

**PHARMACEUTICAL BUSINESS
DEVELOPMENT OPPORTUNITIES**

**THE ART OF DUE DILIGENCE IN THE
LICENSING AND ACQUISITION CONTEXTS**

**Presentation by William J. Kridel, Jr.,
Managing Director of Ferghana Partners Limited**

A. THE SCOPE AND PURPOSE OF DUE DILIGENCE

I am often struck by how similar the analytical processes actually are in:

- attempting to buy a product outright;
- in-licensing a product;
- acquiring or licensing technology;
- acquiring a division;
- and even acquiring a whole company.

In all these cases, a similar process of commercial/legal/financial analysis is used and similar value calculations made. This whole analytic process is also an integral part of the due diligence process - I would call it analytical or "pre-deal" due diligence and is characterised by its being done from outside the precincts of the target company. What I am going to talk about today, however, should really be called confirmatory due diligence, and is what most deals people think about when the word "due diligence" is used, conjuring up a vision of teams of scientists, lawyers, accountants and bankers toiling away in hot and sweaty rooms, verifying the facts and business or technical assumptions upon which the broad deal has usually been already negotiated, or bid for, on a preliminary basis.

I would like to point out right away an important macro-truth about the confirmatory due diligence process: it frequently throws up new questions and later negotiating points, thoughts and questions that perhaps were not even raised in the preliminary deal analysis phases. Those questions were not raised either because they were not thought of before (because of time pressures) or because the information needed to answer them was only made available once the basic deal terms had been agreed or a value range accepted by your counterparty. In short, the later and definitive confirmatory due diligence process and the earlier, preliminary analytical due diligence process that preceded it are

inextricably inter-related: The best and most careful, scientific operating, legal and financial confirmatory due diligence effort is totally in vain if the earlier analytical work was inadequate or inaccurate or simply wrong; for example, perhaps the product in question should never have been initially considered for acquisition or licensing (because it is me-too or a less efficacious product, or does not fit the sales channel profile, or else is about to lose reimbursement status).

It therefore behooves all parties in the due diligence process to keep a continuously open mind about the essential nature of the transaction as they conduct due diligence - i.e. keep an eye on the wood even while analysing the individual trees. In this way, the scope of confirmatory due diligence as it is undertaken becomes not only a matter of verifying statements or confirming informational facts, but also a process of continuously asking questions to test the merits of the contemplated transaction.

It follows that confirmatory due diligence is often accompanied by parallel or subsequent negotiations on the contractual terms of the deal itself.....

B. DUE DILIGENCE IN DIFFERENT DEAL SETTINGS

The scope of due diligence, and the composition of the related work teams, varies quite a bit according to the nature of the deal that is being contemplated. This conclusion can be shown as follows:

Different Deal Structures

<u>Deal Type</u>	<u>Who is Responsible</u>
Marketing Agreement, Licensing Agreement / Product Acquisition	Licensing Department
Joint Venture/Corporate Partnering	Licensing Dept + Business Development Unit
Acquisition of a subsidiary or an entire company	Business Development Unit M&A Group

Generally speaking, the simplest type of deal, and the one requiring the least intensive due diligence, is a marketing agreement or licensing arrangement. A joint venture or a corporate alliance/partnering deal lie somewhere in the middle in terms of deal complexity and weight of due diligence requirements (with corporate partnering being more heavy as it frequently has an equity investment element). The most complex deal of all, and the one requiring the heaviest and best orchestrated due diligence effort, is the outright acquisition of a division or of an entire company. It is in these sale and purchase situations that an investment banker is most likely required, because the due diligence process will involve many people, working in teams - accountants, lawyers (both in-house and external); environmental experts; sales and marketing people; clinical dossier and registration experts; technology assessors and outside patent counsel; with the investment banker in the middle of it all, trying to ensure that the work is done efficiently and well - often in the face of the tight time guidelines and logistical problems (availability of people, travel schedules etc.).

