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# START-UP MID AND LONG TERM STRATEGIC MANAGEMENT USING A BUSINESS MODEL PORTFOLIO

PX Therapeutics and its dynamic approach to business modelling

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Vincent Mangematin (Grenoble Ecole de Management)

The management of a portfolio of Business Models can help high technology SMEs make strategic decisions. This chapter highlights the use of methodology based on a portfolio of Business Models to ensure the medium term development of a company and its long term development, using a balanced grid of Business Models. The case used to illustrate the approach shows how PX'Therapeutics, a French biotechnology company, built its strategy and translated it into its portfolio of Business Models. This grid positions the level of promise and the level of risk for each Business Model. The latter, represented graphically, enable a manager to show the balance of the portfolio.

### **INTRODUCTION**

Small and medium companies in the high technology area are often confronted with a number of specific issues: risk levels in fast changing environments, large investment requirements, launching of R&D projects with uncertain outcomes, etc. Here tools used to assist in decision making, more specifically those related to the managing activity portfolios or programmes often show their limits. For example, a portfolio approach according to the Boston Consulting Group matrix is difficult to apply for a high technology SME; one of the limits of the BCG matrix is that it positions the company according to its market share as compared to the market leaders. However, comparing a microelectronic start-up to the giants of the semiconductor world limits the attraction of the market. Another example is the Arthur D. Little matrix whose drawbacks are that it's long to document and the subjectivity of evaluators can significantly impact results of analysis. All tools used for strategy development can be criticised, the main thing is to use those tools that are adapted to the context of the company. For a high technology SME, the tool proposed is easy to use, helps balance medium term turnover and long term R&D investments. A portfolio of Business Models is defined as the range of opportunities for a company to provide value to its clients whilst ensuring its medium term viability and long term development. This approach is illustrated by the example of PX'Therapeutics (which we will call PX). Initially PX was a start-up from spun-off from the Institute of Structural Biology in Grenoble (France). The company was created by Tristan Rousselle and Nicolas Mouz in 2000, and operates in the biopharmaceutical industry. We see in this chapter how PX created its portfolio of Business Models, first as a result of an initial analysis in 2004, and then in 2010.

The use of a portfolio of Business Models seeks to balance the level of promises made to stakeholders with the level of risk, for each Business Model, and at a company level, to ensure medium-term viability and long-term development. The level of promise here refers to the expected turnover. The risk level is more complex and takes into consideration risks related to interdependency between the company and other organisations, risks related to feasibility and technical implementation and risks related to financial investments. We also have to evaluate the impact of each criterion (low - medium - high) taking into consideration the characteristics

of the industry, as we'll see in the case of the biopharmaceutical industry. A balanced portfolio should over time associate Business Models with low or medium risk levels but with a medium level of promise for the medium term, and more risky but more promising Business Models for long term development.

# 1- The context of the biopharmaceutical industry

1 The OECD defines biotechnologies as: "The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."

2 LEEM report, 2008, L'industrie du médicament en France, Réalités économiques 2007.

3 Source Ernst & Young for France Biotech, Pano-rama 2006-2007 de l'industrie des biotechnologies en France.

Biotechnologies¹ can have application in many areas such as health, agro-food, renewable energy, cosmetics, etc. In this chapter we concentrate mainly on the biopharmaceutical industry which is currently the main application area for biotechnologies. French biopharmaceutical companies had an annual turnover of around 45 billion Euros in 2007, of which 47% was exported². This turnover has been continuously increasing over the past twenty years. In 2008, 107 new drugs derived from recombinant proteins and monoclonal antibodies were commercialised worldwide. 76% of the market for biotechnology companies is the United States against 16% in Europe, and 82% of R&D is carried out in the U.S. against 13% in Europe³.

In the biopharmaceutical industry the highest level of promise is that of the blockbuster, in other words a drug that generates over a billion dollars of turnover for the company that markets it. For example drugs for diabetes guaranty this kind of turnover: the number of diabetics in the world is huge and growing continuously. Other drugs treat less common diseases and have an average level of promise. We also need to consider companies that offer services, or equipment, to other companies. They may have low to medium levels of promise (compared to that of a drug reaching the market).

# [!] The level of risk takes three criteria into account:

The level of interdependence. When a company requires external competencies for its business model, it becomes interdependent to one extent or another. If the competencies are easy to acquire on the market, then the dependence is low; on the other hand if they are specific then the company will be closely linked to the partner that provides them and the dependence will be strong. In this case, keeping control over company's activities becomes more complex, as well as the capacity to capture value from the activity, which has to be shared with other actors.

