The OCS Provides Vital Assistance for Israel's Life Science Industries

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Over the past decade, Israel has introduced a wealth of groundbreaking and valuable innovations in Life Sciences to the world. The development and commercialization of many of these breakthroughs, that have made a significant contribution to the Israeli economy, can be attributed directly to the activities of the Office of the Chief Scientist (OCS) of the Ministry of Industry, Trade and Labor.

The various programs of grants and other support offered by the OCS provide invaluable assistance to Israel's life sciences industries, whether in biotechnology, bio-pharma, or bio-medical. These areas have become one of the top priorities for the OCS and have been designated as a "Preferred Sector" since 2005. This status is manifested by the increased cooperation between academia and industry, dedicated technological incubators, start-up ventures, industrial R&D support and international cooperation. The ultimate goal is to facilitate the efficient transition of cutting edge technologies from start-up stage to profitable enterprises.

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Israel – A Global Biotech Leader

The programs implemented by the OCS have played a major role in enabling Israel to become one of world's leading centers of knowledge-intensive technology entrepreneurship.

Bolstered by a highly skilled workforce, a flourishing high-tech environment, and an entrepreneurial spirit, Israel has evolved to be a vital international hub for start-up activities. Extending beyond electronics, communications, information technology, safety, security and semiconductors, Israeli companies and leading multinational companies have made Israel a world leader in the Life Sciences industry, while global giants, including J&J, Perrigo, GE Healthcare, Philips Medical, Abbott, together with local companies such as Teva (in itself now a

multi-national company), Given Imaging, Insightec, Medinol, Disc-o-tech, Brainstorm and others, have been continuously developing and marketing life-changing medical breakthroughs and innovations.

Biotechnology, one of the fastest growing industrial sectors worldwide, is reshaping in life sciences and in many other convergent technology arenas, such as agricultural, environmental technologies, and the emerging range of clean technologies. Israel's unique capabilities, particularly its large base of science and technology trained researchers, along with a strong entrepreneurial spirit, provide an ideal foundation for building a leading biotech industry. Israel's outstanding interdisciplinary capabilities in life sciences, IT and computer systems, microelectronics and electro-optics, offer distinct competitive advantages in developing groundbreaking technologies.

These accomplishments and the vast growth of the Israeli Biotech industry are evident by the following data:

- Israel's Life sciences industry has over 700 active companies, placing it sixth in Europe. 45% of these companies are already generating revenue.
- 52 bio-pharma companies are currently conducting clinical trials for 61 molecules, of those, 38 are in phase II and III.
- The medical device sector comprises 57% of the industry; about 90 companies are conducting clinical trials.
- Israel ranks No. 2 in bio-pharma patents per capita worldwide and No.1 for US granted medical device patents per capita (US PTO, analyzed by ILSI). Israel is also 2nd in Europe in per capita of private biotech companies' products in pipeline (E&Y's "Beyond Borders").
- VC investment in the industry rose to $250 million in 2008, of which $92 million was investments made by the OCS. However, less than $100 million was invested by VC funds in 2009 and 2010, while the OCS invested $122 million and $113 million in each of these years respectively.

Bio-Therapeutics

Israel's Biotech industry shows particular strength in bio-therapeutics, with specific treatments for neurological disorders, cancer and autoimmune syndromes. About half of all university research projects in therapeutics and most of the biotech drugs in the industrial pipeline are focused on these areas that represent some of the fastest growing markets worldwide. Recently, Israel has become a global leader in the promising new therapeutic area of regenerative medicine and cell therapy. In addition to extensive academic research in this field, a number of Israeli companies reached the advanced phase of multi-center clinical trials.