Part of the early analytical due diligence should be the CHOICE OF THE TYPE OF DEAL to be done, and I would like to say a few words about each of these deal types, as the due diligence requirements are a bit different. There is, by the way, a tendency for deals to start in one category and migrate “naturally” towards another, as due diligence reveals both opportunities and problems that were not originally contemplated.

B-1 Marketing Agreements

A marketing deal is aimed at presumably a launched (or soon-to-be launched) product conferring no technology access... such an arrangement is capable of being expanded to cover a family of products or a therapeutic field... the arrangement can be replicated easily in different countries or regions. For the product originators, depending on the deal struck, it can involve a stream of product-sale revenues less the "sales agency fee" paid as commission, or else just the receipt of royalties, paid on a per unit basis or on sales values. A marketing arrangement allows great flexibility for both parties by its very nature, and by its ease of termination; thus, its risks and its rewards to both sides are relatively limited..... derivatively, the due diligence requirements can be relatively light.

B-2 Licensing Arrangement\Product Acquisition

This type of transaction is like a Marketing Agreement, but there is a greater level of commitment. In economic terms, I think of a Licensing Agreement as a bit like a long-term lease and a Product Acquisition is actually more like a full-payout and up front lease, because a pharmaceutical product has a bell curve-shaped sales pattern over a 10-20 year sales period and eventually fades away. Both of these types of transaction, and a Marketing Agreement, will typically be handled and negotiated by your Licensing Department.

B-3 Joint Venture

Moving ever upward in the complexity charts for due diligence, a JV format involving the creation of a new and free-standing enterprise, usually occurs when two parties with complementary technology, or market coverage, or product ranges, decide to pool resources so as to achieve benefits of scale ($2 + 2 = 5$). Frequently there is a fixed duration of the JV agreement, after which it may be dissolved or else one party may have the right to buy the other out (like Astra is doing with Merck). The main problems with a Joint Venture are: who controls it? And who gets to consolidate it (accounting-wise)? Despite these human and accounting problems, a surprising number of JVs exist and some have worked satisfactorily over long periods of time (Johnson & Johnson/Merck Consumer Healthcare is an example).

B-4 Alliance/Corporate Partnering

This format is basically a means whereby a deep pocketed (but quite mature pharma company), with full manufacturing and selling capability, extends its operating, financial and product development assistance to a smaller, underfunded but highly creative company which has an "idea" (such as a wonderful new gene therapy product or process technology or chemical molecule). Why? Because the smaller company does not have all the necessary business skills or the financial muscle or geographic/functional market presence to develop or market the innovative product or technology. Depending on the deal struck, a Corporate Partnering arrangement achieves, for the large company, a stream of net incremental revenues from eventual product sales, after paying costs such as clinical development expenses, R&D funding, milestones for technical/clinical/regulatory achievements, and royalties. The decision for the large company is whether it gets better value from such an arrangement rather than from an outright acquisition of the smaller company. In other words, "Why buy if you can rent?". Certainly, a Corporate Partnering

arrangement gives a degree of flexibility to the large company, since the acquisition of the smaller company remains an option that can usually be pursued later... and more easily... and even perhaps, pre-emptively by including some sort of right of first refusal provision.

There is an element of acquisition due diligence needed in a corporate partnering deal, because of the frequent inclusion of an equity component, i.e. where Big Pharma invests in the equity of the smaller company at the outset, hoping thereby to recoup some of its outlay by the hoped-for capital appreciation of its investment. Obviously, the scope and the amount of due diligence needed for a corporate partnership goes well beyond that required for a licensing deal. I can illustrate that point by noting that we at Ferghana are engaged on a number of corporate partnering assignments where, typically, we work not only with the Licensing Department, but also with the R&D and Business Development units of our client as well as its CFO, as well as their respective opposite numbers at the counterparty company.

B-5 Outright Acquisition Of a Company

There is a story about a pig and a chicken that were once involved in a discussion of how to solve the problems of the Third World. The chicken was heard to say that it would pledge to give all of its eggs to relieve Third World hunger in future, and perhaps the pig would consider doing likewise with its bacon. To which the pig replied, "What you are talking about is the difference between tokenism and total commitment". Well, the acquisition of a company, when compared with a Licensing Agreement, is like the difference between tokenism and total commitment, certainly as far as the level of contractual engagement and level of supporting due diligence that is required.

