At least since the late 1980s, literature suggests that research and development (R&D), innovation, and spillovers are key factors driving self-sustained economic growth and that these factors are generated from within the economic system in response to economic incentives [Grossman and Helpman, 1991; Lucas, 1988; Romer, 1986; 1990]. Chen and Dahlman [2004] demonstrate this relationship for both advanced and emerging economies. The term “knowledge economy” has been widely used to refer to economies characterized by this wealth generation relationship. A World Bank [World Bank, 1999] document describes the shift towards knowledge as a foundation of growth in the following way:

“For countries in the vanguard of the world economy, the balance between knowledge and resources has shifted so far towards the former that knowledge has become perhaps the most important factor determining the standard of living – more than land, than tools, than labor. Today’s most technologically advanced economies are truly knowledge-based”.

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Today the pharmaceuticals, biotechnology, medical devices, and diagnostics form the backbone of a growing and rapidly integrating life science industry complex (LSIC) estimated to be worth a trillion dollars in sales. There is every indication that the importance of this set of science based industries will grow very significantly in the future. Indeed a number of prestigious reports speak of the emergence of a bio-economy by 2020 or 2030. For example, a very recent report by the OECD predicts that the use of key biotechnologies likely to be commercialized by 2030 will contribute to 35% of chemical, to 80% of pharmaceutical and diagnostic and will approach 50% of agricultural output. According to this report, the use of biotechnology will be pervasive and industrial and agricultural applications are expected to grow even more significantly than biologics and biopharmaceutical applications—which dominate biotechnology today [The Bio-economy by 2030, OECD 2009]. The report predicts also that this increase in the contribution of biotechnology to the economy is also likely to be even more significant in the emerging economies than within the OECD. It is not unreasonable to expect that the life science industrial complex may contribute more than 10% of world GDP within a single generation.

According to the global ranking of Economist Intelligence Unit, the leaders of innovation, measured by the number of patents (the EIU uses as a measure the international patents index averaged for 2002-05 per million of inhabitants), are: Japan, Switzerland, and the US [EIU 2007]. According to this report, the importance of creativity is and will continue to be greater for emerging economies like Poland, than for developed ones. Unfortunately, in this ranking Poland occupies a distant 49th place, behind Bulgaria, South Africa, and Saudi Arabia. The Polish paradox comes from the fact that the country’s potential for innovation, measured by the quality of its science, education, its business and information environment places the country in a significantly higher – 33rd position. The gap between the Polish innovation potential and the innovation results achieved is wider than for most other countries. It is a sign of the dire wastefulness of the nation’s potential. Unfortunately, the forecast part of the cited report does not predict any improvement in the Polish position in the near future, that is until 2011. Since the Polish economy is likely to follow the trend of convergence of wages and costs with those in Western Europe, it will be more and more difficult in the longer run for the country to be competitive in terms of prices. Improvement in the innovativeness of the economy is a condition sine qua non of further growth.

Innovation or the commercialization of inventions happens at the intersection of science and business. Although Polish science is underinvested and the education sector at all levels encounters many problems – as the EIU report documents – the Polish potential to generate new knowledge is still considerable as compared with other emerging economies. But one has to remember that some countries, not long ago ranked lower than Poland in education and science have made vast improvements allowing them to catch up.
POLISH SCIENCE IN THE GLOBAL PERSPECTIVE

- Poland’s outlays on research and development (R&D) have averaged only to 0.6% of GDP in recent years, according to the Central Statistical Office of Poland, which places the country in one of the lowest ranks in the European Union and the OECD. For the European Union the average is around 2% of GDP, and countries like Sweden or Finland spend over 3.5% of GDP on R&D (Israel spends 4.5%). Fast developing countries such as Korea systematically increase the rate of spending on R&D [World Bank, Knowledge for Development, Washington 2007].

- In the latest ranking of the best European universities no Polish university was included in the top 100– the Jagiellonian University ranked 130th [Ranking Web of European Universities 2009]

- In spite of its low financing level Poland took 22 place in the ranking of citations of scientific publication – a marked improvement over the results achieved in the nineties [King D.A. 2004]. As to citations of works in physics and mathematics – the place of Poland is even higher in the 13th position. The life sciences are ranked somewhat lower but ahead of the social sciences [Essential Science Indicators, 2006 as cited by M. Zylicz, Innovations in Poland, Wroclaw, May 2006]

- In terms of science results, measured by the number of most frequently cited works relative to the level of economic development (GDP per capita) Poland achieves above average results, better than for instance Italy, Japan, and Ireland [King 2004 as cited by M. Zylicz 2006]

- According to the OECD, Poland is ranked among the top in the share of public financing of R&D – the share of the private sector funding is still very low – a result that is directly contradictory to the Lisbon Strategy [Nauka i Technika 2004, Battelle Global R&D Report 2008]

- In Poland, the number of registered international patents per million inhabitants amounts to 0.805, while in Hungary it is 10.3, in South Korea 115, in Taiwan 253, 350 in the US, and in Japan 1213. The number of registered patents is considered a synthetic indicator of the innovation level [EIU 2007]. Polish patenting activity as registered by the Patent Office of the Republic of Poland, (UPRP) at approximately 50 filings per million population is comparable with countries at a similar level of economic development, however in terms of international patents registered by Polish residents the country’s performance is clearly unsatisfactory.

Unlike the broad technology sector which includes IT (information technology), biotechnology has higher entry barriers, requires more capital, is more risky and depends much more on science. Of all high tech sectors biotechnology is the most
science intensive. Poland has achieved success with such technology sectors as IT. Much less is known about where Poland stands in the new race toward the bio-economy. The European Union recently funded a complex assessment of “national public policies that stimulate biotechnology research, its exploitation and commercialization by industry in Europe”. This report entitled ‘Biopolis’ also includes the new member states of Central Europe and accession countries [Enzig C et al. 2007]. The Biopolis study (section 8 ‘New member states and accession countries’) is perhaps the first comprehensive attempt to assess the biotechnology potential of new EU member states. However, like other reports including the OECD biotechnology statistics, it suffers from several weaknesses and in our view does not provide a sufficiently deep assessment. The Biopolis study was not based on field work directly with companies, but through the intermediation of the Ministry of Science and Higher Education and does not include any detailed or even general case studies, but rather relies only on numbers provided by government agencies and seems to emphasize public sector rather than private sector efforts. The Biopolis report does not do justice to an accurate and up to date assessment of the nascent biotech sectors of new EU member states.

