



## Collaborative Innovation: The future of BioPharma

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The pharmaceutical industry comprises establishments primarily engaged in manufacturing drugs, medicines and related products for human or animal use. Nowadays, bio pharmaceutical corporations are facing serious inefficiencies in their drug discovery process. The drug discovery process consists of four phases. These are research phase (average 3 years), pre-clinical testing phase (average 1 year), clinical trial testing phase involving human patients (average 10 years) and regulatory approval phase (average 2 years). Undoubtedly, research is the step in which substantial risks are being taken. During this process, researchers develop tests to screen libraries of chemical compounds against therapeutic targets, evaluate the amount of a drug required to effectively treat the disease, study the extent to which a drug interacts only with the target, assess the presence and significance of any harmful side effects and design the way the drug is going to be administered to patients.

The pharmaceutical companies are expecting to cut the drug discovery time line by half, triple the number of compounds delivered to develop new drugs and achieve double-digit growth rates by exploiting the 'Blockbuster' drug/therapy strategy. Unfortunately, 'Bio Pharma' has not been able to fulfil those expectations. The average time line for a new drug candidate to be on the market is still around sixteen to twenty years. There is a shortage in new drug candidates availability, which has not been solved by increasing the Research and Development spending. The 'Blockbuster' strategy has been disappointing, only one in five new launches is considered significant (generating revenue exceeding \$500 million per year).

Drug discovery is a long journey fraught with risks as well as painstaking research and testing. The pharmaceutical companies are willing to invest in any process that could accelerate the drug discovery development. Typically, a new drug addressing a disease previously without an effective remedy can generate revenue of \$1Billion per year. The pharmaceutical industry is a classic winner-takes-all industry as the first-mover with a new drug usually gets over 75% of the market. Given that situation there is no doubt that in pharmaceutical corporations new operating structures to enable collaborative relationships and cost-effective management are needed.

It is generally agreed that efficiency, productivity and quality are the main drivers for the pharmaceutical industry. However, there is a tendency to underestimate the impact that R&D operations, project prioritisation and partnership strategies have in the company output.

### Research & Development Operations

Research and Development operations constitute a big issue in the operating model of pharmaceutical companies. The objective of this unit is to investigate, evaluate and discover new drug candidates to cure, treat or prevent current diseases. At present, these departments are undergoing considerable changes associated to the molecular biology revolution, a thriving discipline that is providing higher numbers of possible therapeutic targets that are not yet validated. The problem then is shifted to assay development, where one of the most serious bottlenecks occurs. There is an unmet need for high throughput assays to be used in the validation of the therapeutic targets. If that problem is solved, then the drug discovery process can change from a linear process to an iterative process in which target validation runs in parallel with drug discovery or drug optimisation activities. Given this, it is important to take into account that research and development operations need to incorporate internal and external data. This is particularly the case with genomic information, which is so vast and complex that cannot be efficiently managed solely in-house.

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## **Project Prioritisation**

Project prioritisation is concerned with allocating the company resources according to the importance of each project. A large number of pharmaceutical companies organise their portfolio of projects by using a similar set of criteria. The typical ones consider commercial value of the possible drug that the company will develop, risk of undertaking an alternative approach to drug identification and the competitive situation of the company in the specific niche of the health industry. A small number of companies also consider the novelty of the drug or the therapy that are willing to develop, the time to clinical trials and the advantageous or disadvantageous position of the company concerning the intellectual property that can be obtained in each project. Unfortunately, project prioritisation is not being carried out in the best way possible. It is often used to track resource utilisation rather than forecasting or modelling the better way to fit each project into the business model of the company.

## **Partnership Strategies**

In today's market, bio pharmaceutical companies are facing increasing challenges in all aspects of their day-to-day business. It is widely recognised that there is a need to bring more drugs onto the market, quicker and at a reduced cost. One option to overcome that situation is carrying out technology-oriented mergers, acquisitions, and company alliances. It is suitable to consider that by increasing the firm size through partnerships and alliances does not guarantee by any means that the company performance would be successful. The need to administrate across multiple sections of the company increases the management complexity, particularly slowing the processes of decision making. Some studies remark that pharmaceutical companies should re-evaluate the idea that 'Big is Better' and integrate through cooperative research the critical mass needed in the vital areas of drug development. With that kind of partnerships bio pharmaceuticals can experiment emerging technologies before bringing them in-house. The idea is shifting from straightforward contracts and licences to 'invasive' deals in which people, technology and strategies are shared. In most cases, the innovation needed to fuel the growth expectations of pharmaceutical companies is occurring in the

biotechnology sector where 'Bio Pharma' can have access to critical capabilities in a relatively short period of time. Partnership strategies are becoming a big issue in the health and pharmaceutical industry. It is clear that a competitive pharmaceutical company cannot stay in the top league if it only grows internally. It must combine crucial capabilities and multidisciplinary professionals.

In conclusion, it seems that the future of bio pharmaceutical companies depends on new portfolio management strategies. The idea is to change the performance of the company by implementing integrated rather than isolated solutions. In other words, consider technical, cultural, strategic and organisational issues that may occur if a management change happens.