[!] The level of technical risk. For a given drug the risk level increases with the dependency of the activity on the success of the drug. Drug candidates can fail at any stage in their development (see fig 1: the external value chain of the drug). In other words, a Business Model based on product discovery and development will have a higher technical risk, compared to a Business Model based on process optimisation.

!! The level of financial risk. When a company has to invest in equipment, manufacturing plants, clinical testing, Intellectual Property Rights, etc., the resulting investment can be extremely high, increasing financial risks. In addition, the time between investment and return on investment can be very long indeed: the development of a new drug can require from ten to twelve years. This further increases the risk perceived by investors.

The development of new medication is done in five phases (Fig. 1): a therapeutic molecule is discovered through fundamental research, it's then studied in an applied research phase to become a drug candidate. The molecule is then tested on animals during preclinical trials. The phase I and II clinical trials involve testing on humans to adjust doses and detect eventual secondary effects. The phase is used to prove the effectiveness of the drug candidate on patients. At the end of

this stage, the medication has to obtain an authorisation to be marketed provided for example by the Afssaps in France or the Food and Drug Administration in the United States. It takes from 12 to 15 years of development and tests to get from the fundamental research phase to a molecule being available on the market. In addition to the very long development lead-time, the investments are colossal; a new molecule costs on average 1.2 billion US\$ .

Fig. 1: External value chain for the medication



Companies today have three major types of activity (Figure 2) which correspond to several Business Models. Below we describe each of the Business Models that can be used to make up a portfolio with their graphic representation and a grid (Table 1) with the two analysis dimension: promise and risk levels.

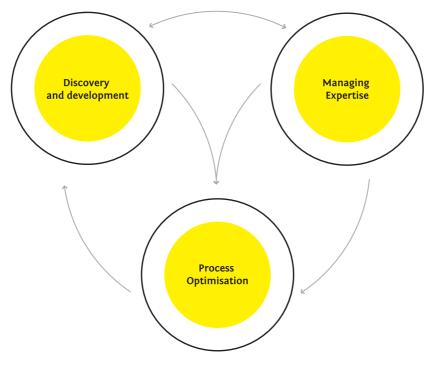


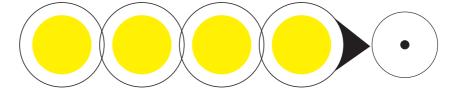
Figure 2: Three major types of activity

### Main activity 1: discovery and development

Discovery and development of drugs constitutes the main activity of the industry. The Business Models based on development are generally perceived to be the most lucrative.

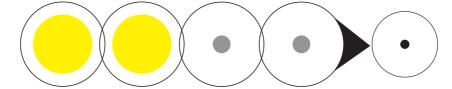
The total integration Business Model is a reference in that it's the best known and the most widespread. The company develops drug-candidates from research up to marketing the drug. The large companies that use this Business Model often set-up alliances with other companies, however, thanks to their size and control over the value chain, their level of dependency remains low.

# Total Integration Business Model



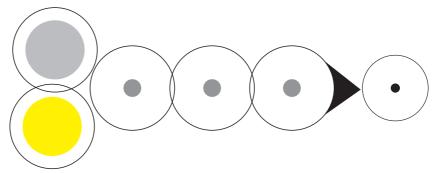
In the case of partial integration, companies carry out part of the development of the drug. For example, they could develop a molecule discovered internally up to the pre-clinical trial phase and then resell it to another company.

# Partial Integration Business Model



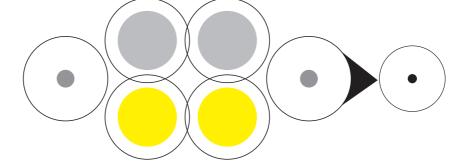
A considerable number of companies are organised to work in the "collaborate in the discovery phases" mode with other companies, or laboratories. The Business Model goes over the company's boundaries and needs to take into account the close collaboration with partners

# Collaboration in Exploration Phases Business Model



The co-development Business Model is also based on collaboration but in this case over the development phases. Various forms of co-development are possible from development in parallel to the creation of a joint-venture between partner companies.