In this paper we set out to provide a case study based assessment of the Polish bio-pharmaceutical industry. We first assess the most important barriers to the commercialization of inventions in Poland. We critically review existing statistical reports of the Polish biotechnology sector. We follow with interview based case studies of selected innovative firms in the sector of health biotechnology. Taking those firms as examples we show that – in spite of numerous barriers – Polish inventors and entrepreneurs often coming from the scientific community are able to achieve success. At the end of the paper we compare the progress of Polish biotechnology with other emerging economies.

RESEARCH METHODOLOGY

The biotechnology industry in Poland is in an early stage of development. The Ministry of Science report of 2007 which is cited below counted the number of biotech companies (OECD definition) in Poland at 20. The 2009 OECD report (which is also cited below) counts 11 biotechnology firms of which only 3 are described as ‘dedicated biotechnology firms’. The discrepancy according to the Ministry panel of experts arises from the fact that a number of known Polish biotech companies failed to respond to the OECD questionnaires. Thus the list of 20 biotech companies identified and carefully screened by the Ministry panel of experts was used as the starting point of this study. The small population of Polish biotech companies dictated a case study approach based on interviews. Out of the 20 companies six firms were selected (a 30% sample), that were judged to be representative for the sector in Poland: one big firm Bioton, two medium sized firms Biomed and Celon-Pharma and three small ones – Biocentrum, Mabion and BioTe21.
Formal interviews were conducted with the managing directors of 5 of the six companies. In the case of Bioton interviews were conducted with a senior member of management responsible for R&D who was designated by the company President. In the case of the small companies the CEOs were also the company founders. Basic company information included: the business/revenue model, key products/services, number of employees, location etc. The interview questions were organized around the following five themes crucial to an understanding of factors that explain company success and overcoming barriers to innovative company formation:

- **Planning the business and selection of enterprise domain**
  History of company. The questions related to this problem revolved around the background and personality of the founder, his/her skills, education and choice to start the company in a particular domain. How this focus may have shifted over time as the company grew and created revenue? Did the company start with R&D and innovative activities or initially not? Key stages in the growth and evolution of the company. Is the company oriented more towards selling a product/service as opposed to developing innovations?

- **Ownership and financing**
  How was initial financing obtained, what were the barriers to overcome? Role of individual investors, banks, venture capital (VC), grants and other vehicles as opposed to revenues from the company itself to finance emerging R&D streams. Role of key individuals and institutions in financing the company as it grew.

- **Acquiring and motivating employees**
  How was the key management team assembled? How difficult was it to find qualified management as compared to the different categories of employees? Issues with skills shortages? Is qualified staff a barrier to biotech development and in what sense? How are staff people motivated to stay with the company and develop careers.

- **Partnerships**
  Company choices with regard to key partners. Their role at the different stages of company development. Outsourcing and in-sourcing decisions. Role of national and international partners. Key issues related to partnership management, mistakes made.

- **Management**
  The most important barriers to entrepreneurial innovation that had to be overcome. Most difficult management challenges company faced and how they changed over time.

Additional interviews about the industry and the companies were conducted with independent experts including: the President of BIO-TECH Consulting
(a leading biotech consultancy firm, specialized in Central Europe), the President of a Warsaw based private equity firm, several members of the Ministry of Science panel of experts responsible for preparing the report on Polish biotechnology, Paris based OECD experts responsible for Polish biotech statistics and also with several international consultants with knowledge of the industry and the region.

A second round of interviews was then conducted with the Polish company representatives to clarify issues that arose from the round of expert interviews. Interviews started in 2007 and were completed in 2008. A number of Polish and foreign articles and reports on biotechnology and similar industries were consulted enabling an analysis that supplements micro level data with macro level assessments (the reports are listed in the bibliography of sources).

COMMERCIALIZATION OF SCIENTIFIC INVENTIONS IN BIOTECHNOLOGY – BARRIERS TO INNOVATION IN POLAND

The US is the undisputed leader in the area of scientific inventions. Many of those are the result of basic research that creates entire new disciplines—such as molecular biology for example. American universities were instrumental in the creation of new industries such as electronics or biotechnology. Universities in the US generate a propitious climate for academic entrepreneurship. In recent years also traditional European universities have started to catch up with American ones in this respect. A favorable climate for innovation means not only the possibility of funding spin-off firms on the basis of scientific inventions, but also an openness and flexibility for new disciplines and subject areas to be developed in universities. In Great Britain, for example, 158 schools gave start to 187 firms [Higher Education Council for England 2007]. In Spain, a country comparable to Poland in population, in the same period 143 spin-off firms were started in 58 universities which took part in the survey. Spin-offs were defined as “a new company that bases its business primarily on knowledge generated by the university” [RedOTRI Annual Report 2007].

In Poland, in spite of numerous barriers to academic entrepreneurship that divide and separate science from industry, several dozen spin-off firms have come into existence. They were established by Polish faculty, entrepreneur-engineers or doctoral candidates. It is expected that this trend of founding new companies, also in the area of biotechnology, will pick up speed thanks to seed funds and other incentives. Nevertheless, the level of academic entrepreneurship in the country could be even higher.

