

## From the Board Room

# The relevance and importance of business development and licensing in the biopharmaceutical industry

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## ABSTRACT

The importance of the business development and licensing (BD&L) function in the global biopharmaceutical industry has grown significantly over the past 20 years as pharmaceutical companies have sought to supplement their internal R&D with innovative products and technologies sourced from biotechnology and drug delivery companies. This has required companies to employ BD&L executives to search, evaluate, negotiate and alliance manage deals ranging from small biotechnology companies to the largest of the Big Pharma companies. Nowadays all the large companies have BD&L teams, sometimes in excess of 100 people. To inform new BD&L entrants and to improve the professionalism of the experienced BD&L executives, various training courses are offered by not-for-profit associations and commercial organisations. The leading not-for-profit association in Europe for biopharmaceutical executives is the Pharmaceutical Licensing Group and in the US it is the Licensing Executive Society. Both organisations offer basic training courses but as far as is known, the only university accredited Master's degree qualification in BD&L is the distance learning MSc offered by the University of Manchester. The dissemination of specialist knowledge and best practice is through the journals and conferences of the professional associations. The need for well-qualified BD&L executives in the biopharmaceutical industry is demonstrated by the fact that 25% or more of Big Pharma sales come from third party products and the cost of licensing deals alone is over \$200m on average.

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## SYNOPSIS

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## **THE RELEVANCE AND IMPORTANCE OF BUSINESS DEVELOPMENT AND LICENSING IN THE BIOPHARMACEUTICAL INDUSTRY**

One of the most interesting and fun jobs in any industry must be one where there is the opportunity to meet people, to travel, to get involved in all aspects of the business, to negotiate deals (which can be exciting or stressful or both) and to have the satisfaction of completing projects. In the biopharmaceutical industry this describes the job undertaken by executives who are responsible for partnering new products and technologies from other companies. These people are called licensing and business development (BD&L) executives/managers/directors. The types of deals they undertake range from simple patent licences to complex co-development and commercialisation deals. They are often, but not always, separate from corporate development executives who are mostly involved with corporate strategy and company acquisitions. A third group of executives involved in BD&L is technology transfer executives whose main work is with early stage technologies and products and who are located in or linked to universities. A fourth group of executives who are often part of the BD&L team are alliance managers who are responsible for managing the relationship between the partner companies post deal signature. It should also be noted that the term “business development” in this article does not include selling activities by salesmen, major account managers, etc. and the plethora of titles given to sales people that disguises the fact that their primary role is involved with selling products.

This article is focussed on BD&L executives but recognises that there is considerable overlap with corporate development and technology transfer executives and alliance managers. It examines the role and responsibilities of BD&L executives in finding, evaluating and negotiating such deals and the importance and contribution of partnering deals in the biopharmaceutical industry.

By the end of the article it is anticipated that the reader will have a deeper insight into the role of BD&L executives, what type of skills and experience they need

and the vitally important contribution they make to the industry.

## **WHY DO DEALS HAPPEN?**

The reason deals happen is because two parties identify an opportunity to achieve a greater success (or a reduced risk) from collaboration with a partner than by working alone. The identification of the opportunity usually arises from a strategic review by one or both companies. The strategic review by a potential acquirer or licensee may have identified a product or technology gap from internal R&D that could be filled by a third party product. The strategic review by a biotechnology company may have identified that the cost and risk of clinical development is too high to be undertaken without a partner company. There are many other reasons for deals such as negotiating freedom to operate for blocking patents, licensing a screening technology, acquisition of a regulatory dossier for a generic product, appointing a co-promotion partner to increase marketing power, appointing a distributor to obtain marketing coverage in distant markets. The range of deals over the life of a product is illustrated in Table 1.