# Co-Development Business Model

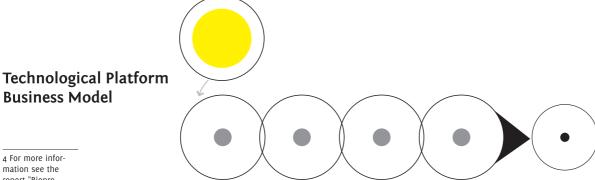


### Main activity 2: Process optimisation

Process optimisation concerns all of the Business Models that focus on the improvement of one stage, or another, of the development process. As the market is a growth market, and the development of new drugs requires a considerable number

of different competencies, a considerable number of companies have chosen to specialise in one or more of the development phases.

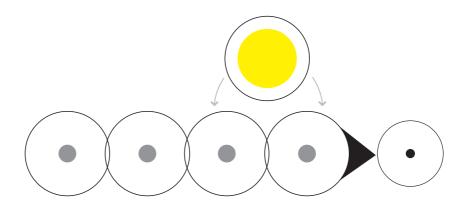
The technological platform Business Model is based on providing high level services in research and development. This type of model proposes a high level of expertise at the beginning of the external value chain. Several types of technological platform exist i.e. open technology platforms, owner technical platforms etc., but they all have in common the fact that they provide the service of technology development based on specific expertise.



mation see the report "Bioproduction en 2008. état des lieux et recommandations pour l'attractivité française". LEEM and the Génopôle. http://www.leem. org/dossier/101/ etude-bioproduction-en-2008-etatdes-lieux-et-recommandations-pourl-attractivite-1297. htm.

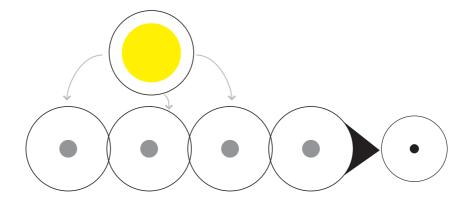
The term CMO, for Contract Manufacturing Organisation, designates a Business Model aimed at producing preclinical or clinical batches or drugs. The production capacity for biotechnologies in France is largely insufficient in comparison with demand levels<sup>4</sup>. This Business Model requires production capacity conform to international standards and certified GMP (Good Manufacturing Practices), a certification which is obligatory in order to be classed a pharmaceutical establishment.





The term CRO, *Contract Research Organizations*, refers to Business Models based on providing services in research but without production, and this is generally done at the beginning and the middle of the external value chain. For example, carrying out pre-clinical tests is part of the CRO services.

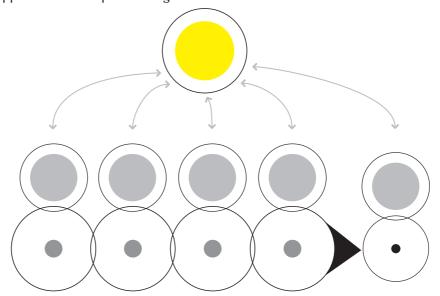
Contract Research Organization Business Model



# General Activity 3: Managing Expertise

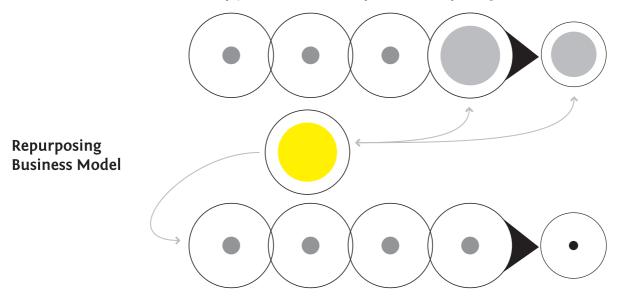
Coordinating or combining know-how is the common denominator of the Business Models related to re-organising know-how, coordinating networks, leveraging or coordinating work with outside expertise. These companies create value by linking different organizations, or by reorganizing different stages of drug development.

The virtual activity Business Model involves the coordination of networks of partners and suppliers to develop new drug-candidates.

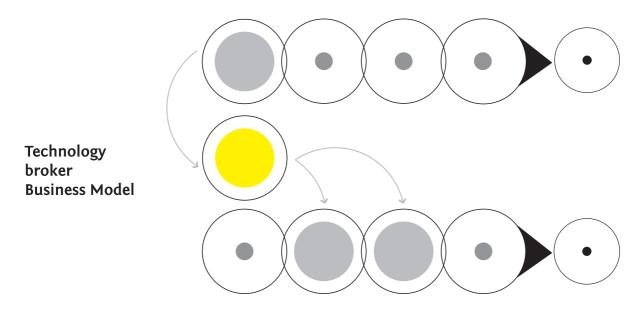


Virtual Activities Business Model

The "repurposing" Business Model involves taking a molecule under development in another company, or already on the market, and developing it for new therapeutic applications. An example would be to use a drug originally intended to combat sleep disorders to develop an application to fight acute inflammation disorders. The new clinical trials to be carried out are less complex and faster, because the molecule has already proved its non-toxicity and efficiency in a given situation.