An entrepreneur planning to establish a biotechnology firm in Poland has to overcome a lot of different barriers. Partly, those are typical bureaucratic barriers making entrepreneurship difficult in general. However, there are also specific barriers related to spin-offs initiatives. On top of that there are special difficulties specific to the sector of biotechnology.
Until recently the most serious obstacles to innovation included: on the one side low outlays on research and development, on the other the lack of opportunities for financing the commercialization of inventions. Lately this lack of financing resources has ceased to be the most important barrier to innovations in Poland. From the point of view of the supply of inventions, the most cited problem is the conservative attitude of Polish academics. Polish science is closed to global competition and its systems of assessment of academic achievement and of career advancement are antiquated (for example internal recruitment to faculty positions is the prevailing practice). In many Polish schools there are no regulations and procedures related to intellectual property and weak support systems for entrepreneurial professors, such as advising, training courses etc. Other barriers are of a typically bureaucratic type: the lack of effective tax incentives for firms, slowness of the Patent Office procedures (4 years on average, compared to 22 months in the US). The ineffectiveness of the system of intellectual property rights enforcement in courts as well as execution of court verdicts are additional difficulties [Mroczkowski T., Krekora M. 2007]

As experience of other countries shows, innovative spin-off companies find solutions and thus often pave the way for legal regulations which are subsequently broadly adopted. Companies come into being thanks to the determination and courage of founders and thanks to their abilities in self-education in the area of business and legal aspects of the enterprise. It is no different in Poland where-in spite of resistance and sometimes animosity or even envy of colleagues from the academic environment – entrepreneurial scholars have been able to spot and seize opportunities, to skillfully use resources and talents and establish firms in areas as difficult as biotechnology. Their experiences presented below may contain important lessons for academic entrepreneurs that face the challenge of commercialization of their scientific inventions.

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**POLISH BIOTECHNOLOGY COMPARED**

- the US, the UK, Germany, Switzerland, Denmark, and Sweden are world leaders in biotechnology. Global turnover in the biotechnology industry totals 85 billion dollars (US billion). There are 200,000 people working in over 15,000 firms globally.
- Poland possesses considerable human capital in the areas linked to biotechnology, with 2800 scholars working in 111 institutions based at universities or research centers. Every year there are 13,000 graduates of biotechnology.

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*The OECD distinguishes biotechnology firms and dedicated biotechnology firms: a biotechnology firm is “a firm that uses biotechnology to produce goods or services and/or to perform biotechnology R&D”, a dedicated biotechnology firm “is a biotechnology firm whose predominant activity involves the application of biotechnology techniques to produce goods or services and/or to perform biotechnology R&D” [OECD biotechnology Statistics 2009]. For Polish statistics the OECD2009 report and the Polish Ministry of Science 2007 report were used. International data was derived from: Beyond Borders reports 2008 and 2009 as listed in the Bibliography.
Polish outlays for research and development in biotechnology are estimated at 42.8 million euro, but only 8.2 million comes from the private sector. This is considerably less than in Hungary, Israel or Thailand, where similar outlays amount to over 100 million dollars and a larger part comes from private funds.

According to a Polish Ministry of Science Report, which uses the narrow OECD definition, there are around 20 biotechnology firms in Poland, usually small (with around 1172 people employed, including 232 researchers) and in addition, there are around 92 biotechnology related firms. For comparison based on the narrow definition, 50 biotechnology firms and about 120 firms related to biotech exist in Hungary. Only 20% of Polish firms dedicate themselves to development of new medicinal drugs. The 2009 OECD report cites lower numbers and cites 11 biotechnology firms. Although Poland has fewer firms than Hungary, the overall turnover of Polish biotech firms is twice as big as of Hungarian ones. Poland attracts twice as much venture capital as Hungary. In Poland there are relatively large biotechnology firms such as Bioton, Biomed or Celon-Pharma, all of which employ more than 100 persons.

Polish biotechnology firms are located in Warsaw, Poznan, Krakow, Lodz, and Gdansk. Krakow, Warsaw, and Wroclaw have plans to create biotechnology clusters around academic center.

Poland – unlike Hungary – doesn’t consider the development of biotechnology a government priority.

ACHIEVEMENTS OF POLISH PIONEERING BIOTECHNOLOGY FIRMS – SELECTED CASES

The most typical form of commercialization of scientific inventions is the creation of spin-off firms. They differ from start ups by having a “mother” institution that provides support. The mother institution can be a university, a larger company or scientific institute. The initiative may come from the management of the mother institution, from the individual inventor or from an entire scientific team. In a developed economy, with well regulated channels of cooperation between science and business, the creation of new knowledge in the form of an invention becomes formalized as intellectual property (patent) and constitutes the incentive for a spin-off firm to emerge.

As has been mentioned already, in the Polish circumstances of weak academic entrepreneurship, the emergence of spin-off type firms is more difficult. Success of science based spin offs depends on solving the typical problems of business creation, but often in the case of spin offs these are of a greater magnitude.
One of the American leaders in the incubation of spin-off firms is Cambridge Consultants – a firm, which helped create 15 companies, of which 13 are still in existence. 5 of them increased capital by way of an IPO (Initial Public Offering), 3 were sold and only 2 went bankrupt. The firm gained a 50% return on its investments. From among the firms created by CC, the biggest success belongs to CSR. It is the designer and maker of Bluetooth technology, commonly used in telephones and computers [Cordis, 2007].

Based on its experience, Cambridge Consultants devised a list of key issues which need to be resolved before we can talk about the success of a spin-off [Cordis 2007]:

1. Choice of enterprise domain
2. Motivation of people
3. Partnerships
4. Ownership and financing
5. Management

To analyze Polish firms we adopted this list. It is characteristic that conditions for success listed by the Cambridge Consultants are not the same as some of the popular perceptions about barriers to entrepreneurship as mentioned by aspiring entrepreneurs or business writers. What makes any business activity difficult – for example: high taxes, high costs of labor, lack of intellectual property protection, bureaucracy, lack of pro-innovation solutions etc. – creates something akin to “hygienic” factors. Just overcoming such typical barriers does not automatically lead to success of the knowledge based enterprise. Something different is needed.

The Cambridge Consultants’ list of key success factors was created from the point of view of the investor, who has to objectively assess, whether and why it may be worth putting money into a new enterprise. Polish spin-offs may differ from the model of the “typical American spin-off”. Our analysis of firms based on the Cambridge Consultants framework will let us uncover specific Polish characteristics. At the same time our analysis may also reveal more universal conditions for the success of innovative enterprises.

PLANNING THE BUSINESS AND SELECTION OF ENTERPRISE DOMAIN

What is the difference between the behavior of an entrepreneur creating any new business and an entrepreneur whose goal is the commercialization of new knowledge (invention)? In both cases entrepreneurial passion is necessary as well as an understanding of the market and a vision of firm development linked to a realistic assessment of risk and competitive advantage. In the case of an entrepreneur introducing an invention to the market additional difficult
requirements are added. Advanced scientific knowledge is indispensable. Without it is not possible to precisely estimate the potential and risks related to the effort to commercialize the invention. In biotechnology this process is exceptionally long and burdened by the risks of failure during preclinical and clinical tests lasting for years. At the same time the potential benefits can be enormous because of the global reach of the pharmaceutical market.

