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Sustainable business evaluation methods: applying real options in the biotech and med-tech industry¹

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ABSTRACT

This study examines the projects' evaluation instruments utilized by the Bioindustry Park, the managing company of the innovative cluster called bioPmed that is dedicated to bio and medical technologies (Italy). This biotechnological and med-tech cluster expresses the will to concentrate the know-how of the territory in a restricted area with a high concentration of structures and facilities for the development of firms. The projects of the innovative companies and start-ups are principally based on products development both in biotech (pharma and diagnostic) and in innovative medical technologies. Long development processes, regulatory requirements, potential patent issues, strong competitive environment, are main elements of such markets. Evaluation plays an important role for these companies, both to raise funds, that can be a key factor in order to develop alliances and partnerships. However, for the same market elements, the evaluation process is difficult and risky. Too many variables have to be considered in a long timeframe.

Effectively, recourse to the real options' method stimulates investment to build sequences of long multi-stage (i.e. continue or abandon the project, reduce or increase the investment). So this method can be particularly useful to identify risks with greater awareness and to select the biotech and med-tech projects that more than others can guarantee the businesses' sustainability.

Keywords: social innovation; real options; biotech and med-tech industry.

1. THE SUSTAINABLE DEVELOPMENT IN BIO-SCIENCE PARKS

The most relevant and quoted definition is the one from the report entitled, “*Our Common Future*”, published by the WCED (*institutional version*): «*Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs*» (the “Brundtland Commission”, 1987).

The modern concepts of sustainability began to take shape during the 1990s. Recent years have seen a proliferation in the business and management literature, with an explosion even of the international literature, in which sustainability is the main theme and is used to describe problems related to technology, economic development and managerial approaches in various areas such as ‘*sustainable technology*’, ‘*sustainable economics*’, ‘*sustainable business*’ and ‘*sustainable agriculture*’. Thus, in order to progress toward ensuring a sustainable economy, various key areas have been explored, such as environmental effects and the consequences for nature from unconstrained economic growth, along with the prospects for economic activity that takes greater account of the social and environmental consequences of market behavior (Lovins et al., 2007).

The concept of sustainability is often associated with the term social innovation. «*Social innovation refers to new ideas that resolve existing social, cultural, economic and environmental challenges for the benefit of people and planet. A true social innovation is system-changing –it permanently alters the perceptions, behaviours and structures that previously gave rise to these challenges. Even more simply, a social innovation is an idea that works for the public good*». (Centre for Social Innovation, 2008). In this context, the institutions and the governance relations

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at the regional and local level have a fundamental role in promoting sustainable growth. In particular we have to underline the role of science and technology parks in the generation of firm level social capital through university-firm relations (Wang, Shapira, 2012).

The term of “life sciences research” is associated with an industry extremely dynamic. For instance, even in international crisis times Italian biotech companies show an ability to grow and optimize the investments in terms of value creation (Assobiotech, 2013). The strength of biotech companies lies in extraordinary potential of the technologies that, once developed, can potentially be used in different industrial sectors; in order to increase efficiency and quality, in respect of environmental impact, is necessary consider the role of biotech clusters and of scientific parks.

Since that “*Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services*” (OECD, 2003) and, in average in Europe and moreover in Italy, biotechnology companies are usually at an early stage or, in any case, are SMEs (is interesting that the 77% of biotech companies are micro - no more than 10 employees - or medium size – no more than 50 employees - enterprises)², during years bio-scientific parks arose in various territories. The aim has been to concentrate single efforts for creating synergies among realities which, if alone, would have been weaker and would have found bigger problems in developing their activities, starting from the research of funds in order to developing the research at the base of the business idea. So, which is the role of a science park? If we consider the case of the Italian territory, is easy to underline that the development of the innovative activities has always been characterized by a limited presence of start-up, if compared to what has been happening abroad. This fact, combined to the strong.