The Technology Broker Business Model works in a similar way to stock brokers or brokers. They provide links between different companies or organizations. They may, for example, look for buyers for a company that has a pipeline of drug candidates.

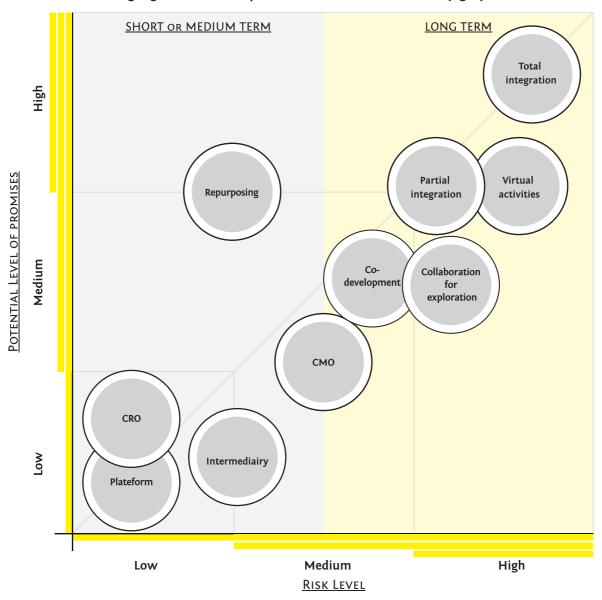


These ten generic Business Models have different levels of promise and different risks. Companies need to adapt Business Models according to the opportunities and specific situations of their own organisation.

Table 1: Impact table for each Business Model

Business Model	LEVEL OF PROMISE	RISK LEVEL (detailed)			RISK LEVEL (general)
		Interdependence	Technical Risk	Financial Risk	
Total Integration	High	Medium	High	High	High
Partial Integration	Medium to High	Low	High	High	High/Medium
Collaboration for exploration	Medium	High	Medium/ High	Medium	High/Medium
Co-development	Medium	High	Medium/ High	Medium	High/Medium
Technological platform	Low	Low	Medium/ Low	Low	Low
CRO	Low	Low	Medium/ Low	Low	Low
СМО	Low to Medium	Low	Medium	Medium	Medium
Virtual activities	Medium to High	High	High	Medium	High
Repositionning	Medium to High	High	Low	Low /Medium	Medium/ Low
Technology intermediary	Low	High	Low	Low	Medium/ Low

# Representing the level of promises and risks in the form of a diagram highlights the various positions of the Business Models (fig. 3).



A balanced Business Model portfolio involves having Business Models for the short to medium term with low to medium levels of promise and risk, and Business Models with higher levels of promise and risk for the long term (see the separation between the two zones of the diagram in Fig. 2). In particular, for SMEs in this sector it's difficult to support long term development without having Business Models that ensure short to medium term profitability. The case of PX'Therapeutics illustrates how a small company uses this approach to ensure its development.

#### 2- PX Episode 1: A Business Portfolio to support growth

In 2000, PX was created and implanted in a science park in the high technology city of Grenoble in the French Alps. This region hosts two internationally competitive research clusters: the MINALOGIC cluster, which specialises in products and services around smart miniaturized solutions for industry; and LYON BIOPOLE, a centre of excellence for vaccines and medical diagnosis.

From the outset, PX based its activity on its expertise in the engineering of recombinant proteins<sup>5</sup> using two Business Models from the research platform's model. The first is the open-platform Business model. Here PX uses IP free technology and capitalizes on its know-how. The clients (companies and public laboratories) use PX

<sup>5</sup> Proteins are macromolecules present in living organisms and essential for their well-being. >>>>

>>>> They can be used in diagnosis techniques, laboratory equipment and drugs. The term therapeutic protein means proteins that are at the heart of a drug. These proteins are complex to produce and stabilize. But it is now possible to produce a given protein in vitro by inserting its gene into a bacterium. or a yeast, insect or mammalcell. The resulting protein is called recombinant protein. the term used to identify proteins produced by cells whose DNA has been altered.

to carry out stages of the engineering process. The second is the shared platform Business Model (a mixture of platform and collaborative models), in partnership with the Institute of Structural Biology. This latter platform allows costs related to purchasing equipment to be shared. This, in turn, enables PX to provide a new offer to drug developing clients: the high-speed production of proteins. With the two Business Models, the level of promise in terms of turnover is relatively low, but the risk is too.