In developed countries such as the US, or the UK, spin-off firms come into existence on the basis of discoveries or ideas introducing disruptive innovations and leading to a new product or technology. In general, new inventions are brought to patent offices in order to protect the intellectual property. Granting the patent or at least registering the patent application creates a defined and unique market value of the intellectual property which constitutes one of the main assets of the firm. It happens now more and more often that the firm comes into existence even earlier that is on the basis of promising test results that only open the possibility of creating intellectual value (and property) in the future. The spin-off firm is the classic case of a marriage of two elements – entrepreneurial leadership and unique intellectual value – most often in form of a discovery or invention. The inventor can, but does not have to be the firm's founder. Now, more and more often, so called serial entrepreneurs, specialized in one area of business become managers of the newly created firms.

The more revolutionary the discovery, the greater the opportunity for the creation of unique market value and of competitive advantage. In the situation of relatively easy financing of commercialization of inventions as in the US, it is discovery that provides the incentive for the creation of the new firm and also the direction for its development. Innovative spin-offs can count on different forms of financing. Having secured seed funds for early stages of development they do not have to worry about income from their own activity. Revenue appears only after the successful registration of the medicine and its market launch. Income from the sale of medications protected by patents then serves to finance research on new drugs. Such is the business model of big integrated biotechnology firms as Genetech or ImClone.

In the case of the majority of Polish biotechnology enterprises single revolutionary discoveries did not play the crucial role, at least not in the beginning. Securing an immediate revenue stream was a priority imposed by limited access to seed capital. Revenue was thus often secured by production and sale of generic drugs, products or “tools” used in biotechnology research or by sales of more or less specialized services. Questions of selecting the initial area of business to be in were limited to the classical assessment of local market opportunities rather than of creating a new market for a new invention.

Only after securing a reliable revenue stream did Polish biotechnology firms search for new products through R&D projects undertaken in addition to their core income providing activities. And here the choice of research targets became a complex strategic assessment of capabilities and opportunity that had to be assessed on a much larger scale than that of the local market. The ability to
understand changes and trends in global business surroundings as well as the ability to connect this with scientific knowledge become crucial in this stage. Similar patterns of biotech spin off development exist in emerging economies where seed financing is scarce. But that too may be changing and certainly recent developments in Poland may bring it closer to the model of spin-off development that is typical in most OECD countries.

**Bioton**

Bioton is the biggest Polish biotechnology firm. The company started in 1993 as a spin-off, founded by a group of scholars working in the state owned Institute of Biotechnology and Antibiotics (IBA) in Warsaw. This group was headed by Dr. Edward Zukowski. At present, the firm is listed on the Warsaw Stock Exchange and has been pursuing an expansive, global strategy on the markets of Europe, former COMECON countries and also in Israel, India, China, and Australia. Human insulin and its derivatives made under license (over 61% of sales) and antibiotics (over 30%) are the main products of the firm. In 2007 the income of Bioton amounted to over 235 million zlotys. It employed over 600 people.

In Poland Bioton is a rare example of a group of researchers being able not only to communicate with business but also willing to undertake new roles resulting from founding a firm. Principal positions in the firm were occupied by former Institute researchers. “We had to learn new things constantly, especially the rules of business” - says Dr. Piotr Górecki, Bioton’s scientific director. Three elements were at the origins of the firm’s birth – a team of dynamic, flexible and talented people willing to learn, a good leader with a clear vision of the opportunities resulting from the emergence of a free market economy after the fall of communism in 1989 and an external opportunity in the form of an opportunity availability to acquire a license to produce insulin Even earlier the IBA had worked on an insulin project, so the license offer from a foreign patent owner reached the right entrepreneurial group ready for changes exactly at the right time. Earlier, the same offer had not been accepted by Polfa Tarchomin, another Polish firm. Thus, a state research institute proved to be more open to innovations and entrepreneurship than a state pharmaceutical firm.

In 1993 Bioton starts production of antibiotics, utilizing knowledge and potential of the Institute and relying on the determination of its personnel to succeed. At the same time the firm begins to carry out innovative projects and gets ready to introduce to the market recombinant human insulin as the fourth company in the world to do so. In 2001, 17 products in the Gensulin series were registered.

Having the license was just a start. Mastering complicated biotechnology procedures of human insulin production in the Polish situation at the time and then introducing this product – so it would be internationally competitive in terms of price and quality – was the big challenge. Nevertheless, the Bioton team was able to do this very fast and ahead of competitors. It was the speed to market that gave the firm the advantage over other license takers in Asia and
Western Europe. Since 2004 Bioton has been expanding beyond Poland onto the global market. At present, the development of the company goes in two directions:

- the firm develops market resources through expansion and acquisition of firms producing and distributing its products (examples are: Bioton-Trade Co, Sci-Gen LTD, Singapore, Sci-Gen Australia PTY Limited).

- the firm carries out its own research projects in the area of genetic engineering, biotechnology and pharmacology, but also takes over firms having drugs in the stage of advanced clinical tests (for instance BioPartners AG (Switzerland, Germany) or Gen Biopharma Private Limited – (India).

The case of Bioton shows the importance of: leadership in mobilization of knowledge resources and team motivation, of having a company wide vision leading to well targeted domain choice and of continuous learning.

**Celon Pharma Sp. z o.o.**

The utmost importance of continuous learning is demonstrated also by the the Celon Pharma company, employing over 80 people and reaching sales of 20 million zlotys (PLN). Celon-Pharma was founded in 2002 by Maciej Wieczorek, economist and entrepreneur in the first place, and also scientist. Mr. Wieczorek graduated in engineering, majoring in organization of production, as well as in economics and marketing at SGH – The Warsaw School of Economics. Next, on an exchange scholarship he studied international finance in Portugal and finally he added an MBA from the University of Minnesota. He gained knowledge in the area of pharmacology working from 1994 as production manager and later creating and heading the research & development section in the pharmaceutical firm Adamed. As he recalls: “my scientific interests came with the need to better understand complex production processes. They later went in the direction of innovative technology and molecular biology”. A PhD in molecular biology was the next stage of completing a knowledge base indispensable in the biotechnology business.