Before to focus on parks and more in general clusters actions on the environment in which they are, is interesting to consider that three kinds of advantages are also identified by Porter (1998), when we talk about clusters: productivity advantages (reduction of transaction costs), innovation advantages (biotech clusters that mostly mainly arose near research centres of excellence in biotechnology-based disciplines), and new business advantages (the role of environment in the creation of new biotech companies). Prevezer and Stout (1998) identify other advantages concerning the demand side: input-output multipliers (strong local demand), hostelling (spatial competition), search costs, and information externalities (transfer of tacit knowledge between people working within a cluster. On the supply side, major advantages are: technology spillovers, specialized labour and, infrastructures.

Biotechnology is a set of enabling technologies that have applications in various industrial sectors, and could change and innovate already implemented process lowering impact on use of renewable resources. It is therefore easy to understand why the European Commission reserves the bio-economy as a winning strategy to accelerate the transition to a new economic model, based on smart, sustainable and inclusive growth.

Eventually, the constitution of territorial clusters – in which are fundable scientific parks and start-ups incubators - is, therefore, an essential step, both for support the growth of the Italian biotech and to promote economic development and competitiveness at regional and national level.

This is even more true in a sector in which the efficiency and effectiveness of research has more to do with the intensity of the flow of knowledge with dimensional aspects. Clusters and parks also play a key role in harmonizing and enhancing the different regional, national and European level to support innovation. Moreover, the importance of clusters and bio scientific parks is demonstrated by the fact that, despite financial conditions and the average dimensions of innovative firms, Italy is at 29th place as innovations according to the Global Innovative Index (2013).

Each territory promotes and subsidizes those skills that are part of the own tradition, for example

² Assobiotec (2013).

the pursuit of high technology has always been a factor of excellence of Piedmont Region in Italy. As well as the great development of the automotive, telecommunications and information technology over the years has resulted in a growing demand for skills with a high degree of technology, contributing to the emergence of modern history the Polytechnic University of Turin , the same need for technology - but this time in field of life sciences - has seen, in more recent times (since the late 90), the development of the School of Biotechnology of the University of Turin (MBC) , research center of excellence. To meet the needs of the pharmaceutical firms in terms of give the research in outsourcing (Büchi et al., 2010), and to make them willing to invest in the poles of excellence, the Piedmont region from the end of the Nineties he worked to the realization of works of incentives and promotion of university research , so that this will interface with more and more local businesses. Move the research on its territory, make sure that the start-up meet the big businesses and promote local search, it means being for the territory. Moreover is to consider that if large companies are opting to outsource basic research, this could take not only to create capital but also new jobs opportunity, ability to create new structures, well-being. They are therefore engines of the local economy (Almus, 2004).

Moreover, the fact that a scientific park and more in general a cluster, in general, is mainly composed by many little realities, all together, means that geographical proximity played a key role in network formation, company growth, and knowledge diffusion (Salvador, Mariotti, Conicella, 2012). Eventually, the existence of clusters and parks has frequently been identified in the literature as an important factor in regional development (Porter, 1990, 1998; Buchi, Casalegno, Pellicelli, 2010; Salvador, Mariotti, Conicella, 2012). Above all Porter (1990) writes about the importance for small and medium firms to be bounded in specific territories. In which way the territory contribute to the competitiveness of its territorial for profit realities? To understand it better, is useful to consider the Italian reality as item. According to results coming from Assobiotech (2013) analysis, science and technology parks are playing an increasingly important role in the development of biotechnology, especially in a very delicate phase represented by the technology transfer, that is when scientific research results can represent the base of some industrial applicability.