From 2000 to 2003, the company developed its expertise and capacity to produce proteins. Its turnover grew steadily along with its workforce: from 14 employees in 2002 it went up to 25 in 2003, while turnover increased from 600 000 euros to 2200 000 euros over the same period. The portfolio profile over this period supported growth of both the payroll and turnover, which was multiplied by a factor of four. At the end of 2003 the management team decided to add another Business Model to the portfolio in order to increase the level of promises.

## Three possibilities were identified:

The research for new antibiotics targeting bacteria more specifically. The approach is innovative but requires considerable technological development. To carry this out PX would have to work with a public research laboratory and find a way to create value out of the molecules produced. This would involve a Business Model based on a discovery and development activity.

The discovery of new antifungal targets: PX participates in a collaborative project, funded in part by public institutions, and whose aim is to build a range of their own proteins as drug candidates. If the project succeeds, PX will also find a way to create value from these proteins by selling them to pharmaceutical companies.

The production of therapeutic proteins according to GMP standards. This project requires considerable investment but will allow larger scale production, sufficient for pre-clinical and clinical tests. The main activity here would involve process optimisation.

PX to continue to develop along the lines of process optimisation. It's still a young company, capable of investing, but the investments wouldn't be sufficient to set up an activity based on the discovery of molecules and the development of drugs. Also, the team believed that it would be through synergy in their Business Models that the company would be able to provide a more attractive value proposition to its clients. The managing team therefore started work on building synergy through a balanced portfolio of Business Models, creating synergy either in terms of complementary value propositions or resources used, or by being based on the existing activity of the company.

At this point, PX was able to engineer therapeutic proteins for clients and could in addition produce them in small quantities for applied research. The next logical step would be the production of clinical batches for preclinical and clinical trials. This new Business Model is based on existing activity and, in addition, provides a complementary value proposition. By drafting a Business Model impact grid, it appeared that the promise level was more interesting and there was a corresponding small increase in the risk level (table 2, fig. 4). The choice was therefore made to set-up a production subsidiary in order to produce clinical batches. This new model was launched in 2004 under the name of PX'Pharma.

Table 2: Impact table for the 2005 Business Model Portfolio

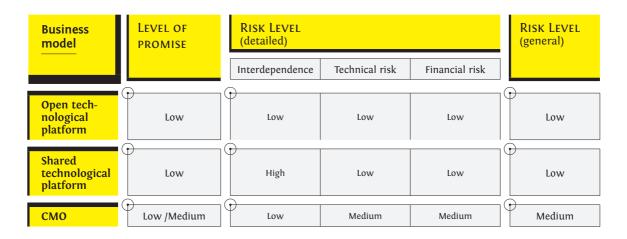
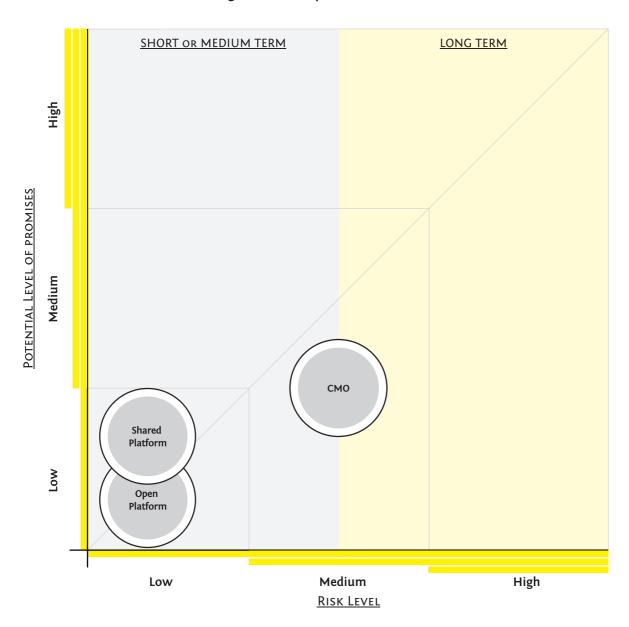