The idea of founding Celon-Pharma consisted in more fully utilizing the knowledge and previous experience of the founder. He understood the market as well as the management of innovation. His business idea was to introduce to the market complex generic drugs at lower cost and price than competitors could match.

The first two products were registered already in 2004, and the next – in 2005. Such a short time-frame was a big success. Success came thanks to lower costs. The profit of the firm was successfully reinvested in the development of subsequent generic products. At the present moment Celon-Pharma has three of its own products in its portfolio, and another three are in the process of being registered. However, the development of generic drugs is not a strategic target for Celon Pharma, only a jumping board for a future in biotechnology. “In a 5 year perspective we will observe a culmination of multiple factors unfavorable for small
makers of generic drugs. The expiration of patent protection for many drugs will mean the intensification of competition among makers from the Far East for whom it will be easier to register new drugs in Poland” – Maciej Wieczorek explains his new vision of development “it is necessary to use this time to search for innovative drugs based on biotechnology. Thanks to revenues obtained on the generic drug market, the company is pursuing a program of development of revolutionary original drugs, based on research on RNA interference”. For this purpose, together with a group of investors, Maciej Wieczorek founded a separate, new generation biotechnology firm MABION. For this, not only the experience and know-how of its founder were needed, but also the ability to choose correctly the therapeutic area. The ability to find and convince a group of private investors to finance the firm was also highly significant. “In this sector it is indispensable to understand risk and to be objective. One has to determine marginal conditions of the planned project at the in vitro level, to establish where the competitive advantage is and to estimate the selectivity and potency of the compound” – says Mr. Wieczorek about the elements of his success. He adds that those capabilities are lacking among scientific circles in Poland.

**BioCentrum Sp. z o.o.**

Biocentrum is the very first biotechnology firm created at the Jagiellonian University by a group of researchers, under the direction of Prof. Adam Dubin. The firm operates in Kraków in a lab rented from the Faculty of Biochemistry, Biophysics and Biotechnology of the university and specializes in the production of highly purified and highly active enzymes, inhibitors, and other biologically active proteins (using an original method of recombination). The firm also makes small laboratory equipment and it is the regional representative of such companies as Millipore, Kucharczyk and Polgen.

In Biocentrum 4 people work full time and additional persons work on contracts, depending on needs related to the project requirements. Experience in research and specialized equipment are the main resources of BioCentrum.

The BioCentrum team started in 1989. First, the idea of owning a business advanced slowly. But it ripened quickly a few years later, thanks to experiences gained by the founder during his US fellowship, when he collaborated in the creation of the new enterprise: Athens Research Technology. “I had this idea earlier, in Athens (Georgia, US) I saw how the biotechnology firm starts and develops and I concluded that it can be done in Kraków” – says Prof. Dubin.

For the Polish researcher those pioneering experiences became a ‘sui generis’ informal course on how to start business. It was nevertheless necessary to adapt this knowledge of American academic entrepreneurship to Polish conditions. As Professor Dubin recalls: “The beginnings of the firm were painful – the lack of one’s own lab space, lack of legal system in terms of intellectual property protection, unrealistic taxes for the small academic firm, restrictive bank financing requirements all had an impact. But amid numerous problems, family tradition and penchant for
entrepreneurship won out”. At the present moment the firm also undertakes innovative projects. The incentive for such further development of the firm happened as a result of it being taken over by the bio-informatics company SELVITA. Combining bio-informatics with the know-how in the area of lab research was meant to be the basis for strictly innovative projects at the crossroads of both fields. This kind of fusion or take-over testifies to the maturing of the Polish biotechnology sector and to changes in the financing of innovative undertakings.

BioTe21
Adam Master who founded the BioTe21 company also at the Jagiellonian University (UJ) is another example of an entrepreneur operating with some success at the junction point of science and business. He graduated from the Faculty of Biology and Earth Sciences of the UJ as well as from the Department of Chemistry of the Cracow University of Technology. The firm, similar to BioCentrum, operates in the Faculty of Biochemistry, Biophysics and Biotechnology of the UJ in a lab rented there. BioTe21 offers services in the field of synthesis and sequencing of DNA, genetic engineering and genetic identification, including paternity testing. The firm came into being thanks to structural funds from the EU, in a program of support for new enterprises. Those funds were then used to buy equipment for the bio-genetics lab. The owner of the firm, as a former full time employee in different firms developing technologies for industry, had the opportunity to gain unique knowledge and experience in the field of molecular and medical diagnosis.

Having his own company was a planned stage in his professional career, one characterized by continuous learning: “Even at the moment of choosing my studies I knew what I wanted to do – all the stages of studying, and afterwards of my work career in different firms were meant to prepare me to start my own firm” – says Adam Master. In 2007 the income from the provision of services activity amounted to not much over 100 thousand zloties. This is barely enough to cover the current costs of business. Over 90% of activity however is based on resources from different kinds of research grants and dedicated to research and innovation projects.

IBSS Biomed S.A.
Biomed Kraków is an example of a firm undergoing rapid restructuring and advancing its innovative capabilities at the same time. This firm, unlike the ones mentioned earlier, has a long history, reaching the year 1945. The Institute of Biotechnology, Sera and Vaccines BIOMED S.A. had been privatized in 2001 as one in a group of national pharmaceutical firms. At the time of privatization Biomed Kraków was the biggest maker of vaccines against diphtheria and tetanus. Its market share of 80% allowed a nearly monopolistic position. Right after the
privatization the firm faced a choice of development path: how to deal with the necessity of modernizing production, with European Union membership, new market conditions, new rules and growing competition.

After 2001 the success of Biomed was determined by its past strengths: the firm’s position in the market, contracts securing the continuity of long term sales, access to distribution channels, and the firm’s reputation. In the present new situation renovation of production infrastructure and widening of products portfolio have become necessary. The firm abandoned its plans of building a new plant and decided on the gradual remodeling and adaptation of existing facilities to European standards and requirements. New production technologies were implemented and in 2007 the firm obtained the European certificate of Good Manufacturing Practice (GMP) and the Common Technical Document certificate (CTD), related to production documentation – no less important than the required compound purity.