Concerning the studied reality, Piedmont Region presents important data, considering the presence of bioPmed cluster in which Bioindustry Park science park play a key role. bioPmed work in an environment where investments in venture capitals national and international - including some seed capital initiatives (Piemontech and Eporgen) - as well as the presence of specialized incubators and science parks (2I3T, I3P, ENNE3, Incubator, Bioindustry) are elements of internal dynamics. Moreover, bioPmed has the goal to have a positive impact on the regional innovation system, in synergies with the implementation of specific strategic initiatives at regional level – such as Bioindustry Parkand "Health City initiative" - the international positioning, planning system based on a European scale and on cooperation agreements with neighboring land areas, such as the Rhone-Alpes district

2. THE SCIENCE PARK ROLE IN ATTRACTING CAPITALS CAPABILITY

As shown above, science park could play a key role in creating links with other territories and in attracting risk capital and in supporting the creation of trans-boundaries partnerships and company alliances (Semrau, Werner, 2014). Since a high development degree is considered when talking about a biotech firm, is fundamental to understand the reason why we are talking about alliances: they can help these firms share resources and technological knowledge in order to create new products and technologies (Gopalakrishnan S., Scillitoe J.L., Santoro M.D., 2008).

Who can attract capital? And who can make capital raise if the investment in Italy has always been

perceived as too risky (Buchi, Casalegno, Pellicelli, 2010)?

The science parks are catalysts in attracting capitals. As Assobiotech (2013) states, the localization at a business incubator or in a science park is often the only opportunity for the birth and growth for a business in the biotech industry for a number of reasons among which surely the availability of financial instruments and the need to confront a global market. In this sense, PST, beyond the offer localization, are able to give concrete answers through the attraction of seed financing necessary to support the activities of the new businesses in their first years of life and allowing access, right from 'beginning, at a national and international network of professionals.

Concerning Piedmont reality, by focusing on the territorial system of Piedmont, despite a rapid growth of the importance of biotechnology research, is possible to analyse lacks of the entire system concerning the systemic problem of venture capital in Italy not easy to solve. If this is true in general for other sectors of the Italian economy, it is even more true for the life sciences whose research is evidently perceived as a risky investment not only by the Italian lenders, but also and especially by foreign ones (Buchi et al., 2010; Dotzler, F., 2012; Klačmer Čalopa et al, 2014; Korosteleva et al, 2011; Stucki 2013).

The development of internationalization actions considered above may represent a response to the deficiency; is useful to consider works in progress in the center of the Bioindustry Park, in which research funds, as well as infrastructures and facilities funds, comes mainly from the private sector (70% of the total amount), rather than the public one (30%) (Buchi et al., 2010).

Since for Italian biotech firms is difficult to attract capital, the role of bio parks and scientific cluster is fundamental in order to develop the territory awareness and to build long term national and international relationships. Eventually the final question is: how to find a good way to evaluate firms and their project, in a business model driven by a very long term run?

3. REAL OPTIONS AS SUSTAINABLE EVALUATION METHOD IN THE BIOTECH AND MED-TECH INDUSTRY

The projects of the innovative companies and start-ups are principally based upon products development, both in biotech - pharm and diagnostics - and in innovative medical technologies. Long development processes, regulatory requirements, potential patent issues, strong competitive environment are main elements of such markets.

Evaluation plays an important role for these companies, both to raise funds, which can be a key factor in order to develop alliances, and partnerships.

However, for the same market elements, the evaluation process is sometimes difficult and risky.

In this overall context, it is necessary to analyse continuously:

- *risks and potentials* of each project;
- available *resources* for each project;
- *comparison* of the potential of different projects.

Therefore, in the biotech and med-tech particular fields it can be more useful to evaluate the single projects in order to guarantee sustainability of innovative start-ups in the biotech and med-tech industry and use the real option method, that is more dynamic than traditional approaches and capable of competitive strategies in an uncertain environment.

As a number researches have shown, environmental discontinuities can make a firm's investment - in specific technologies, markets, or business models - obsolete (Henderson & Clark, 1990; Eisenhardt & Martin, 2000; Zollo & Winter, 2002; Vassolo et al, 2004).