Figure 4: The PX portfolio in 2005



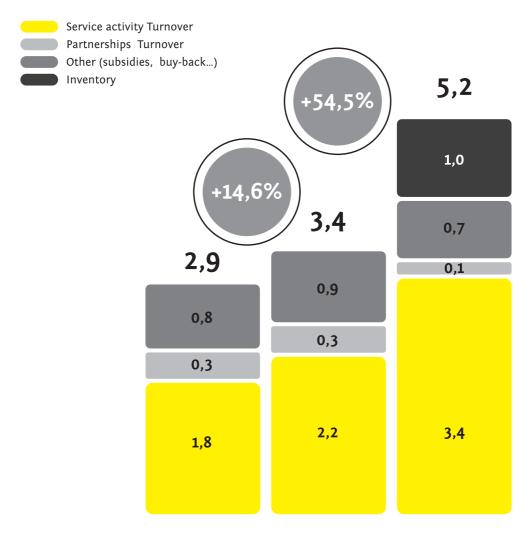
6 Agence Française de Sécurité Sanitaire des Produits de Santé. Equivalent to the Food and drug administration in the US In January 2005, PX'Pharma was recognised officially by the AFSSAPS<sup>6</sup> as being a pharmaceutical organisation. This approval allows PX'Pharma to produce and release batches of therapeutic proteins for clinical trials. The PX subsidiary is one of the first bio-manufacturing units to in France to obtain this authorisation, and this new Business Model allows to generate revenue for PX.

# 3- PX, Episode 2: Developing a more promising long term portfolio

7 Monoclonal antibodies are a specific type of proteins. The market of monoclonal antibodies is very promising. Antibodies are principally aimed to fight cancers; and the Food and Drug Administration has already approved some of them: Rituxan, Erbitux, Xolair, Raptiva, Remicas or Heceptin.

In 2006, the management team identified a new opportunity, close to their core business: R&D services for monoclonal antibodies<sup>7</sup>. As a result, the subsidiary PX Monoclonals (PXM) was created to provide research services into monoclonal antibodies. In 2009, PX opened a sales office in Boston, USA, to develop links with the American market. In addition, PX set-up several partnerships providing knowhow in protein development for drug development projects, and here started to generate additional revenues through these partnerships (fig. 5). The shared platform activity progressively became marginal and in 2010 hardly any contracts went through it. The open platform model for recombinant proteins however, continued to be central to the company's activity.

Figure 5: Evolution of revenues (source PX)



In 2010, PX defines itself as a company specialised in the research, the optimisation and the production of recombinant proteins for research laboratories and companies. The company employs around fifty people. In ten years, PX has developed more than five hundred projects for one hundred and twenty client and partners,

such as Merial, Pfizer, Exonhit, Galderma, Biomerieux and Fovea Pharmaceuticals.

The company's strengths lie in its strong expertise in research and production of recombinant proteins: it is able to develop extremely effective production methods, using a range of different technologies. The company also has a good level of production capacity for the manufacture of therapeutic proteins.

In 2010, the management team aims to develop the Business Model portfolio which keeps the lower risk models that ensure the medium term viability of the company, whilst developing Business Models that could generate more revenue in the long term and prepare the technologies of the future. The Business Models on which PX's activities are based are well established, the company can therefore take more risks. Six areas to be explored are identified:

- Reinforce the company's presence in the United States. Opening the sales office in the United States doesn't appear to be an efficient way to access the market and PX is thinking about other ways of increasing its presence in North America.
- Additional co-development projects. The first co-development projects have paved the way for PX, through the acquired experience, to move into the development of a more product oriented offer rather than purely services. Co-development appears an ideal way to move towards products without going completely over to a product-logic.
- Internal development of drugs. The development of the company's own candidate drugs is a line of thought because several co-developments have already started. Some biotechnology companies specializing in services have already launched products, but they often encounter difficulties due to conflicts with their service activities: customers are afraid that they'll spend less time on their projects, or even that they'll re-use work done for clients in the development of the company's own products.
- Increasing the production capacity: PX has proved its capacity to produce batches of products for critical preclinical and clinical tests. Production on a larger scale, as done by a number of competitors, could be foreseen. One of the challenges is to develop the production of drugs using mammalcells, a technique which remains relatively undeveloped.
- Build on existing competencies. Is possible that the company find a way to use existing competencies and resources, developed over the past six years, through new Business Models.
- The emergence of new technologies, such as nanotechnologies and approaches such as systems biology, poses new questions on how the industry will evolve. In the long term, it is possible that expertise in these new technologies will become a source of competitive advantage.

To choose the next Business Model portfolio, PX first needs to analyse the existing portfolio, then go through the six areas identified to see how best increase the expected levels of promise, whilst keeping the risk level sufficiently low.