Together with these organizational changes projects of development of new products were carried out by the firm in its own lab and also in collaboration with outside researchers. The firm was interested in the niche market of probiotics. Success in this area secured the firm’s monopolistic place in the Polish market. Grzegorz Stefański, Bioton’s CEO, explains the innovation strategy of the firm: “We were never buying licenses – the firm focused on creating vaccines of its own. The fact that we were able to introduce innovative products on the market during the restructuring of the firm was a bonus”. In fact this is an example of the success of innovative projects under conditions of deep restructuring. No difficulties concerning the development of innovations were spared: bad regulations, lack of resources, lack of qualified employees etc. According to Mr. Stefański, an aggressive managerial approach combined with very specialized knowledge constituted the key to success. According to Mr. Stefański: “In high technologies, when every project is new, one has to assess the unique character of the product and to know when exactly to stop any given stage of research. It is necessary to keep a balance between profit and the cost of research. Lack of understanding of the economic importance of the so called information curve disqualifies most researchers as business people”.

Biomed plans to create its own research center to replace outsourcing it to existing scientific institutions in Poland.

In all reported cases, the combination of two kinds of competences – highly specialized knowledge in the area of targeted biotechnology with very good knowledge of a particular, highly regulated market, are considered essential preconditions for a business strategy enabling the firm to sell specialized products or services generating a revenue stream. The real success that all firms presented here want to attain by different means and at a different pace however depends on how they are be able to manage the more ambitious scenario of revolutionary innovations which need to be financed from their own funds or increasingly from available seed capital and investors.
ACQUIRING AND MOTIVATING EMPLOYEES

Knowledge and creativity are essential for firms operating in areas of high technology. The biotechnology industry hires personnel with very high expertise and pays them well. Typical for biotechnology firms is that demand for employees with specific expertise changes according to the stage of development of the firm. At the stage of discovery research biologists and chemists of different specialties are needed. At the stage of pre-clinical trials – toxicologists are in demand. Next come the specialists in clinical testing. Specialists in drug documentation, production, marketing and financing enter at later stages. In addition, depending on research success or failure and related financing support, the biotechnology firm continuously either increases or decreases its employment, at the same time modifying its expertise structure. The biotechnology firms in the US, especially those in the healthcare area, like to concentrate in clusters because it gives them – among other things – access to the vast pool of needed specialists who “travel” from one firm to another depending on project needs.

The majority of Polish biotechnology has not reached advanced stages of commercialization: approval of original patented drugs, mass production, and distribution. This is why the employment structure in Polish biotechnology differs considerably from the one found in American firms. In the Polish situation talented and competent scientists in biotechnology area are not lacking. Instead there is a shortage of people with both science and business expertise, especially experienced managers. The inflexible Polish job market and the habit of looking for a job in the area of residence constitute challenge for firms. The solution to this problem is recruitment at the national level, and motivational packages which not only attract the most talented but also give competitive promotion prospects – competitive in relation to scientific institutions and universities, while at the same time motivating them to study and deepen their knowledge according to the needs of the firm.

Thus, the firm’s ability to learn new knowledge, transform employee mentality and organizational structures is essential to success. From the beginning in Bioton a substantial group of people showed themselves capable of welcoming deep changes. “From being a state owned institute to becoming a manufacturer of human insulin was like crossing the Rubicon. We became ‘borderline people’ between science and business” – says Dr. Piotr Górecki about Bioton’s beginnings. “We needed to acquire totally different abilities. In Polish industry there were no models for us to follow, we had to learn ourselves. For example we learned marketing and sales from our foreign contractor. Tasks such as managing production, safety and quality control, totally new to scientists, were undertaken by our team members. We definitively didn’t want to pick up bad habits from the public sector institutions. The first manufacturing plant was created on the outskirts of Warsaw, in the countryside, using an old animal feed facility that we transformed. We provided training to the former employees who had only experience with animal feed production – it was a huge opportunity for them to learn new skills” – comments Dr. Górecki.

2 Those functions tend to be carried out by big international firms that often buy licenses.
From the moment Bioton joined the capital group Prokom, the firm entered a new kind of organizational culture. It acquired new people with expertise including strategic management and marketing. Today Bioton employs almost 600 people in Poland, of which 60% are in skilled jobs. Taking into consideration easy access to human resources at IBA and talent gained thanks to acquisitions of biotechnology firms outside the country, Bioton does not suffer from skills barriers that may be the object of worry of other developing biotechnology firms.

Maciej Wieczorek of Celon-Pharma, sees the development of his firm as related to its abilities of finding and keeping talent – “Celon-Pharma wants to be the firm for talented and ambitious people. We have to find, attract and train them. High pay, job advancement, including option of working on a Ph.D. and new challenges, must be more interesting than what is offered by universities” Celon-Pharma employs 100 people, of whom 30 possess advanced scientific degrees such as a Ph.D or higher.

Biomed solves the problem of knowledge and expertise resources differently. “Because of the deficit of people with experience it is rare for us to be able to acquire the best” – maintains Grzegorz Stefański from Biomed, where only 2 out of 270 hired employees possess advanced science degrees. This is why Biomed reached for the „best” through the systematic cooperation with different experts from universities and research institutions. However, as was mentioned earlier, they are considering changing this R&D outsourcing strategy by creating an in-house research facility.

Adam Master from BioTe21 so far has not had to fight to attract talented individuals graduating from universities. He cites that many graduates lack the ability to think creatively. “In a small firm this is not a worry. I deal myself with the majority of complex problems – our graduates have high levels of expertise as technicians, and that is where need them most in the company”. He acknowledges nevertheless that the firm approaches the moment when without new creative people it will not be possible to “process” all new ideas.