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Strong Academic Base

Israel has an exceptionally strong academic base in the full range of life sciences' disciplines alongside a large reservoir of scientifically trained workforce. Israeli academia boasts 900 senior faculty members in biotech related departments and one third of all PhD graduates studied in biotech related programs. Israel has the largest number of scientists per capita in the world and devotes 35% of its research to the life sciences. Research is carried out in seven universities, five colleges and seven major hospitals. There are currently more than 800 ongoing academic projects in the life sciences, many of which are headed for industrial commercialization as a result of the efforts of Israel's modern technology transfer operations and OCS programs, such as MAGNET, which support consortia of academia and industry.

The Role of the OCS

The OCS is responsible for the implementation of government policies with regard to the support and encouragement of industrial R&D in that it fosters high added value R&D, thus enhancing the knowledge base of Israel's high-tech industries. The OCS also promotes extensive cooperation in industrial R&D at the international level, in both bi-lateral and multi-lateral frameworks that facilitate opportunities for Israeli companies to develop strategic relationships worldwide.

In 2010 biomedical industries became the leading sector in total OCS grants; R&D grants to biomedical industries in 2010 accounted for 28% of the total OCS budget, an increase from 18% in 2002, while communications industries, which was the leading sector until 2009 and accounted for 40% in 2002, dropped down to 24.7% in 2010.

The following is a short overview of the different programs utilized by the OCS to realize the maximum potential of the life sciences and biotechnology industries.

The R&D Fund

In 2005, the OCS designated Biotech as a "Preferred Sector" for purposes of expanding the funds granted to this sector by its largest support program - the R&D Fund. As a result, the resources allocated to Biotech were increased - from just 10.3% of the R&D Fund's total budget in 2000, to more than 24% in 2010. Additionally, the amount of requests for support in this field grew substantially. In 2010, the R&D Fund received 156 requests for project support in biotechnology and pharmaceutics of which 81% were approved representing an investment of NIS 170 million, and 114 requests for project support in medical devices, of which 82% were approved, representing an investment of NIS110 million.

The Technological Incubators Program

The OCS' Technological Incubators Program provides a supportive framework which enables novice entrepreneurs with innovative concepts to establish their own companies and translate their ideas into commercial products.

In 2010, life sciences projects continued to take the lead in the number of approved projects in the technological incubators, comprising more than 50% of the projects, out of which, approximately 10% were in biotechnology in comparison to 15% in 2009 and 18% in 2008. Nevertheless, the 2009 economic recession is clearly continuing to take its toll on the biotech industry and private investors are less inclined to invest in early stage high-risk biotech projects. In comparison with 2009, the number of biotech projects submitted to the OCS by the technological incubators in 2010 has dropped by 10%.

In 2005, the Technological Incubators Program launched the first biotech designated incubator in Jerusalem. Three projects have graduated from the incubator and are undergoing clinical trials. A tender for establishing one or two additional biotech incubators is underway, and should be ready during Q3 2011. In order to satisfy biotech needs of a much longer time period for R&D, biotechnology projects are entitled to a three year incubator period, as oppose to a two year incubator period for other projects. Additionally, biotech projects that are admitted into the biotech designated incubator, enjoy a $1.8 million three year budget, in comparison to a $750,000 three year budget, in other incubators.

A number of successful Biotech companies are incubator graduates, among them, Protalix and D-Pharm which are publicly traded, and are undergoing Phase III clinical trials.

The success of the incubator program is indicative of the huge potential biotechnology represents, once greater involvement of the venture capital sector is realized.

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Some of the major accomplishments of the MAGNET program in this field include:

- The completion of the six year MAGNET "Genesis" consortium that developed generic technologies for cell therapy and stem cell derived products, at the end of 2009.

- The completion of the five year "BioTov" consortium that focused on agro-biotech and genomics.
- The "BMP" consortium, which started its 5th year of activity. The activity of the consortium is aimed to improve Patient Management in gastro-intestine track diseases. The consortium consists of 20 industrial companies, three medical centers and five academic institutes that are collaborating in converging technologies of biology, medicine and electro-optics micro-electronics micro-systems, in order to achieve technological and conceptual breakthroughs.