### 4- METHODOLOGICAL LESSONS

From the information above, the reader can identify PX's four Business Models at the beginning of 2010: the open platform for developing proteins, CMO for the production of pre-clinical and clinical batches, CRO for antibody services, and the co-development through close partnerships with companies that develop drug-candidates. Based on the characteristics of the four Business Models (table 3 and Fig. 6) it appears that risks are measured and under control; while the level of promise is improving compared to the portfolio of 2005.

RISK LEVEL RISK LEVEL LEVEL OF **Business model** (detailed) PROMISE (general) Interdependence Technical risk Financial risk Open techno-Low Low Low Low Low logical platform CRO Low/Medium Low Low Low Low СМО Low/Medium Medium Medium Medium Low

Table 3: Impact table for the PX portfolio at the beginning of 2010

The platform, CRO and CMO Business Models are based on process optimisation activities. Co-development combines both process optimisation and development, which allows PX to acquire and develop new competencies.

Medium/High

Medium

High/Medium

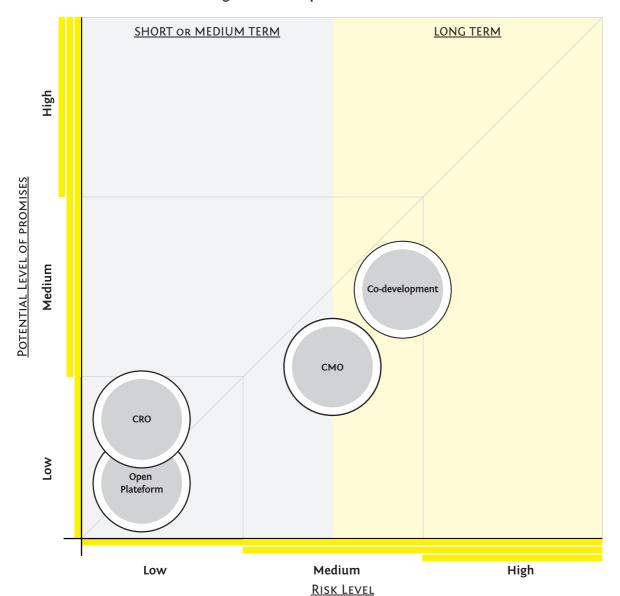


Figure 6: The PX portfolio in 2010

High

Co-development

Medium

To choose new Business Models, the management team must see how the new models could be developed on the basis of existing activities and on their creation by building on the resources developed thanks to the other Business Models. Next, they need to check that the promise and risk levels are balanced, and that the portfolio contains a balance of medium and long term Business Models.

For PX, based on the main process optimisation activity, three Business Models appear possible:

- Shared platform: The shared platform, developed at the outset of the company, could be re-mobilized in new emerging types of development such as nanobiotechnologies. The proximity of the Minatech research cluster could provide an ideal opportunity to create a shared platform in these new technologies
- CRO: The R&D services have given PX its solid reputation. Risk are low, the activity is well known and PX is already expert in antibodies and in recombinant proteins.
   CMO: New markets are appearing and this Business Model has more promises in terms of turnover than both the platform and CRO models. Setting up this Business Model will require investments but the need for bioproduction capacity in France is considerable.
- Co-development is a way of progressively acquiring new competencies. There is a real risk that clients of the service Business Models will view this model negatively and the times to market are very long.
- Total integration is a Business Model which is very far from the existing models and would require very high levels of investment both in acquiring new competencies in R&D and in infrastructure.
- The partial integration model would result in a highly visible activity of discovery and development with the associated risks of client alienation discussed previously. It also requires large investments.

The knowledge orchestration activity poses the question of whether or not to acquire new competencies and Business Models. The company is ten years old with a strong well developed network, a large number of clients for who projects have been successfully carried out.

- The intermediary Business Model is based on this type of resource and the company might provide the service of setting up client contacts for drug-candidate transactions as well as propose carry out the technological development and produce the pre-clinical and clinical batches.
- As far as the virtual company Business Model is concerned, PX doesn't yet have the resources not the necessary competencies. The company would have to know the whole drug development process in order to be able to coordinate all the actors. The risks are high; the cycles are long and the interdependency high.
- A very good knowledge of the network is necessary for "repurposing", but detecting opportunities requires internal researchers capable of detecting scientific opportunities. PX's researchers are more orientated towards technologies rather than products which implies a competency gap.