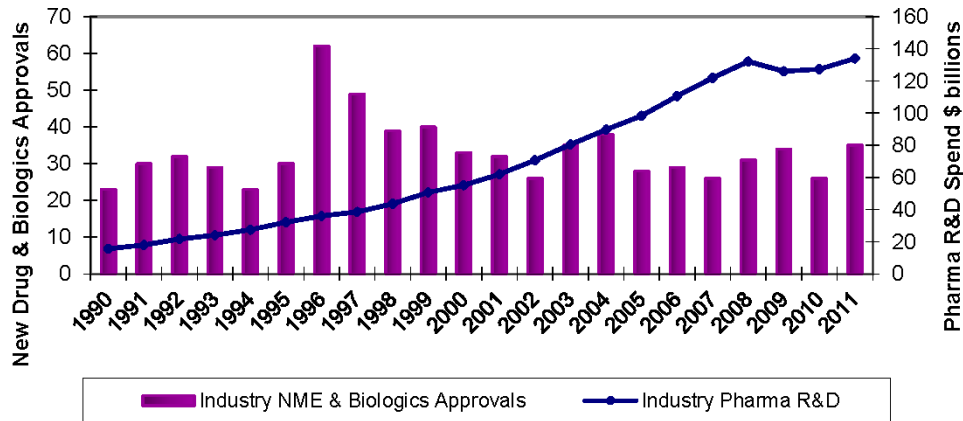
BD&L executives are usually involved in all these deals and often instigate and manage the deal from start to finish.

## **THE NEED FOR PARTNERING PRODUCTS AND TECHNOLOGIES**

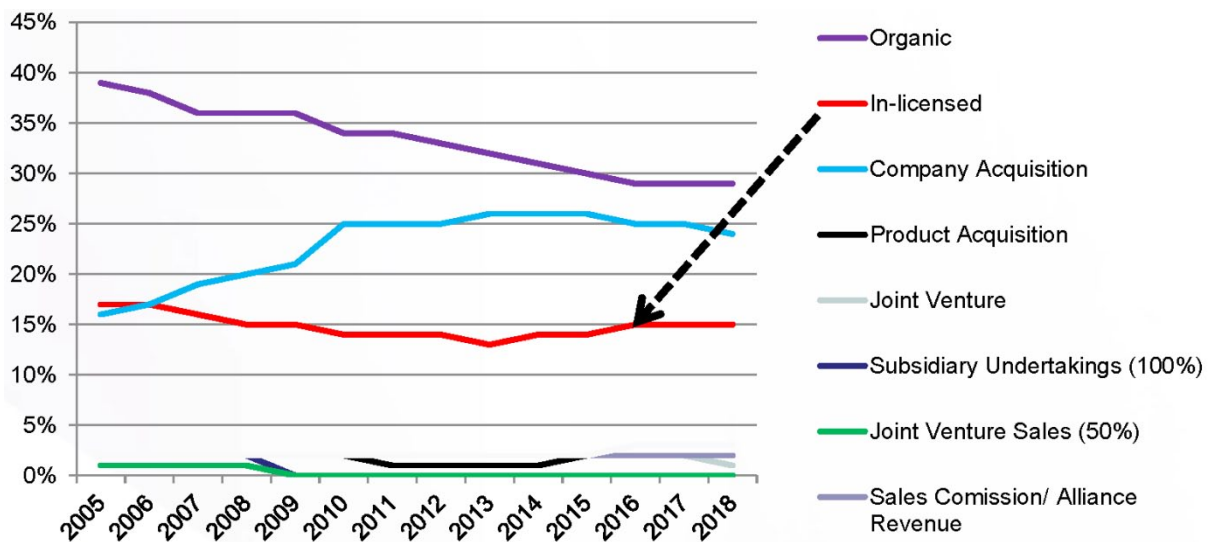
The opportunity to achieve a greater success by collaboration with a partner than by a company working alone most frequently involves new products and technologies. These deals range from new molecules to generics and where the stage of development ranges from discovery to post launch. The reason for partnering is driven by the pharmaceutical industry's need for a constant flow of innovative new products and these new products are often developed, not by the pharmaceutical companies, but by small entrepreneurial biotechnology and other product development companies or academic institutions. Overall R&D productivity has been declining as costs have been inexorably rising, often driven by new regulatory requirements, while the number of new molecules gaining approval has been declining or at best has been static. This is reflected in the chart below presented by Evaluate Pharma at the European Pharmaceutical Licensing Group meeting in Budapest in September this year. It shows a continual increase in R&D costs from the early 1990 to today with R&D spending now over \$130bn while the number of new molecular entities obtaining approval has declined or at

**Table 1:** The range of deals over the life of a product

	EARLY STAGE DEALS			MID TERM DEALS			MARKETING DEALS			
	Research	Pre-Clinical	Phase I	Phase II	Phase III	Pre registration	Launch	Post launch	Patent expiry	Post patent expiry
Confidentiality										
Material Transfers										
Options										
Evaluations										
Screening										
Research alliances										
Contract research										
Co-development										
Patent licensing										
Product licensing										
Co-marketing										
Co-promotion										
Product										
Distribution										
Supply										



**Figure 1:** R&D costs and NME launches



**Figure 2:** Aggregate sales by strategy (top 500 companies)

best has remained static (Figure 1). As a result the productivity of R&D in the top 20 companies has declined by 60% as the ratio of new product sales to R&D spend has slumped from nearly \$2.50 in the period 1996 to 2005 to less than \$1 in the period 2006 to 2015.