MAGNETON

The MAGNETON program, promotes technology transfer from academia to industry via mutual cooperation between individual companies and specific academic research groups. Four of the new projects approved by the MAGNETON program in 2010 were in life sciences with awarded grants of about NIS 8 million.

NOFAR

The purpose of the NOFAR program, which is part of the MAGNET program, is to bridge between basic research and applied research, which is still within the universities labs. Twenty four biotechnology projects were granted funding in 2010 with a total of $2.5 million budget. Each project is assisted by an industrial company that helps it reach the specific milestone that is of importance to the industry.

TELEM Initiative

The OCS also promotes, through the TELEM initiative, different projects to support technological infrastructure. One of these projects that will be launched this year is intended to upgrade the skills of service laboratories in Israel, and enable them to support the R&D activities of academia and early stage companies, with full compliance to GLP or GMP requirements. It is expected that by the end of this 3-year program, laboratories that supply major technological services will be established in Israel.

Another initiative that the OCS intends to launch in 2011 is the establishment of a national bio-bank, dedicated to Cancerous tissues. It is a 5 year program that will cover thousands of tissues that will be available for the R&D community.

ISERD and the FP7

As worldwide R&D in biotechnology increases exponentially, Israel's cooperative agreements with many countries take on a greater significance. The access to foreign technologies, manufacturing and markets is of paramount importance to Israel's globalization efforts. Israel is one of 40 countries and the only non-European nation taking part in The Seventh Framework Program of the European Union (FP7), and the Chief Scientist of MOITAL is the chairman of the steering committee of ISERD that represents Israel in the FP7. The themes involving medical research under the "Cooperation" pillar of the program have a budget of nearly €7.5 billion for seven years. The main areas of research will remain stable for the next three years while the specific topics will change. The program is divided into 3 main areas: Biomedical Technologies and tools for human health; research on specific diseases; and optimizing delivery of health care to the citizen. The last area is completely new and will involve a whole new sector of the Israeli research community. The main areas of research are Personal health systems, Patient guidance Services, Safety and healthcare record information reuse, ICT for ageing and wellbeing and virtual physiological human.

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FP7 funding, so far, for medical related projects involving Israeli entities has reached €50 million. Examples of such projects include Winzsof Israel Ltd, a company which coordinates a project aimed at assessing long term risks and advances towards better Epoetin driven treatment modalities; IBM Israel Ltd which is involved in a project aimed at developing

a European network for Genetic-Epidemiological Studies; MaimoniDex RA Ltd, which is a part of a project for developing innovated therapy choices for Rheumatoid Syndromes; Pronto Diagnostics Ltd which participates in a project for developing models for early diagnosis, prevention and innovative treatment of TNF Receptor Associated Periodic Syndrome (TRAPS); Agilent Technologies Inc. which is a part of a project dealing with Glycomics by High-throughput integrated Technologies; Cellcure Ltd is a company which is participating in a project that develops a novel "all in one" toxicity test platform based on embryonic stem cells; D-Pharm Ltd is a part of a project that focuses on plasticity in Alzheimer's disease, stroke and damaged visual system; and Protea Vaccine Technologies Ltd which belongs to a consortium for combating Antibiotics resistant Pneumococci by novel strategies based on in vivo and in vitro host.

The TNUFA Program

Another OCS initiative is the TNUFA Program, which assists Israeli entrepreneurs to develop promising ideas to the point where commercial investment decisions can be made. TNUFA provides support for experimental development and related pre-commercial activities that develop the idea from a concept or from previously conducted scientific research to a working prototype or similar "investor-ready" stage. The assistance, provided as a conditional grant (repayable on success), may be used for protecting intellectual property, technological feasibility study, business planning, etc. TNUFA awards the most promising proposals a pre-seed grant of up to IS 200,000 IS which makes up 85% of the approved budget.

