-50: 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>51-100: 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 3</td>
</tr>
<tr>
<td>44</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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.
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.

<table>
<thead>
<tr>
<th>Company</th>
<th>Estimated Revenues</th>
<th>No. of Employees</th>
<th>Established</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syneron Medical</td>
<td>$228.3M (2011)</td>
<td>605</td>
<td>2000</td>
</tr>
<tr>
<td>Alma Lasers</td>
<td>$100M (2009)</td>
<td>150</td>
<td>2005</td>
</tr>
</tbody>
</table>
A relatively large number of therapeutic devices companies, 32%, are already selling their products.

<table>
<thead>
<tr>
<th>Company</th>
<th>Medical Field</th>
<th>Estimated Revenues</th>
<th>No. of Employees</th>
<th>Established</th>
<th>Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alma Lasers</td>
<td>Dermatology &amp; Aesthetics</td>
<td>$100m</td>
<td>150</td>
<td>2005</td>
<td>Private</td>
</tr>
<tr>
<td>Company</td>
<td>Field</td>
<td>Stage</td>
<td>Year</td>
<td>Value  (m)</td>
<td>Stage</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------</td>
<td>---------</td>
<td>------</td>
<td>-----------</td>
<td>---------</td>
</tr>
<tr>
<td>AngioScore</td>
<td>Cardiovascular</td>
<td>N/A</td>
<td>2003</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Galil Medical</td>
<td>Urology</td>
<td>N/A</td>
<td>1997</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Home Skinovations</td>
<td>Dermatology &amp; Aesthetics</td>
<td>$40m</td>
<td>2006</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Impulse Dynamics</td>
<td>Cardiovascular</td>
<td>N/A</td>
<td>1996</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Lumenis</td>
<td>Multi-field</td>
<td>$247m</td>
<td>1991</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Medispec</td>
<td>Multi-field</td>
<td>N/A</td>
<td>1991</td>
<td>N/A</td>
<td>Private</td>
</tr>
<tr>
<td>Syneron Medical</td>
<td>Dermatology &amp; Aesthetics</td>
<td>$228.3m</td>
<td>2000</td>
<td>N/A</td>
<td>Public (NASDAQ)</td>
</tr>
</tbody>
</table>

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.

Source: IVC
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.

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

![Segmentation of Monitoring & Diagnostics Companies by Medical Field](image)

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 usually 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

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

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

- **Never Incubated**: 97 (69%)
- **Incubated in the Past**: 23 (16%)
- **Incubated Today**: 21 (15%)

**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

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>74</td>
<td>Cardiovascular</td>
<td>Seed: 29</td>
<td>1-5: 45</td>
</tr>
<tr>
<td>Public Companies</td>
<td>Orthopedics</td>
<td>R&amp;D: 26</td>
<td>6-10: 12</td>
</tr>
<tr>
<td>2</td>
<td>Oral &amp; Dental</td>
<td>Initial Revenues: 13</td>
<td>11-20: 7</td>
</tr>
<tr>
<td>Companies Incubated (Now or in the past)</td>
<td>Revenue Growth: 2</td>
<td>21-50: 5</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td></td>
<td>51-100: 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 100: 3</td>
<td></td>
</tr>
</tbody>
</table>

- 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:

**Active Implants**
- An implant operating through a source of power that does not originate in the human body.
- Examples: Heart pacemaker, muscle stimulators, drug pumps, monitoring devices

**Passive Implants**
- Non active devices that are implanted in the body.
- Examples: Stents, artificial joints, hearing aids, artificial valves, bone prosthesis
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.
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 & prosthetics companies, 3 develop dental implants.

**Dominant Implants & Prosthetics Companies Active in Israel**

<table>
<thead>
<tr>
<th>Company</th>
<th>Year of Establishment</th>
<th>No. of Employees</th>
<th>Product</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medinol</td>
<td>1992</td>
<td>200</td>
<td>Stents</td>
<td></td>
</tr>
<tr>
<td>MIS</td>
<td>1998</td>
<td>200</td>
<td>Dental implants</td>
<td></td>
</tr>
<tr>
<td>Alpha Bio</td>
<td>2008</td>
<td>125</td>
<td>Dental implants</td>
<td>Foreign R&amp;D Center</td>
</tr>
<tr>
<td>AB Dental Devices</td>
<td>1990</td>
<td>100</td>
<td>Dental implants</td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventor</td>
<td>2009</td>
<td>55</td>
<td>Heart valve</td>
<td>Foreign R&amp;D Center</td>
</tr>
<tr>
<td>Technologies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