The decline of internal R&D productivity has been an acute problem for many Big Pharma companies and as a result these companies have increasingly sought to obtain innovative new products from other companies. An analysis by Evaluate Pharma of the top 500 pharmaceutical companies for the period from 2005 to 2018 (forecast) shows significantly declining share of company sales from organic R&D, stable share of sales from licensed products accounting for 15% of sales plus a 25% share from company acquisitions (Figure 2).

## THE DEVELOPMENT OF BD&L

The sales contribution from third party projects compared to internal R&D is difficult to measure especially as a pre-registration product sourced from a third party requires substantial development support from internal R&D to get to market. However the overall picture is clear, all pharmaceutical companies these days require external collaborations to obtain products to supplement internal R&D. It was not always so, in the 1980s, when pharmaceutical companies internal R&D was able to regularly develop and launch new products, the need to source new products from third parties was limited or non-existent. In addition commercialisation deals were usually confined to appointing distributors in export markets or, for example, co-marketing deals in Southern Europe. If a BD&L manager existed the typical profile was a person who was nearing the end

of their career with a commercial background, usually sitting in a small office in the basement! In the last 25 years as pharmaceutical companies internal R&D departments have struggled to develop new innovative medicines and in parallel the biotechnology and drug delivery industry has grown based on innovation, there has been an increasing trend to in-license or acquire technologies and products from other companies. This has spurred the creation of BD&L jobs and in the bigger companies there are teams in excess of 100 people worldwide to facilitate partnering deals. In many of these companies the BD&L roles are separated into “silos”. For example in the first silo there are scouts who search for new opportunities and make initial contact. The second silo may consist of evaluators, the third silo negotiators and the fourth silo alliance management. In contrast in small companies the BD&L executive is expected to undertake all the roles.

## **HOW DO DEALS HAPPEN – RESOURCES**

Once the strategic objective to partner has been agreed the next step is to secure the BD&L resource and set direction to ensure the objective can be met.

Finding potential partners can be done either using external or internal resource. The external resource may be a consultancy that has contacts in target companies or it may be an investment bank especially if a company divestment is planned. The internal resource is the BD&L executive or equivalent resource. In small biotechnology companies the CEO, COO or CFO may act as the BD&L representative. Most companies, particularly the larger companies, use internal BD&L resources especially where the company’s product or technology requires specialist scientific knowledge or it is a country specific commercial deal.

## **HOW DO DEALS HAPPEN – SEARCHING AND INITIAL CONTACT**

Whatever the reason for seeking a partner, one or both companies have to put in place a process to find, evaluate, negotiate and complete a deal. The first stage is to search for companies that have the target product, technology or development and commercialisation capability. This involves searching databases containing company, patent and product development information and also making other companies aware of your requirements via websites and contacts.

Once the target companies have been identified the next step is to make contact. The preferred approach is by

personal contact especially where the contacts know each other. These personal contacts can be obtained by company visits or via industry or professional associations’ (PLG, LES) conferences. Alternatively there are partnering conferences such as BIO/BioEurope that provide an electronic appointment system between companies and provide facilities for short meetings. After a dozen half hour meetings in a day this can be very tiring and boring ... it is like speed dating without the excitement!

The task of searching for opportunities already starts to define the profile of the ideal BD&L executive, namely, knowledgeable about products/technologies and companies, good contacts in other companies, good interpersonal skills, patience and stamina.

## **HOW DO DEALS HAPPEN – EVALUATION AND DUE DILIGENCE**

Once the initial contact has been made and information exchanged the BD&L executive will arrange the internal company evaluation of the opportunity. This requires input from many of the company functions including patents, R&D, medical, regulatory, manufacturing and marketing. A team may be established once the project has reached an advanced stage. In this situation the BD&L executive needs to be able to persuade or cajole specialist colleagues who have a full time job within their respective function e.g. medical, to devote time to reviewing the new product while still having to achieve their functional objectives. In addition the BD&L executive needs to have sufficient knowledge of each functional area to ensure the review undertaken by the specialist is both comprehensive and addresses the key issues. So, while the BD&L executive almost certainly will have joined BD&L after working in a specialist function such as R&D, regulatory or marketing, it is important that during their career they have gained awareness of the challenges facing other functions.