The Program for Cooperation in R&D with Multinational Corporations

In the past few years, the OCS has started implementing its global corporation R&D collaboration initiative with special emphasis on leading bio-pharma enterprises. Under this framework, joint R&D projects between global corporations and Israeli companies that are approved by the OCS, will be entitled to financial assistance from the OCS in accordance with prevailing regulations.

Agreements have been signed with Merck KGaA, a Germany based global pharma company; GE and Philips, focusing on their healthcare divisions; Abbott and B. Braun, a Germany-based medical device company. Four projects have been approved in the Merck framework and two approved with GE Healthcare division. Other agreements and projects are in the pipeline.

The Life Science Funds

The biomedical field has been characterized in the world for years by double-digit growth rates, and has a high economic potential but also a high risk. In Israel, there is a substantial failure of investments in Biomedical companies due to short-term funding model preference of venture capital funds and lack of Bio-Pharma companies as a strategic partner (with the exception of Teva Pharmaceuticals).

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The fund will invest in life sciences companies, with an emphasis on Bio-Pharmaceuticals, which was identified as a field in which Israel has an excellent but not fully tapped infrastructure. The Israeli Government, an anchor partner, will allocate funds of $76 million, while Orbimed met the

fund tender's high threshold conditions as well as the requirement to raise at least $76 million. The company succeeded in raising $160 million, more than double the minimum - no small achievement given the current difficulty in raising capital. The amount raised maximizes the Government's investment. The set up of the new life sciences fund together with Orbimed's entry into Israel are expected to boost foreign investment in Israel's life sciences industry by $200 million through co-investments with foreign venture capital funds.

The National Institute for Biotechnology in the Negev

Since 2010, the OCS together with other ministries has supported the newly established National Institute for Biotechnology in the Negev (NIBN). The cost of establishment was $90 million with government participation of $30 million over seven years.

NIBN is the first independent research entity of its kind to be established in Israel, seeking to link top-level multidisciplinary basic research to applied research. The innovative structure of the NIBN within Ben-Gurion University encourages NIBN scientists to cross the academic barriers that separate traditional research disciplines and to engage in synergistic biotechnology research. NIBN conducts multi-disciplinary convergent research projects with clear biotechnology goals, while working to bridge the current gap between basic and applied research, thus enable new advances in biotechnology and serving as the glue that links academia and industry.

NIBN's members strive to develop novel vaccines, biomarkers for human genetic disorders, novel approaches for cancer therapy and novel antibiotics. The core facilities providing access to equipment and services in many cases not found elsewhere in the country along with close monitoring of projects by industry consultants maximizes the potential of scientists to produce lead-stage projects.

NIBN is steered by its own International Scientific Advisory Board (SAB, includes 3 Nobel laureates).

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Summary

As access to healthcare advances and as the world continues to demand new, effective therapies and devices, the search for innovative products and systems will accelerate. Knowledge-intensive industries will flourish in an ever more competitive global economy. With its wealth of skilled multi-disciplinary human resources, and entrepreneurial talents, Israeli industry is well positioned to play an important role in international life sciences industrial development.

Biomedical technologies are increasingly driven by other new and converging scientific domains such as nanotechnology, smart materials, advanced sensors and cutting-edge IT, electronics, and communications technologies. This emerging convergence presents enormous opportunities for Israel. Among the immediate deliverables are improved targeted drug therapies, tissue regeneration and tissue engineering solutions, minimally invasive procedures and novel diagnostic tools.

The inherently long development times, particularly in bio-pharma, that characterize biotechnology in comparison to other knowledge-intensive industries, makes the supporting role of the OCS particularly critical.

I believe that keeping Israel in the forefront of the global arena of the life science technology industry obliges a vigilant effort for improvement, a constant striving for excellence and support for an innovative society that will ensure the health and welfare of all the people in the State of Israel, in the years to come.

In order to achieve this challenge and contribute to a strong, competitive and growing Israeli economy based on knowledge and technology, the OCS will continue to operate the wide variety of different instruments and activities as described above.

I wish to all of us, that our creativity and initiative will make 2011 a successful and fruitful year.