C. DUE DILIGENCE PROCEDURES

Turning now to the procedural side of the due diligence exercise, I will discuss the main due diligence needs, such as might be appropriate for a demanding Acquisition, and leave you to draw your own conclusions as to which parts may be “played down” somewhat in a Marketing Agreement or Licensing deal.

C-1 Sourcing Information On The Products/Technology/ Finance of a Counterparty

A careful person should assume (a) that there may be no formal document from your adversary pulling together all needed information for you to use, and (b) if an Information Memorandum exists, that it is incomplete, even if it may be correct..... as far as it goes. Here are some sources that should be looked at by a careful buyer or in-licensor (this confirmatory work can be seen, by the way, as an extension of the prior analytical due diligence process):

1. Material published by the Counterparty, such as annual reports and science/technology/product introduction and press release packages (for public companies, some larger, older private companies and many aspiring but young biotech/pharma companies still in their private larval stage).
2. Industry publications (like Scrip, Clinica, Animal Pharm, InVivo, Start-Up and R&D Focus, Drug Market Development, Nature Biotechnology and its sister magazines)

3. News archives from magazines and science or clinical pieces in learned journals and institute proceedings...including electronic databases for literature searches on patents, mechanisms of action, scientific theories and experimental results. This process is crucial in evaluating the excellence and uniqueness of the product or technology at the heart of your deal.
4. The Internet, linking (a) to hubs on topics like neuroscience or diabetes or (b) to company-specific sites or (c) to databases on the therapeutic segment or industry sub-category to which the targeted product, technology or company belongs.
5. Research reports from brokers, industry analysts or consulting firms on the company, or on its technology or on the relevant industry segment.
6. Interviews with industry experts, sometimes retirees from the target company or from comparable businesses with market/technology expertise.
7. Biographies of, and news interviews with, the company founders or leading executives, usually vanity pieces in which unusually clear and proud disclosure is made.....including their personal/work histories that may intersect with your most feared competitors.
8. Dun & Bradstreet or Equifax reports for determining the financial strength of your counterparty...especially important if there are ongoing obligations such as funding R&D or paying milestone bonuses. This data can be supplemented by informal, but penetrating, chats with the bankers to, and investors in, the Counterparty...to see the nature and extent of financial support for it. If any doubts persist, talk to suppliers and other alliance/marketing partners.

9. Filings at the local company registration agency, supplemented by published material on the Board and Management of the Counterparty, will start to reveal who holds power and has significant ownership. Further probing of consultants, allies and grant-making agencies will show who are the real-decision makers in this deal context.

It should be noted that the pressures of business and your development team's desire to succeed might tempt them to go beyond the bounds of what is proper and legal in gathering information. There are not very many Rules, but here are a few caveats, to which you should be particularly sensitive:

- A. Do not pretend to be someone else and do not permit your inquiring agents or advisors to tell lies or disguise their identity inappropriately, such as saying they are from a newspaper or television company
- B. Do not hire people to go and work inside your competitor or a counterparty, with the specific objective of procuring non-public information, which will be later conveyed to you openly or clandestinely
- C. Do not engage in wire-tapping or mail interception, as these two activities are highly illegal
- D. Do not hire away employees from your competition or potential alliance counterparty and then induce them to break their ongoing Confidentiality Agreements....

Otherwise almost everything else, managed with common sense and an overriding concern for fairness, is permitted as you do indeed need to get clear and unbiased information about the facts concerning, and the intentions of, “the other side”.

