

February 2010

The face of biotech*

a roundtable summary on the medium and long-term biotech landscape



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PricewaterhouseCoopers organised an exclusive think-tank with key opinion leaders from the biotech industry on how biotech will look like in 2020 (vision about the middle and long-term biotech landscape). The aim was to collect ideas as input for a research paper "biotech 2020" which is in line with previous PwC publications "Pharma 2020", but now dealing specifically with the issues for the biotech industry. The document set forth highlights the outcome of the first roundtable session of 15 December 2009 in Brussels. A second roundtable session will be organised on 11 March 2010. The outcome of both roundtable sessions will be consolidated with the similar initiatives by PwC in other European countries.



Describing biotechnology as a sector is something of a moot point. Biotech stands for biotechnology and therefore, technically-speaking, it cannot be described as a "sector" as "biotechnology" is fundamentally research & development that can be used across a number of sectors (such as pharma, agriculture, etc.). Once the technology reached the phase of commercial application, the technology lends itself to other sectors and hence cannot truly be considered as a sector. The confusion may have arisen from European legislation, media and associations, which have been responsible for creating the term "biotech sector".

Upcoming trends & future business models

More and more synergy is expected between biotech and pharma, with both merging into one as the boundaries between them start to blur: pharma companies need to fill their product pipeline and are looking to biotech companies for innovative new products; biotech companies are turning to pharma for production capacity and market openings. Each is thereby leveraging on the strengths of the other.

Whilst the majority of pharma companies today are still focusing on pure pharma, this is expected to change in the future; pharma is set to move into biotech (biopharma) which is growing at a much faster rate than major pharmaceuticals; the growth rate of small molecules is 0.6%, whereas it is over 10% in the field of monoclonal antibodies. And, as long as biotech companies continue to focus on research and look to outside investors for their funding, it remains attractive to be called a biotech company.



Innovation and the differences between pharma and biotech

Pharma activities are in general based on mass market and large screening (high throughput), whereas biotech is often based on the therapeutic outcome of specific patient groups; this makes biotech seem more innovative. In addition, biotech firms are often smaller than the big pharma companies and tend to be more active in niche product areas with smaller portfolios, and faster product development. As a result, their “thought model” and approach is different: to learn from life, to learn from genes.

The success of a biotech company can be measured in three ways: the commercialisation of its technology; the investor’s exit either through IPO, M&A or management buy-out; its licensing and royalty agreements. A key obstacle, however, is funding, coming primarily from venture capitalists with whom the sector is strongly associated. This is especially true in Europe which is very different from the US.

In the EU, seed money from venture capitalists can be counted in its thousands whereas it’s in the millions in the US. Once companies start looking for larger investment funding, they are better off going to the US, where there are greater possibilities; as a consequence, a lot of biotech companies are moving there. The fact that some Belgian companies are successful in obtaining large amounts of money from investors is rather the exception than the rule. In general, successful EU biotech companies, such as Genzyme, originally Dutch, end up as US quoted companies.

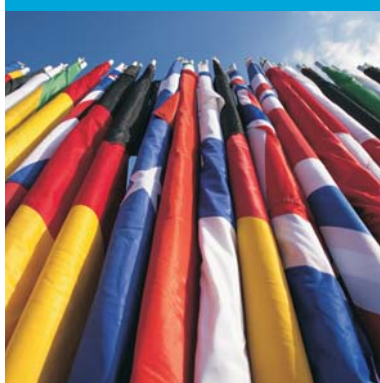
In order to break this mould, a number of questions are being asked. Should there be more, “bigger” small biotech companies? Should there be fewer sources of funds, but with more money? Should there be more cooperation with US companies that have greater amounts of available cash? The answer however may be sought in the degree of “innovation” and therefore it is not necessary to move into a bigger organisation. The operational differences between companies in the US and the EU are small: they have the same types of capabilities, organisation, etc. However, the main difference is the level of risk the company is prepared to take and that is a huge difference.