So the second dimension of the profile of the ideal BD&L executive is to be both a generalist, that is someone who has a broad knowledge of the business, and to be good at organising and managing a team of specialists.

## **HOW DO DEALS HAPPEN – NEGOTIATION**

Once two companies have established there is sufficient technical or commercial interest for a deal, the next step is to negotiate a formal agreement. There is likely to be a number of steps such as an initial meeting,

preparation of a term sheet, preparation of a draft agreement and further negotiations until the final agreement is signed.

So the third and perhaps the most important feature of the ideal BD&L executive's profile is the ability to negotiate. This means not only the ability to negotiate with other companies but also internally. The internal negotiation is often more difficult than the external one particularly where the top management have to be persuaded that the commercial terms of the deal make sense in comparison to internal and external benchmarks. It has been reported that in one Big Pharma company more than 20 signatures are required from different stakeholders to complete a deal!

## WHAT IS THE IDEAL BD&L EXECUTIVE PROFILE?

In summary the profile of the ideal BD&L executive who is involved in all aspects of business development and licensing includes good interpersonal skills and ability to negotiate, excellent team organisation and management skills, a general knowledge of products and companies, good contacts in many companies and plenty of patience and stamina. In fact these attributes are very similar to those of a CEO and as a result there are many cases where a BD&L director in a biotechnology company is appointed to a CEO role.

Not all BD&L executives are able to develop the complete range of skills needed for their role. For example, negotiating requires a certain type of interpersonal behaviour that can be trained but if the executive is not comfortable negotiating, it is unlikely they will be good in this aspect of the role. This is why the larger companies organise BD&L executives in silos where each person's strength in each skill can be maximised.

Whatever the organisational structure, a word of warning is appropriate: the success rate of in-licensed product opportunities is very low. The number of opportunities reviewed by Merck & Co in 2011 is shown below. Less than 1% of the in-license opportunities

	Number	% of received	% of reviewed
Opportunities received	8672	100%	
Opportunities reviewed at committee	1290	15%	100%
Opportunities where CDAs signed	697	8%	54%
Alliances signed	52	<1%	4%

received and 4% of the opportunities reviewed resulted in deals.

Similar statistics were presented by Roche some years ago where the number of alliances signed as a percentage of new opportunities was less than 2%.

A BD&L executive who closes more than 2 in-licensing deals a year is doing well. Out-licensing has a higher success rate particularly with platform technologies and product divestments but if a biotechnology company has only one lead product and a year or two year gap until the next one reaches proof of concept, the BD&L executive may only have one deal to close every two or three years. In this biotechnology situation the BD&L executive may find their work mainly consists of alliance management once the deal has been completed.

## HOW DOES THE BD&L EXECUTIVE OBTAIN THE NECESSARY SKILLS AND KNOWLEDGE?

Very few executives enter the BD&L profession direct from university. Most new BD&L executives have begun their career in some other function. In biotechnology companies most come from R&D or have a scientific background as the BD&L role requires detailed knowledge of the technology/product. In pharmaceutical companies most BD&L executives have a scientific or marketing background depending on the types of deals to be achieved. There are also some entrants from finance, legal or patents. Whatever their background, new BD&L entrants need some form of training to enhance or develop their skills and knowledge. In addition there is increasing demand for training from executives in other functions who interact with BD&L.

Training courses in BD&L are offered by non-profit making associations and commercial organisations. These vary from introductory courses for new entrants to specialist courses in say, negotiation or valuation. The top non-profit making organisations in BD&L are the Pharmaceutical Licensing Group (PLG) which is the leading professional association for biopharmaceutical BD&L executives in Europe and the Licensing Executives Society (LES) which leads in the US. Both these organisations offer basic courses in BD&L. These organisations also offer their members the opportunity to network at association conferences, access to other member contact details and a regular peer-reviewed journal.

The quality of the courses varies substantially partly depending on the target audience but most of the basic

training courses cover most of the knowledge aspects of BD&L. To assess the quality of a training course it is important for the potential delegate to understand the scope of the course and how it will meet their needs and to critically assess the number and quality of the specialist speakers and the number of delegates allowed to attend. For example a basic training course delivered by one or two speakers to 50 delegates, depending on the delegate's requirements, is likely to be of less interest and less interactive than one where there are 10 specialist speakers presenting to a maximum of 20 delegates.