Source: IVC

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

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>68</td>
<td>Surgery</td>
<td>Seed: 22</td>
<td>1-5: 41</td>
</tr>
<tr>
<td>Public Companies</td>
<td>General Health</td>
<td>R&amp;D: 21</td>
<td>6-10: 12</td>
</tr>
<tr>
<td>2</td>
<td>Cardiovascular</td>
<td>Initial Revenues: 22</td>
<td>11-20: 10</td>
</tr>
<tr>
<td>Companies Incubated (Now or in the past)</td>
<td>Revenue Growth: 3</td>
<td>21-50: 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>51-100: 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 1</td>
</tr>
</tbody>
</table>

- 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.
15 companies develop devices intended for surgical procedures.

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 optometrical products employs 1400 workers. According to IVC, the company’s annual sales for 2010 were estimated at $156 million. Shamir, which was once traded on NASDAQ and TASE is now a private company.
The medical equipment sub-sector is the only sub-sector in which the number of commercial stage companies (initial 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.

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%.
### At a Glance

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>General Health</td>
<td>Seed: 10</td>
<td>1-5: 21</td>
</tr>
<tr>
<td></td>
<td>Multi-field</td>
<td>R&amp;D: 19</td>
<td>6-10: 9</td>
</tr>
<tr>
<td></td>
<td>Oncology</td>
<td>Initial Revenues: 16</td>
<td>11-20: 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revenue Growth: 4</td>
<td>21-50: 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>51-100: 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 6</td>
</tr>
<tr>
<td>Public Companies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Companies Incubated (Now or in the past)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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 treatment, 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 evolution 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**

- **InSightec**: Bringing therapy into focus
  - Combining different imaging technologies for better results.

- **Arineta**: Cardio Imaging
  - Imaging devices dedicated to a specific organ (lowers the cost of the device).

- **aspect imaging**: From massive stationary devices to portable devices resulting in easier access for patients and lower costs for health plans and consumers.

- **ActiViews**: Lowering exposure of patients and doctor to radiation.

- **Walsh**: Wide Beam Molecular Imaging
  - Improving resolution of images and shortening the time of imaging.

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 3 biggest imaging companies in Israel are all foreign R&D companies of multi-national conglomerates (GE Healthcare Israel, Philips Medical Technologies & 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.
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 successful 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 approximately $600m.

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 across many medical fields or for general health purposes.
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%).

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.
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**

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>Diabetes &amp; Obesity</td>
<td>Seed: 7</td>
<td>1-5: 23</td>
</tr>
<tr>
<td>Public Companies</td>
<td>General Health</td>
<td>R&amp;D: 18</td>
<td>6-10: 6</td>
</tr>
<tr>
<td>2</td>
<td>Respiratory</td>
<td>Initial Revenues: 12</td>
<td>11-20: 7</td>
</tr>
<tr>
<td>Companies Incubated</td>
<td>(Now or in the past)</td>
<td>Revenue Growth: 1</td>
<td>21-50: 1</td>
</tr>
<tr>
<td>17</td>
<td></td>
<td></td>
<td>51-100: 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 0</td>
</tr>
</tbody>
</table>

- 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 with eye drops. Yet all the above forms have their limitations:

<table>
<thead>
<tr>
<th>Lower Effectiveness</th>
<th>• Drugs are spread out throughout the whole body instead of targeting a specific area.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity of the Drug</td>
<td>• Higher dosages may expose the whole body to dangerous toxicity instead of attacking only the sick area.</td>
</tr>
</tbody>
</table>
| Inconvenient         | • Children and even some adults find it hard to swallow a pill.  
                       | • People tend to forget to take the drugs prescribed to them.  
                       | • Some people suffer from fear of needles. |
| Increased Side Effects| • Side effects may be severe as the whole body is subjected to the drug. |

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.
The leading medical fields in which Israeli drug delivery companies specialize 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.
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.