Factors distinguishing the US and Europe

One of the factors distinguishing Europe from the US is the fact that in the US, there are more mature technology transfer offices; they started to create them much earlier. There is also more entrepreneurship and commercialisation amongst university teachers. This is changing in Europe, but there is still a long way to go.

Another factor is **fragmentation**. In the EU, there are 27 countries and even in just one country (like Belgium) there is fragmentation.

Social security also has an impact: if you lose your job in the US, there is no welfare, so you need to become an entrepreneur and take more risks. In Europe, we have a low-risk culture/fear of failure mentality: if you lose your job, you can live off benefits. Whilst social security is not bad, it does have an influence on the culture, which does not always favour entrepreneurial behaviour, as the figures show.



In Belgium, a lack of trust and self-confidence to become entrepreneurs exists, although there are plenty of opportunities and available skills. To reverse this thought process, the education system could play a bigger role. In the US, if you are successful you are admired. In the EU, success bears a stigma.

The latest biotech revolution that is taking place is “Cell and tissue” research at hospitals. We can expect hospitals to go through the same phases as biotech companies. Regrettably in Belgium, legislation is far too complicated: it will cost a lot of money and there is a lot of legal uncertainty and unpredictability which risks hampering innovation. In the US it is perceived that more coherence exists and that everybody is moving in the same direction. In Europe, policies are mismatched in terms of time and geography, even between sectors.

Biotech is very multidisciplinary: technology, science, finance, regulatory, etc. learned mostly in-house and not enough through the education system (such as regulatory, intellectual property). The possibility of going back to university for a time mid-career could be considered. Additionally, better cooperation and interaction between universities and the industry is critical for success. The same can be said between hospitals, industry and educational institutions: there could be more interaction among the different players in conducting proper clinical trials. As an example, hospitals will need to have more skills in the field of good manufacturing practices (GMP)/good laboratory practices (GLP) to be able to conduct clinical trials. But GMP/GLP are not adequately taught in higher education; researchers in hospitals therefore need retraining. The job descriptions of hospital researchers/scientists are bound to change. Funds for retraining are limited and in some cases are only available from certain institutions such as IWT (Innovatie door Wetenschap en Technologie).

Macro-economic factors to be considered

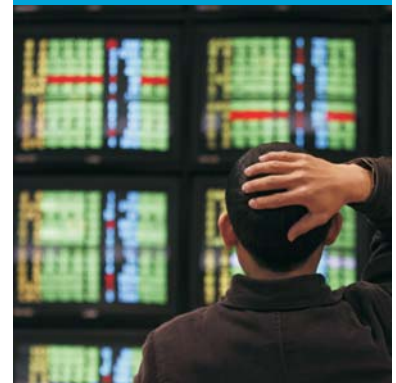
The success and development of biotech is strongly influenced by macro-economic factors. Country X may depend on, say, rice imported from country Y. If X decides to produce its own genetically modified rice (and stop importing from Y), then Y may threaten to cease imports of other products from X.

A lot of research and clinical trials are moving to India, China, Singapore, etc. China is moving faster, in part because of coherence: everybody is going in the same direction. If Europe wishes to compete, more added-value should be given to research programmes and the management of clinical trials, for example by setting up a good biobank structure, data sharing, innovative ways of IP, etc.

When it comes to innovation, some consider the regulatory burden as the key obstacle; whilst others (especially CEOs) struggle more with funding.

Biotech has nevertheless already met with success. However each company has its own business model and, because of the broad diversity, it's difficult to say what the critical factors for that success are.

One thing is sure: the future lies in the collaboration between small biotech and large pharma companies. One large pharma company may have relationships with multiple small biotech companies; this lends it much greater agility (the “open innovation model”).





What will be the salient features of the sector come 2050?