The management team makes three choices:

First choice: Reinforce the Business Models based on process optimisation.
Reinforcing the CMO Business Model along with the creation of a new production unit will increase risks but also potential revenue. The CRO and open platform Business Models are sustainable and efforts will be made to penetrate the American market.

- Second choice: Explore the technologies of the future. To do this, the aim is to set-up a partnership in order to spread the investment and the risks related to the technology. Having already experimented the shared platform Business Model, and due to the proximity with the regions research clusters, the management team's aim is to set up a partnership with a neighbouring public laboratory.
- Third choice: Progressive acquisition of new competencies. By looking over the Business Models on activities other than process optimisation, the management team agreed on progressively developing competencies in discovery and development. To do this co-development work will be reinforced. This should enable PX to improve the promise level but with relatively little increase in risk.

The new Business Model portfolio has a higher promise level and maintains an average risk level (table 4). The company has three Business Models which ensure the medium viability of the company and two more risky Business Models, but which are more promising for the long term (fig. 7).

LEVEL OF RISK LEVEL RISK LEVEL Remarks **Business** (detailed) (general) model PROMISE Technical Financial risk Interdependence risk Re-enforcement Open techno-Low Low Low Low Low of sales in the logical platform USA  $\odot$  $\odot$ Re-enforcement Low/ CRO Low Low Low Low Medium in the USA. Re-enforcement of production capacity СМО Low/Medium Low Medium Medium Medium (mammal cells) + re-enforcement in the USA  $\odot$  $\bigcirc$ Increase Co-develop-Medium/ Medium High/Medium High Medium in the number of projects Shared plat-Shared form for explo-High Medium/High High Low Medium/High investments in ration of new new technologies technologies

Table 4: New PX Business Model Portfolio

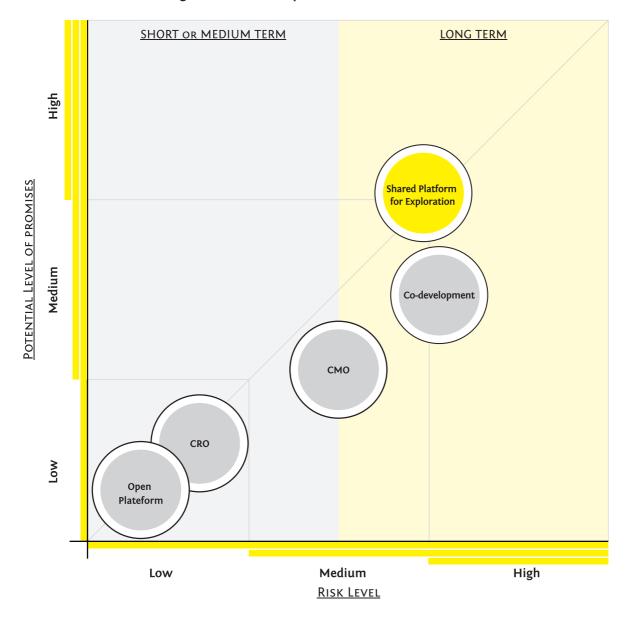


Figure 7:The new PX portfolio of Business Models

The strategic analysis with the construction of a portfolio of Business Models went through a number of steps which are summarised below:

- $\underline{1}$ : Analyse the existing Business Models: Determine the company's Business Models and on which activities they are based. For each Business Model, evaluate the promise and risk levels and then determine overall if there's a balance between the short to medium term, and the long term business models.
- <u>2</u>: Determine the areas to explore and that the management team will analyse. To do this, consider the evolutions in the industry and in the target markets. In the pharmaceutical industry, PX explored future technologies, the evolution of market needs and their localisation.
- 3: Define the new Business Models: Firstly, from the core activities on which the existing Business Models are based, imagine what new Business Models could be possible and discuss them in relation to the areas being explored. Then think through what Business Models could be created based on the resources and competencies that have been developed with other Business Models.

4: Balance the Business Model portfolio: The use of the impact grid and the associated graphical representation should show whether the various Business Models in the portfolio balance promises and risks and whether both short to medium and long term developed is ensured. A balanced portfolio should have short to medium term Business Models and long term one. The short to medium term ones will be less promising, but also less risky, hence supporting over the long term the more promising and more risky Business Models.

The management of a Business Model portfolio requires that a strategic analysis on each company Business Model be carried out by the management team. The impact grid should then be analysed at a general level. This approach takes into consideration both the medium term and long term aspects in the aim of balancing the risk and the expected benefits. It's especially for this reason, that the management of portfolios of Business Models with the analysis grid is particularly relevant for small to medium sized high technology companies.