In addition to the introductory courses, there are more advanced courses for experienced BD&L executives and there are specialist courses that not only cover knowledge but also skills such as negotiation. There is, to the author's knowledge, only one University accredited course that is focussed on all aspects of BD&L and that leads to a Master's degree qualification and that is the distance learning MSc in BD&L offered by the University of Manchester in conjunction with the Pharmaceutical Licensing Group. In practice it has been found that many students choose to take one module in a specialist subject such as Legal or Finance rather than to apply for the full MSc. Also it has been found that many of the modules are taken by non-BD&L executives such as lawyers, project and regulatory executives.

In addition to the knowledge that can be gained from training courses, membership of the professional associations such as PLG and LES can provide valuable information, as well as contacts. For example, imagine a scenario where a US biotechnology company with a primary care product in Phase 2 is seeking a 20% royalty rate. The company has also calculated that the cost of goods will be 20% of the target ex company selling price. So if the licensee company agreed to these terms their gross margin would be 60%. Would this be acceptable to a licensee pharmaceutical company? The answer is probably not according to a survey undertaken amongst European PLG members. According to the respondents, over 50% of branded and generic companies have internal guidelines regarding minimum gross margins. The median minimum gross margin guideline for a prescription speciality product in Europe was in the range 60% to 70% but nearly 20% of companies reported that their minimum was over 70%. Based on this information the US company BD&L executive would be better equipped to understand and negotiate a deal with a European company. Similarly the LES in their journal *Les Nouvelles* from time to time report results of royalty surveys they have undertaken that provide BD&L executives with benchmark data.

## THE IMPORTANCE OF BD&L TO ACHIEVING SALES GROWTH

The contribution of third party collaboration projects to overall sales and growth of a company is very difficult to assess. Part of the reason is the time lag between signing a deal and the product reaching peak sales. It is even more difficult to assess the profit impact of such deals. Over the years some estimates have been made and even allowing for the error in the data, the conclusion is that BD&L projects are a major contributor to sales and profit in most biopharmaceutical companies. In the extreme case, biotechnology companies would not survive without a collaboration not least of all because their business model assumes its products will be licensed out at some stage of development. At the other end of the product spectrum, the generic companies buy regulatory dossiers from third parties to obtain access to products and manufacturing they do not possess or cannot develop. Co-promotion deals provide a useful contribution to sales and profit for one partner and profit for another.

The data showing the contribution of BD&L projects to overall company sales varies enormously. In 2003 Boehringer Ingelheim presented data showing that over two thirds of sales of three of the top 15 pharmaceutical companies were from in-licensed products. 10 companies had an average in-licensed sales of 22% of the total and only two companies sales were entirely from own R&D products. Since 2003 much has changed three of the companies have merged and today not one of the Big Pharma companies has sales solely from own R&D. For example, nearly a third of Abbott's pharmaceutical sales in 2009 (prior to the Solvay acquisition) were from one in-licensed product, Humira (adalimumab) from Cambridge Antibody Technologies. At the European Pharmaceutical Licensing Group meeting in September, Merck & Co reported that 25% of their sales were from in-licensed products.

In many cases the new product sales have come from acquisition of biotechnology and product development companies. For example, AstraZeneca acquired Medimmune in 2007 for over \$15bn and in August GSK acquired Human Genome Sciences for over \$3bn. On a broader basis, over the period from January to September 2012 the aggregate value of biopharmaceutical deals reported in the Deal Watch articles published by Medius was nearly \$77bn. Three quarters of that value was accounted for by company and product acquisitions with an average deal value of \$650m but with an enormous range from GSK's \$3bn acquisition of Human Genome Sciences to \$8m for the acquisition by Alliance Pharma of three products in the UK. In-licensing deal values over the period averaged \$225m, about one third the value of

acquisitions, with a range from \$1bn for a global deal to \$8m for a one country deal. Although pharmaceutical companies now, and perhaps in the future, increasingly depend on collaborations with third parties, the licensing deals are not cheap.

In conclusion, third party collaborations are now an essential part of biopharmaceutical companies' strategy to supplement product pipelines and to maximise revenues using commercial deals. The need for all types of deals and

the high cost of such deals has driven the need for more professional BD&L managers. This in turn has created the provision of training courses to improve knowledge and skills and in parallel the professional associations have provided dissemination of knowledge and best practice to increase the level of professionalism. The contribution to companies' growth of partnered projects and the BD&L executives are fundamental to that success.