In most of the bio pharmaceutical companies there is a tendency to create value via knowledge management and intellectual protection. It is now widely accepted that these corporations should retain in-house only those activities where their specific expertise truly adds value to the company. The idea is to use alliances to gain critical mass, incorporate technological breakthroughs and improve shareholders value. Nowadays, as the number of biotechnology products in clinical trials increases, pharmaceutical firms are progressively looking at biotechnology companies to fill their pipelines. It is now generally recognised that drugs developed in biotech-pharmaceutical alliances perform better than products developed solely in-house by biotech or pharmaceutical firms. That evidence confirms that co-development adds value that is sufficient to outweigh any moral hazard problems that result from sharing development responsibilities.

It should be considered that biotechnology and pharmaceutical companies are to some extent complementary. Biotechnology firms are mainly concerned with the generation of new drugs using breakthrough technologies, while pharmaceutical corporations are usually cash-abundant and can buy innovation from Biotechs. Then, Bio Pharma can effectively take those novel drugs and navigate them through the regulatory affairs conundrum and subsequently bring them onto the global market place successfully.

With the time and costs involved in drug discovery and development, it is vital that Biotechnology and Pharmaceutical companies come up with appropriately balanced deals where the contributions, rewards and strengths of each collaborating party are clearly recognized. This is especially relevant as biotech and pharmaceutical companies are turning with increasing frequency to in-licensing and collaboration agreements.

On the whole, the continued expansion of the global bioscience sector drives a clear demand for the

development of scientists at postgraduate level skilled in biotechnology and business. There is a shortage of skilled scientists with business expertise who can take an active role in solving the challenges highlighted above.

The following table summarizes a number of postgraduate programs that combine science and business, which may prove of great value to enthusiastic bio-entrepreneurs looking to play a part of the future of BioPharma.

Selected bio entrepreneurial programs	Program	URLs
Institute of Biotechnology at the University of Cambridge (Cambridge, UK)	Masters in Bioscience Enterprise	<a href="http://www.bio.cam.ac.uk/bioenterprise/">http://www.bio.cam.ac.uk/bioenterprise/</a>
Graduate School of Business, San Diego State University (San Diego, CA, USA)	Joint PhD/MBA in Life Sciences	<a href="http://www-rohan.sdsu.edu/~cba/grad/phd.html">http://www-rohan.sdsu.edu/~cba/grad/phd.html</a>
College of Management at the Georgia Institute of Technology (Atlanta, GA, USA) and the School of Law at Emory University (Atlanta, GA, USA)	Technological Innovation: Generating Economic Results (TI:GER) graduate certificate program	<a href="http://mgt.gatech.edu/tiger/">http://mgt.gatech.edu/tiger/</a>
Center for Bioentrepreneurship, University of California, San Francisco (CA, USA)	Courses and seminars, planning a certificate program	<a href="http://www.ucsf.edu/cbe/">http://www.ucsf.edu/cbe/</a>
The William J. von Liebio Center for Entrepreneurism and Technology Advancement, Jacobs School of Engineering, University of California, San Diego (La Jolla, CA, USA)	Courses, project support, networking	<a href="http://www.vonliebio.ucsd.edu/">http://www.vonliebio.ucsd.edu/</a>
Universidad de Torcuato di tella (Argentina)	Master de Biotecnología y negocio	<a href="http://www.utdt.edu/download.php?fname=_118425733757165500.pdf">http://www.utdt.edu/download.php?fname=_118425733757165500.pdf</a>
Instituto Empresa (Spain)	Master in Biotechnology Management	<a href="http://www.master-biotechnology.ie.edu/">http://www.master-biotechnology.ie.edu/</a>
Macquarie University (Australia)	Master of Biotechnology with Master of Commerce in Business: North Ryde (Sydney) - 2007	<a href="http://www.international.mq.edu.au/study/areas_coursedetails.aspx?cse=278&amp;CourseLevelID=2&amp;StudyOptionID=1&amp;Location=North%20Ryde%20(Sydney)&amp;mi=221">http://www.international.mq.edu.au/study/areas_coursedetails.aspx?cse=278&amp;CourseLevelID=2&amp;StudyOptionID=1&amp;Location=North%20Ryde%20(Sydney)&amp;mi=221</a>
Oxford Brookes University (United Kingdom)	Biotechnology with Business MSc / PGDip	<a href="http://www.brookes.ac.uk/studying/courses/postgraduate/2007/biotech_bus">http://www.brookes.ac.uk/studying/courses/postgraduate/2007/biotech_bus</a>
RMIT University (Australia)	Master of Biotechnology and Business incorporating Graduate Diploma and Graduate Certificate	<a href="http://www.rmit.edu.au/browse/Study%20at%20RMIT%2FTypes%20of%20study%2FPostgraduate%20Programs%2FB%2F;ID=MC129;STATUS=A">http://www.rmit.edu.au/browse/Study%20at%20RMIT%2FTypes%20of%20study%2FPostgraduate%20Programs%2FB%2F;ID=MC129;STATUS=A</a>
Stanford Biodesign Network and Stanford Entrepreneurship Network, Stanford University (Palo Alto, CA, USA)	Forum, networking	<a href="http://mdn.stanford.edu/">http://mdn.stanford.edu/</a> <a href="http://www.stanford.edu/group/eship/">http://www.stanford.edu/group/eship/</a>
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