C-2 Major Steps in Due Diligence

Before getting into due diligence proper you have to pick and organise your Due Diligence Team:

C-2-A Setting up The Team and Preparing for the Project

The "team" can vary from a couple of licensing experts, in a simple Licensing deal, up to a full panoply of lawyers, accountants, scientists, patent agents and environmental experts (drawn from inside and outside your company) in the event of an Acquisition. It behooves you to prepare some key elements before moving further down the transactional road:

1. Confidentiality Agreements - are they needed or not? Frequently, we at Ferghana advise clients to insist on a Confidentiality Agreement, even if not requested by the Counterparty at the outset, so that both sides can proceed rapidly to substantive talks and avoid an initial meeting where the parties spend a lot of time hedging their remarks on the product, science, technology or clinical development programs. Such a Confidentiality Agreement can be written in a unilateral mode to protect the licensor or acquiree but equally often is in a two-way format permitting each party to share data with the other freely.

2. As the chief negotiator, do you have the approval of the highest authority at your own company before you proceed (to avoid the equivalent of a soccer "own goal" which often happens, even within quite sophisticated deal-doing companies).
3. Do you have the resources (financial and people) that you need to fulfill the investigation and conclusion of this project, sometimes (as in an auction process) with tight guidelines, on time and coverage, imposed by the counterparty?

Once you have organised these intangible elements, here is what follows:

Selection of your "inside" management team, including deciding who leads the due diligence, who runs the actual negotiations, and with what authority.

Allocation of tasks, and clear lines of responsibility, to outside advisors, especially:

- (a) lawyers (for the legal context of a deal and IP rights);
- (b) accountants (to analyse the financial data, especially where presented in foreign languages and under unusual accounting formats);
- (c) technology/clinical development assessors (to analyse the excellence and uniqueness of the underlying science and appropriateness of the clinical program);
- (d) consultants (for environmental and product liability matters);

and, most important!

(e) Investment bankers (to aid with strategic advice as to valuation, structure and negotiation, and in putting all the legal/accounting and other deal elements together).

Establishment of time deadlines for various phases of the deal.

Provision of clear guidelines on secrecy (both inside and outside your organisation).

C-2-B Evaluating Size And Fit Of The Counterparty

Here is a checklist of key questions to note in looking at the data generated:

Is the size right, i.e. are the anticipated revenues from the Acquisition Target or Licensed-in Product/Technology in the “right” proportion to your existing business?

Is the location right, i.e. does the deal fill out your operations in a given country (with resulting synergies) or put you into a marketplace where you are not present. In the latter case, can you handle the marketing with your existing people resources?

Is the therapeutic fit right?

This question interrelates closely with the next one...

Generally, does the deal complement your existing product line? Or supplement your existing product line?

This fit issue is a huge topic which would rate a speech in itself....and in purely a due diligence sense, I am talking not so much about seizing opportunities, as

avoiding mistakes. If you add product X to your portfolio, do you spur on the sales of your existing product Y (for a $2 + 2 = 5$ outcome) or do you in fact cannibalise the sales of your existing product Y (making $2 + 2 = 3$).

Do we know enough about competing products?

The better-performing anti-cancer drug that you have in your sights may not be worth so much if you ascertain that your major competitor has a promising next generation product for the same malady in Phase III!

Can your Company market the product in the relevant territories - will you have the necessary scale of salesforce or a salesforce that is properly oriented (i.e. hospital salesforce for hospital products) or even if you do have such a salesforce, will it respond enthusiastically to the product/technology that you have in-licensed or acquired for them?

How is the product/technology viewed by researchers, doctors, prominent industry commentators and by the general public?

Who will manufacture the product - the vendor or licensor under a contract with you, your own factories, or a third party?

C-3 Estimating and Analysing the Financial Potential of the Deal

What is the revenue potential? Size of the relevant market? **Ability to penetrate it?** (is the target the first or the tenth product coming to market in that category?)

What do the product's existing or expected **gross margins** look like?

What will the **operating margins** look like (they could be fabulous, if no new sales infrastructure needs to be added)?