**PARTNERSHIPS**

Global competition has made partnerships crucial in business. In biotechnology it is absolutely the key factor. Partners are needed to supplement and enhance the limited capabilities of mostly small biotech firms most of which focus on just a few components of the value added chain. Partnerships increase the value obtained by the company at particular stages of the biotech business cycle from discovery research, clinical trials to manufacturing and marketing of the product. In the case of so called virtual biotech firms, the only asset these possess is the intellectual property. All remaining resources and needs are supplied through various forms of outsourcing, licensing, and partnering. Maciej Wieczorek (Celon Pharma) lists three managerial competences essential to effective “partnership management”: 1) being aware of the need to create a partnership, 2) the ability of finding the right partners while being open to the whole world, and 3) the capability of taking full advantage of a partnership.
Celon-Pharma has partners in the whole of Poland – chemical testing is carried out in the universities of Poznań and Łódź and clinical testing in Białystok. Thus the firm meets critical needs without having to build up its own capabilities in all areas. For one of the firm’s products the marketing in Poland is done by the international pharmaceutical giant Pfizer— an example of a partnership which gives strong market access. In Celon-Pharma the decisions about partnerships are not automatic – rather it is a systematic process of choosing the optimum solution. “The time factor is also important” – says Maciej Wieczorek giving an example of problems related to patent protection – “without finding the right partner in time, the firm may not be able to carry out all of its testing on time, the patent protection period may elapse and new competition may enter the market. It happens all the time”.

Mother institutions are natural partners for spin-offs. The Institute of Biotechnology and Antibiotics is founder and shareholder of Bioton. But at the same time the Institute constitutes the main research arm of the company. The possibility of using the labs of the Jagiellonian University was the condition without which the firm Biocentrum could not have come into existence. For this firm the Faculty of Biochemistry, Biophysics and Biotechnology was the main technical and organizational support system but the partnership is not limited to the mere renting of the lab. Biocentrum also uses the logo of the University which is a very important advantage for a small company functioning in a market dominated by big, often global players. As we mentioned, at the beginning of 2008 Biocentrum was offered a strategic partnership with the company Selvita, which besides money also brought in projects and plans of research leading to possible radical innovations.

Biomed solves the problem of resources needed for innovation through cooperation with teams of scientists from outside the firm. Small new undertakings, such as the BioTe21 firm, are “condemned” to partnerships. Selvita, which was able to secure sufficient funding from the beginning, in order to increase development opportunities, seeks experience and complementary knowledge from its partner company Biocentrum. Mabion is an example of a strategic partnership created at the formation stage of the firm. A consortium of investors and founders brought in complementary resources: indispensable knowledge and scientific experience, experience in organization of lab production on an industrial scope, the management of research and development projects, strategic marketing, and finance. Mabion’s goal is to register its drug by the year 2012 – all test results must be ready by that date.

**OWNERSHIP AND FINANCING**

The relative advantage of high technology in the US as compared to Europe has largely resulted from a bigger and more developed system of venture capital financing. Since the Lisbon Strategy was launched in the EU, a lot has changed for the better in Europe. Policies of actively supporting academic entrepreneurship have been established. In Poland previously lack of financing opportunities forced biotechnology firms to conduct two parallel forms of operations – one focused
on securing current income and the other focused on research, development and break-through innovations.

In recent years as a consequence of Poland joining the European Union, large funds for research and development – in the form of open competition – are available to Polish scientists. Also because of additional initiatives of the Polish government new national funds are available. Such government programs as the “Technology Initiative” grant funds which facilitate and require partnerships between universities and firms. The private capital market has also ripened in Poland. Quite a few funds are now available to finance innovations at more advanced stages of development. Examples of such institutions include: Krajowy Fudusz Kapitalowy (National Capital Fund), various investment societies and capital groups. Besides, foreign venture capital, is active in Poland. Thus, the problem of innovation barriers is no longer a question of supply of funds, but rather of a deficiency of good cooperation between business and scientist-entrepreneurs. Of some importance is also the small number of big national firms ready to undertake commercialization of innovative products and services on a bigger scale. But in the global age this factor is not decisive.

Thanks to the fusion with Selvita, the small but wealthy informatics firm, Biocentrum- for years held back by lack of resources for development, now gains a new perspectives for growth and an opportunity of much faster implementation of its innovative projects. The firm Mabion, totally focused on the development of a new innovative drug, was formed from the initiative of a consortium of firms and investors, including Celon-Pharma. To the same category we can add the brand new firm Celther, founded by the larger company LEK-AM. Privatization and growth of Biomed Kraków would not be possible without external capital, but the real turnaround came thanks to capital investments made by members of the management board. As in the case of Mabion, the same persons played key roles giving the company strategic direction and at the same time providing crucial scientific and business expertise while also being able to secure investment funds. Grzegorz Stefanski, the company’s manager, is the co-author of several patented solutions. Self-financing of innovative projects through current activity of the firm is gradually being replaced by private capital. Bioton is the only Polish biotechnology firm that takes advantage of financing from the private capital group Prokom, from capital of shareholder investors and also from foreign funds such as Franklin Templeton. As the Polish biotechnology sector continues to mature, one can expect diversification and development of financing forms (seed funds, business angels, venture capital etc.). The sale of licenses for new drugs or acquisitions of Polish firms by a large Western firm will be the test of the success of Polish bio-pharmaceutics.

MANAGEMENT

The success of the biotech firm depends not only on good results from its scientific research and testing, the quality of company management is also a factor. The lack of professional experienced managers, who know how to deal with particular
challenges, constitutes a well known barrier to the development of biotech firms worldwide – especially outside of the US where the supply of experienced biotech managers is weak. It is worth mentioning that the importance of particular managerial skills changes with the development of the biotech firm – at the discovery and trial stages most crucial is the scientific knowledge and know-how of testing procedures both pre-clinical and clinical. Next comes knowledge of procedures linked to the registration of the drug with institution such as the FDA (US Food and Drug Administration) or their equivalents. Later come problems of production and marketing. During the whole process the manager needs to know how to secure money for the development and functioning of the firm and to manage all the partnership relations of different kinds. The typical mistakes of biotech firm managers include: misjudging the market value of the discovery (most often overestimation), postponing the decision to abandon an ineffective research project (typical mistake of scientists), omission of effective protection of intellectual property and unsuccessful partnership relations consisting of too much or too little control of the partner. Often excessive control over the biotech firm is surrendered to a consultant or financing partner – often a VC or a large pharmaceutical firm. The weaker the managerial abilities of the firm’s leadership – the greater the chances of making one of those mistakes.