Looking ahead to 2050, we see a number of developments:

- Technology is likely to become mainstream with more focused medicines, **greater personalisation and more curing of diseases**, “repairing” instead of “replacing” (example repairing an eye, repaired skin, etc.). This will develop in line with the work evolving in cells and tissues.
- Knowing and **understanding the “real” disease** will be the norm, with more hospitals doing research in collaboration with biotech and pharma companies.
- Prevention rather than cure will be inevitable based on **biomarkers**: these will be used in predicting diseases with each disease having its own biomarker.
- The sector will face challenges as **good biomarkers** come along with the development of good biobanks. Furthermore, we can expect private companies to build their own biobanks in the future, which is already the case in Germany.
- **Image and reputation** will be important for biotech’s success. There is a lot of negative press on the lines of “big pharma is earning a lot of money”. E.g. vaccines with adjuvants are viewed negatively (because the adjuvant is expensive) whereas in reality adding an adjuvant makes the vaccine more effective. There is a gap between the public’s general understanding and reality. Communication will therefore become even more important, especially as the science will make information much more complex. As long as biotech is not making money, it will continue to have a good image. However, as soon as it starts to earn a lot of money, the risk of a negative image is there.
- **Information** will become more important as patients search for more of it. In certain countries (like the US), patient associations have much more influence and more financial means. In Belgium, patient groups are on a voluntary basis and less organised. The biotech industry could educate more effectively its patients and the patients associations and take more account of them, as they can influence the whole industry.
- **Independent and objective expert views** and opinions may influence positively the sector’s negative image “pharma/biotech companies earning money on the back of the patient”.
- **Relationship-building** will play a key role. Biotech companies will have a responsibility to listen better to patients and build stronger relationships with them. Some patient organisations are already offering help with clinical trials and some patients are even saying “I want to take risk if it can help me or others”.

Intellectual property: its role in the future

As it will take more time to bring a product to market in the future, patent protection will need to be longer.

Is FMCG (Fast Moving Consumer Goods) therefore a model for biotech to follow, where no or limited IP in place? This is unlikely given the challenge pharma/biotech companies face with engaging in long-term research; in the long run it's essential to have the IP, which is not the case, however to be the first on the market will be key in the future for FMCG.

As far as products are concerned, a healthy balance between existing and new products should be encouraged as too much innovation is very costly for the healthcare system. [The challenge lies in finding the one-time "cure" versus prescribing drugs that need to be taken 3 times a day for the rest of a patient's life – a much more expensive option.](#)

In the future, biotech companies will have the IP from the clinical trials/research conducted at hospitals, which should in turn receive royalties. But, as a hospital, you cannot have IP for every piece of research. Policy on how to evaluate researchers is also going to become an issue that will need managing. Hospitals will have many more partnerships or even "open campus" or "open innovation" models as currently established in the industry. Hence, [hospitals' IP is a critical area for focus where action needs to be taken.](#) Within a few years, we can expect there will be a European patent authority; this will avoid having to apply for protection in every country thereby facilitating the process.

We can expect exchanges of IP to become more complex, for example between universities and companies, between companies or between hospitals and companies. There is even a different perception of IP depending on the point of view (universities vs. industry) and this also requires a multidisciplinary approach including science, law, technology and finance. As a result, [more multidisciplinary teams will be required to manage and review the different uses and aspects of IP.](#)

Universities could play a more significant role in filling the pipeline and becoming a better stakeholder as biotech is an extension of the universities. More initiative needs to be taken and for them to become more professional (IP, science, etc.). Certain universities are already good at that: for example the VIB (joint effort of universities and industry) gives direction and prioritises funding, and even coaches on how to take innovation to market as well as managing publications. It's a competitive process, but effective. The challenge always comes at the later stage: getting more funding resulting in a gap between academic spin-outs and further funding.

Although the biotech industry faces a lot of challenges and obstacles to be dealt with, it will remain a promising and diverse discipline. Will it bring more breakthrough in cell therapy or will the next iTunes® in healthcare be developed? Will successful spin-offs arise from hospitals or will it provide breakthroughs in wellness or pharma applied in food? Will biotech solve current challenges in the diagnosis of unknown diseases or will intelligent vending machines analyse ones DNA and produce a customised cocktail to stay healthy?

Biotech 2020 is approaching!





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