For a specific product or product family (in a Licensing or Corporate Partnering context), does the size of the local geographic market mean that you should do a **co-marketing deal** (usually appropriate in a larger territory), or should you really aim for an **exclusive** marketing deal for a territory? (usually smaller)

If the target involves an **enabling technology for a product**, like a slow release delivery modality, or a chiral/single isomer construct, **in what way will it be additive** in terms of revenues, profits, or marketing potential, and what will be the financial costs and other risks that your company will incur before the first revenue is even earned?

What about different fields-of-use or new therapeutic indications for the same product? Check these out and think them through. Also, check that **sub-licences** to the product have **not already been granted by the counterparty** in certain territories and are thus available to you for use or for further out-licensing.

To swap or not to swap? Many Big Pharmas do not want cash as they are awash with it; hence, they would sooner swap technology or products. I believe that swaps are very hard to do (for commercial, not technical, reasons) and rather few are actually done.

C-4 Intellectual Property

Obviously, conduct a full check of patent status in all key territories (granted, allowed or merely just filed).

Hire a patent agent or counsel to make sure that the counterparty owns the exclusive rights to what he is trying to sell or license to you.

Be aware that even then, you may not be in the clear on patent dispute issues. The battle between Biochem Pharma and Emory University as to who had the "prior filing" in the case of 3TC(*lamivudine*) may seem crystal clear to both contestants, but in reality may end up with one party paying the other a royalty simply to end the dispute.

C-5 Quality of the Product Dossier

The due diligence requirements are arguably less onerous for an already marketed product than for a product in clinical development - simply because the approval process of the FDA (and the equivalent bodies in other countries) is itself a massive due diligence exercise that can be relied on quite heavily. Thus due diligence for a marketed product is more in the nature of a quality assurance (QA)/quality control (QC) exercise.

A. Due Diligence For A Marketed Product

The key questions here are:

Have adverse events been properly documented and reported to the appropriate regulatory bodies?

Is the product being manufactured according to GMP and the agreed specifications?

Is the product being marketed in accordance with the labelling and other approved specifications?

Has the dossier been kept up to date?

B. Due Diligence For A Product That Is Under Clinical Development

The key questions here are:

Who is the “sponsor” of the clinical trials?, and is it in agreement or conflict with the outside CROs, or its internal counterpart, with respect to the integrity of the submitted preclinical and clinical data?

Are all the clinical trial procedures appropriately set up and properly documented?

Do the experiments conducted demonstrate the stated objectives?

Is the methodology that is used for the trials fair and reasonable (appropriate sample size; appropriate statistical power for P and OR; appropriate dosage levels chosen; is a formulation used one that is likely to be the final marketed form? etc).

Have the timelines for the various stages of clinical trials been realistically drawn up?

Have the costings for the various stages of clinical trials been realistically done?

Are the clinical endpoints properly chosen to ensure successful registration?

Is the requested labelling compatible with clinical trial results and the company goals in the context of the regulators’ advice?

Most important, is the time and money to be spent commensurate with likelihood of eventual success(or the risk of failure)?

D. TRANSACTIONAL ELEMENTS - ACQUISITION ONLY

There are additional elements of due diligence that are applicable only in the Acquisition of a division or an entire company. Some of these form part of the Analytical Due Diligence process and some really come under the Confirmatory Due Diligence heading.

1. Does a deal for the Target even look feasible, given the ownership structure or financial needs of its shareholders? Key factors are the existence of a large shareholding, the transfer of which can facilitate a deal; the realisation needs and time-frames of early investors other than management, such as venture capitalists or loosely-affiliated industrial shareholders; is there a founding family involved still in ownership and/or management roles? If so, what are its goals? Etc.
2. Is the management any good, or will you have to provide your own?
3. How will any deal be paid for, in cash or in your shares? (for example, acquisition for shares is less acceptable in Southern Europe than in the UK or Northern Europe).
4. What minimally acceptable level of ownership is sought... for control and/or for accounting purposes....and what are the impacts of the different outcomes on your reported profits?
5. What is the prospect of being overbid by a competitor, once a given deal is “in the air” but not yet finalised, with all the attendant costs of advisors and wasted management time.