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

Source: IVC
TELEMEDICINE

At a Glance

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>General Health</td>
<td>Seed: 2</td>
<td>1-5: 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R&amp;D: 6</td>
<td>6-10: 0</td>
</tr>
<tr>
<td>Public Companies</td>
<td></td>
<td>Initial Revenues: 5</td>
<td>11-20: 5</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Revenue Growth: 2</td>
<td>21-50: 3</td>
</tr>
<tr>
<td>Companies Incubated</td>
<td>(Now or in the past)</td>
<td>Revenue Growth: 2</td>
<td>51-100: 1</td>
</tr>
<tr>
<td>0</td>
<td></td>
<td>Over 100: 2</td>
<td></td>
</tr>
</tbody>
</table>

- 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?

- **Lowering Expenses**: Saves costs to patient, provider & system by reducing hospitalization time & transportation costs.
- **Patient Comfort**: Patients receive medical care in the comfort of their home without waiting in line.
- **Emergencies**: Faster response to emergency situations.
- **Remote Locations**: Better treatment for people living or working in remote places.
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.).

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.

<table>
<thead>
<tr>
<th>Segment</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue Growth</td>
<td>2</td>
</tr>
<tr>
<td>Initial Revenues</td>
<td>6</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>5</td>
</tr>
<tr>
<td>Seed</td>
<td>2</td>
</tr>
</tbody>
</table>

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

Source: IVC

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

At a Glance

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Rehabilitation</td>
<td>Seed: 5</td>
<td>1-5: 6</td>
</tr>
<tr>
<td></td>
<td>Diagnostics</td>
<td>R&amp;D: 5</td>
<td>6-10: 3</td>
</tr>
<tr>
<td></td>
<td>Surgery</td>
<td>Initial Revenues: 1</td>
<td>11-20: 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revenue Growth: 21-50: 0</td>
<td>51-100: 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 0</td>
</tr>
</tbody>
</table>

- Public Companies: 1
- Companies Incubated (Now or in the past): 8

- 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:

- Robots performing surgeries
- Robots assisting the surgeon in a surgery
- Restoration of normal function after injury or illness
- Assistive equipment for the disabled and elderly (intelligent prosthetics)
- Reduce the invasiveness of diagnostic intervention
- Tiny wireless medical robots to navigate through human body

...
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
- **Diagnostics**: 3
- **Rehabilitation**: 5

*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 Number of Employees](source: IVC)

![Segmentation of Robotics Companies by Business Stage](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.
8 of the 11 robotics companies have passed through technological incubators. 4 of them are currently 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.

<table>
<thead>
<tr>
<th>Company</th>
<th>Established</th>
<th>No. of Employees</th>
<th>Business Stage</th>
<th>Medical Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simbionix</td>
<td>1997</td>
<td>100</td>
<td>Revenue Growth ($15m)</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>NAN Instruments</td>
<td>2003</td>
<td>3</td>
<td>Seed</td>
<td>Electrode Positioning</td>
</tr>
<tr>
<td>Semantic Medical Simulations</td>
<td>2010</td>
<td>6</td>
<td>Seed</td>
<td>General Health</td>
</tr>
</tbody>
</table>
MULTI-SECTOR COMPANIES

At a Glance

<table>
<thead>
<tr>
<th>No. of Companies</th>
<th>Dominant Medical Fields</th>
<th>Companies by Business Stage</th>
<th>No. of Employees per Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Multi-field</td>
<td>Seed: 3</td>
<td>1-5: 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R&amp;D: 0</td>
<td>6-10: 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initial Revenues: 3</td>
<td>11-20: 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revenue Growth: 2</td>
<td>21-50: 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>51-100: 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Over 100: 1</td>
</tr>
</tbody>
</table>

Public Companies

Companies Incubated (Now or in the past)

- 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

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.

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.

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 R&D cuts across many companies.
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 sanitized 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. Cryoaablation, a process which uses extreme cold to freeze and destroy diseased tissue, has been used by medical
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 reconstruction 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 successful 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 because they enable especially minimally invasive procedures they also reduce recovery time. Medical robots also have a great contribution to preventive medicine as they can reach places in the human body that otherwise 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. Additionally, the Renaissance has been recently approved by the FDA for brain surgery.
**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 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. 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.
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 modern 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.
ABOUT MEIDATA

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With a wide range of Intelligence services and products, Meidata is constantly developing new methodologies to match clients' requirements, in order to ensure significant value measured in higher returns and revenue.

Meidata utilizes unique methodologies for data collection and analysis, using professional databases and advanced proprietary tools to support decision-making and business processes led by CEOs and strategy directors.

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