Besides, the initial investments for the projects are not rarely very expansive and the firm's management has to adapt and revise investment decisions in response to market developments.

The term ‘*real options*’ indicates the ‘*nodes*’ in which the management can decide whether to continue to invest, abandon or change the amount of the investment.

As a financial option gives the right, but does not involve the obligation to buy or sell financial assets, real options give the management the right, but not the obligation to proceed in the sequence of the phases of an investment.

If an investment has more stages of progress, following the end of each stage the management has new information; may decide to continue or abandon; can assess whether the project is likely to add value or not.

Lueherman (1998), by comparing the methodology of real options valuation with the Net Present Value (NPV), writes: “*In financial terms a business strategy is much more like a series of options than it is like a series of static cash flows*”.

Morin and Jarrell (2000) argue that resorting to the theory of real options to build sequences stimulates investment along several stages (continue/abandon, reduce /increase the investment). This can help to identify risks with greater awareness. Anyway we need to outline the possible risks in using real options with an evaluation method.

The implementation of the whole process could encounter four major risks:

1. risk of developing a product that meets the expectations of the market;
2. the risk that a question arises with the volumes and rates of growth than projected;
3. the risk that the strategies of competitors conflict to launch the new product;
4. the risk of the advent of a new technology that makes it more convenient not what you plan to adopt.

The management can estimate the initial investment, but it is not able to predict the extent of subsequent adjustments that may be forced to do. It can, however, identify a set of critical strategic decisions that may be forced to take.

The risk in proceeding in stages is thus less than what is assumed in the analysis NPV, and this risk is embedded in the cost of capital by estimating the same.

Is very difficult to apply a real option based methodology in biotech sector, at list is very difficult to prove that this is the most effective reasoning in evaluating long run project value creation. This happens because the high innovation degree present in every biotech and medtech project. On the other hand is useful to remember evaluation methods tell investors or potential investors “whether it is worthwhile to risk the bet and how much you should bet, but it does not tell you whether you are going to win”. (Villinger, Bogdan, 2005). Knowing this, when is necessary valuation applicable?

According to various authors (Denison, C.A.; Farrell, A.M.; Jackson, K., 2012) “The most popular, widespread methods of evaluating long-term investment decisions are internal rate of return and net present value analysis”. In addition, the classical managerial approach rather concerns the concept of *discounted cash flow*, even if various authors sentence that this could be not the most suitable way to evaluate high tech projects (Villiger, Bogdan, 2005).

The attempt of the present paper is to show, starting from the analysis of the literature, that it is possible to use real options in order to estimate, considering the presence of the prototype – which is the result of an already financed long standing research, after the approval of a business plan – which can be the most suitable path in order to reach profit. While in DCF calculations the estimated future trends are a given numerically, in real options valuation the sales estimate fluctuates. The degree of this uncertainty is called volatility (Villiger, Bogdan, 2005).

The construction of a model, of a simple (even if limited) model can help evaluators to understand which path is advisable to finance.

4. REAL OPTIONS AND DECISION TREES FOR RESEARCH PROJECTS IN LIFE SCIENCES

The objective is to define a tool/methodology that permits the identification and valuation of hypothetical development paths related to a research project and consequently to determine the most promising scenario. Such methodology has to be easy to implement, it has to consider the main (not all) scenarios and has to be considered a tool to identify suitable development path for a project results. The methodology is not conceived as a company evaluation methodology but instead a decision support methodology. The methodology components and steps are structured in: 1) Decision trees, 2) Parameters and score, 3) Identification of the most promising scenario.

4.1 Decision trees (applications and related final markets)

The first step consists in designing a decision tree that represents all main possible development strategies for a technology starting from results obtained at an early stage of the research project. The objective is to develop the decision tree until to reach final markets. This concept is based on the fact that a technology can find applications in different markets.

The second step is to attribute a score (intermediate score) for any development paths chosen at each intersection (node) based on the evaluation of different parameters.