A lot of problems linked to managing the biotechnology firm in the Polish situation were described above. The scarcity of experienced management personnel is especially salient in countries like Poland where there is not a single postgraduate program preparing managers in biotech and similar sectors. Such programs are well developed in the US and in Western Europe. Operating in the conditions of difficult financing the Polish leaders of biotechnology were forced to acquire not only the knowledge of how to manage the research and development side but – as was described earlier – more often than not had to take care of market oriented production and/or sales of services in order to be able to finance their innovative activity. The constant learning and managerial skills improvement were key factors of success. In the new, more “normally” financed biotechnology firms “production experience” may be of less importance. Of greater importance will be the ability of undertaking complex international partnerships in the global landscape of biotechnology industry.

DISCUSSION AND CONCLUSIONS

At the beginning of this paper we posed the broad question: how well Poland was building a foundation of success for the next major revolution which will usher in the era of the bio-economy. Although our study was limited to just six companies in the biopharmaceutical sector and did not include companies in industrial or agricultural biotechnology, the results permit some significant conclusions.

The case studies reveal important success factors of Polish biotech ventures showing in which ways they are similar to innovative companies world wide and
what are some important distinctive features that set them apart from biotechnology companies in the West.

We can summarize the key success factors of Polish biotech companies according to the list below. These success factors are also applicable to other branches of high technology industry based on the commercialization of scientific inventions:

1. At the time of choosing the business domain it is indispensable to combine two types of highly specialized knowledge: scientific expertise in the area of the targeted biotechnology (core business) and business knowledge of the market, commercial value of the discovery and of competitive risk. This scarce combination of competences in business and also in science is fundamental to the development of a vision leading to the right selection of goals and directions for the research and development effort and also for attracting investors. Although still scarce in Poland, such biotech entrepreneurs are able to operate successfully in the Polish market.

2. The Solution to the problem of acquiring and motivating employees consists in recruiting talent at the national level and in creating motivational packages which will not only attract the most gifted persons, but will offer them ongoing advancement opportunities competitive with universities and scientific institutions while at the same time giving them incentives to learn and gain business expertise in areas crucial to the firm’s progress. Polish biotech companies are able to attract talent and provide career opportunities that are often more attractive than in the academic sector.

3. Professional management of partnerships includes three competences of the manager: being aware of the need to create partnerships, ability of finding the right partners while being open to the whole world and capability of extracting the full benefits from a working partnership. The use of partnerships is growing in Polish biotechnology, but is still limited mostly to the national market. More international partnerships will be needed in the future.

4. The ability of taking advantage of ever growing national and international forms of financing of innovative enterprises. The old financing barriers forcing firms to pursue two parallel forms of activity – one aiming at securing income, the other concerned with research and breakthrough innovations – will become less important as the sector matures. However, under the conditions of the present global recession and lack of VC financing the “hybrid” model enables the Polish companies to survive.

5. Organizational learning is perhaps the most important factor of success and “dynamic capability” at all the stages of the firm. This continuous learning pertains to management and all personnel. Polish biotechnology companies demonstrate a remarkable ability to learn.

The company case studies also help us better understand and interpret the broad macro information about biotechnology development in Poland. Poland has
fewer dedicated biotech companies than Hungary or the Czech Republic. Total employment in Poland’s 20 biotech companies is 1172 of which 232 persons are directly employed in R&D. Interestingly the fifty Hungarian companies employ a total of 1192 employees of which 370 are in R&D – a higher proportion than in Poland [Dubin A. ed. 2007, Hungarian Biotechnology Association 2008]. Although Hungary has more dedicated biotech companies as well as somewhat more companies that are active in biotech related fields than Poland, biotech industry turnover in Poland is almost twice that of Hungary and Poland attracted more than twice the venture capital [Eurostat, 2006]. In evaluating Polish biotech, it should be added that the country graduates 1300 persons in various biotechnology fields annually and has recently instituted a variety of venture capital funds specifically designed to support academic spin-offs and high-tech start-ups [Dubin A. ed. 2007]. Nevertheless relative to the potential of the country’s scientific base and the size of its economy (GDP of $ 476 billion at average exchange rates for the year 2008, The World in 2010, Economist Publications 2009), the biotechnology sector is relatively underdeveloped. For example South Africa with a smaller GDP than Poland and similar levels of public spending on biotech research ($43 million) has 47 core biotech companies and three bio-parks under development. Thailand which has a smaller GDP than Poland, but also similar levels of public spending on biotech research has created 70 core biotech companies and has two sizeable bioparks [BIO International Convention, 2008. Country profile, South Africa; BIO International Convention, 2008. Country profile, Thailand] The implications are clear: Poland’s policymakers need to dedicate more resources to the life science based industries and to R&D. This is already happening at the local and regional level. In Kraków, Gdansk and Wroclaw efforts are under way to create life science clusters.

Our study shows that in spite of limited R&D spending, Polish entrepreneurs have achieved success in creating and developing biotech companies – most of which have survived and grown (there a few known cases of Polish biotech companies that have gone bankrupt). Unlike the capital intensive model focused on exit strategies prevalent in the West, Polish biotech companies have shown a remarkable flexibility and long term orientation and have survived often using revenues from competitively priced products or services to finance internal R&D. Such a hybrid model may carry lessons for European biotech companies today – many of which, especially in the UK – are going out of business due to lack of VC financing in the present global recession. It is the innovators and entrepreneurs who pave the way to the future. Under improved conditions of a reformed scientific establishment with greater resources Polish biotechnology could indeed enjoy a bright future.

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SUMMARY

In this paper we set out to provide a case study based assessment of the Polish bio-pharmaceutical industry. First, we assess the most important barriers to the commercialization of inventions in Poland. Than, we critically review existing statistical reports of the Polish biotechnology sector. Finally, we follow with interview based case studies of selected innovative firms in the sector of health biotechnology and identify the critical factors of their success.

Out of the small population of 20 Polish biotech companies six firms were selected (a 30% sample) and judged to be representative for the sector in Poland: one big firm, two medium sized firms, and three small ones.

We show how this representative selection – in spite of numerous barriers – Polish inventors and entrepreneurs often coming from the academic community is able to achieve success. Finally, we compare the progress of Polish biotechnology with the condition of this industry in other emerging economies.

Keywords: biotechnology industry, science based business, innovation, emerging economies, Polish biotechnology firms.