4.2 Parameters and score

Parameters used to determine the intermediate scores can be classified in 5 main categories:

- Team: evaluation of the capacity of the team to bring the technology to the market.
- Intellectual property: evaluation the project in terms of legal property according to the status of the claims and the geographical coverage.
- Time: evaluation of the remaining time to reach the market based on the typology of the technology, the development stage and the age of the patent portfolio.
- Risk: evaluation of technological and regulatory risks based respectively on failure rate and requirements needed for health authority approval.
- Market: evaluation of market environment related to the project based on market size/appeal, competition and freedom-to-operate.

For each parameter, that has to be assessed in a subjective way, a score from 1 to 5 is attributed (except for some criteria that better require a ranking from 0 to 5, for example criteria related to intellectual property).

The intermediate score corresponds to the association of the scores obtained for each parameter.

4.3 Identification of the most promising scenario

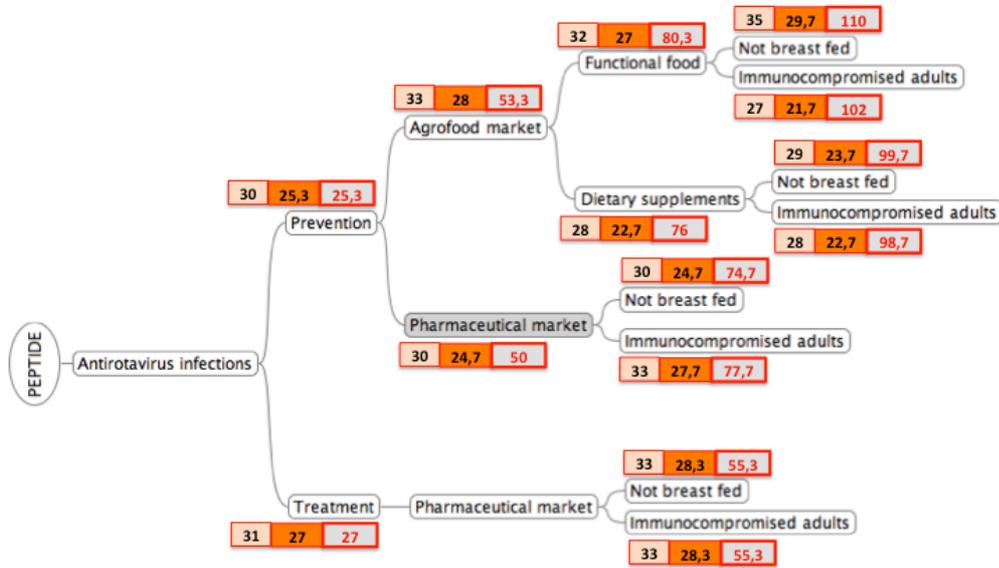
For each single hypothetical path, a final value (or final score) that corresponds to the association of intermediate scores obtained at each intersection is determined. The research project's best paths are defined as those that have obtained the highest final scores.

4.4 The experiment

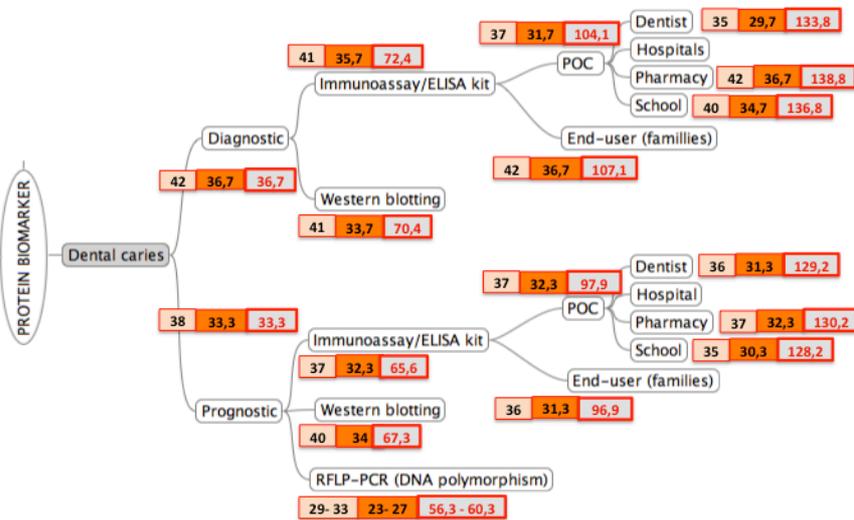
The methodology previously described was tested on three research projects:

- 1: A peptide to treat or prevent a viral infection (Iaro);
- 2: A protein used as a biomarker for the prognosis/diagnosis of dental carie (TrCD);
- 3: A protein used as a biomarker for diagnosis of auto-immune diseases and development of a therapeutic approach (I-Data).

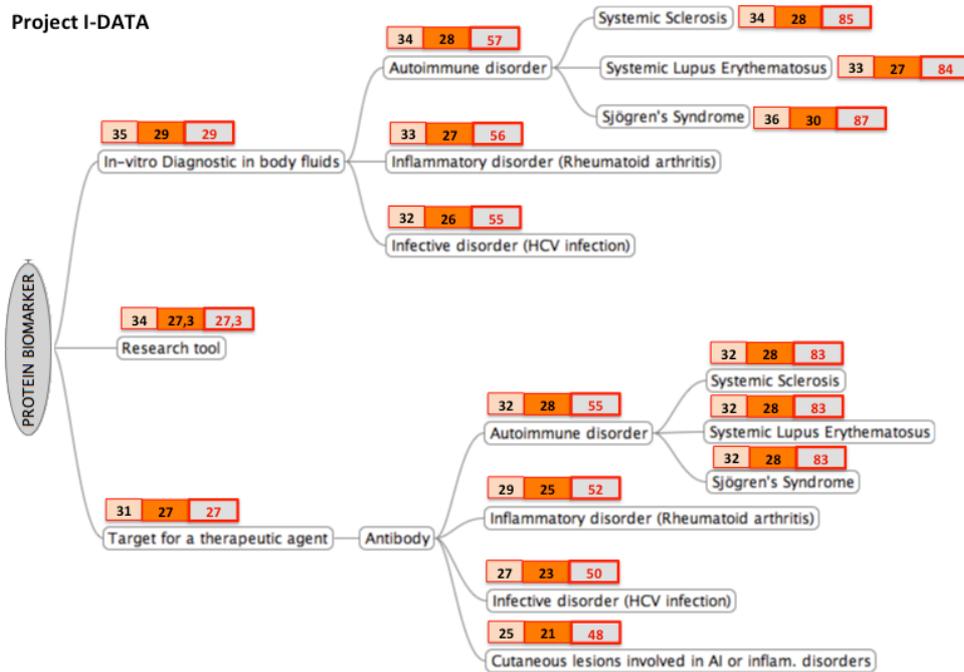
Project IARO



Project SMILE



Project I-DATA



5. CONCLUSIONS

In conclusion the real options' method can be used for the projects evaluation and to guarantee the sustainability of innovative companies and start ups in the biotech and med-tech industry. Recourse to the real options' method stimulates investment to build sequences of long multi-stage (i.e. continue or abandon the project, reduce or increase the investment). This method can be particularly useful to identify risks with greater awareness and to select the biotech and med-tech projects that more than others can guarantee the businesses' sustainability. However, once the industry has overcome the beginner's problems of this valuation method, biotech companies (as the ones considered in present cases) and scientific parks management need to take real decisions in terms of project and portfolio management (Villiger, Bogdan, 2005), license contracts and empirical evaluation of the market potential with real and proved arguments rather than a vague experience.

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