6. You need to pay attention to local rules, such as the UK Stock Exchange “Blue Book” rules, containing requirements such that an Acquiror buying 30% of a public company must bid for the remainder.
7. Are the accounts audited to your satisfaction? The lack of audited accounts for even a key subsidiary can cause all sorts of problems, as can accounts that are not prepared in the Generally Accepted Accounting Principles of the acquiring entity.
8. What about foreign currency considerations? This factor has a high impact on reportable earnings, if the Target’s business is in a volatile currency locale.
9. Watch out for obligatory filings with securities regulators (take-over codes) or merger authorities (anti-trust rulings) and, in some countries, Foreign Investment Review agencies regulating the acquisition of a local company by a foreign entity. These elements frequently cause a delay in closing a deal (sometimes, closing follows exchange of contracts by some weeks as a result of these factors)... and might leave completion susceptible to a hostile intervention by a third party... so tie up the loose ends early.

E. WHAT TO DO WHEN THE DEAL BLOWS UP OR TERMINATES PREMATURELY

There is much pharmaceutical industry consolidation, some of it involving the merger of two large Pharma companies with each other, like Sandoz-Ciba Geigy or Synthelabo-Sanofi or RPR-HMR; hence, there is a diminishing number of attractive and big counterparties to partner-seeking biotechs. One of the less attractive aftermaths of such a merger is a brutal review of R&D programmes, both internal and external. Since one of the objectives of most of the large-scale transactions is the rationalisation and re-focussing of R&D, there is a high degree of risk that a small biotech company will see its alliance agreement cancelled.

Moreover, there are other non-merger factors which can lead to the termination of an alliance: disagreement over the course of basic research or the conduct/design of clinical trials, loss of financial strength in the external funding partner, discontinuance or decreased emphasis by your partner in the therapeutic sector in which your biotech company is participating or the worst of all...your programme, beloved by the initial Counterparty B, is in now conflict with merger Party A who insists on its termination. Equivocal clinical results leading to a loss of confidence in the approvability of your compound and the advent of better compounds or supportive technologies can lead also to your big partner to “drop out”.

At this point, you may be asking yourself “What can I do to protect right now my little, but ambitious, company?” My answer is: “very little right now....you should have done it at the start of the alliance, by drafting the contractual papers appropriately.” If you do not have legally enforceable provisions in the alliance documents, you must throw yourself at the mercy of your partner in hopes that it wishes to protect its reputation amongst other biotech companies for future deals, or because you have excellent personal relations with the CEO and other

decision-makers at your exiting partner. If you are truly treated unfairly and have no pre-existing legal protection, there are not many judicial theories that can protect you.....except perhaps *quantum meruit*, a theory of equity which says that a party must be compensated for the value of the thing conferred by itself upon the counterparty.....a very difficult matter to prove in a court of law especially if the compound has failed or the clinical program has been delayed, etc.

So, assuming that we are right back at the beginning of the alliance, you should enter into the appropriate type of protection which involves claw-back arrangements. These provisions involve the fate of the intellectual property, compounds, back-up compounds, clinical trial protocols and results, plus related matters like specially created enabling technology, all of which would be returned to you upon specific termination of the alliance. Even these provisions might involve a continuation of R&D funding by the Pharma partner for one and two quarters, since it is too cruel for the small biotech company to cut out the beating, pulsing research heart of its organisation overnight. Moreover, these extra provisions may contain a revenue claw-back, in favour of the original external partner in that they provide for a very modest level of royalties to be paid by the biotech company or by its later alliance partner in the event that the compound or technology is ultimately commercialised.

CONCLUSION

Although my remarks to date may have sounded like a declamation of a diligent laundry list, I hope that they will have been generally helpful in organising your quest for knowledge. I would like to summarise with three overriding and overlapping messages:

1. Analytical Due Diligence goes on at all times, even during the Confirmatory Due Diligence, deal negotiation or deal closing process.
2. Proper organisation of the Confirmatory Due Diligence process is essential - even for apparently simple Licensing transactions but especially for complex deals such as Acquisitions.
3. Use an investment banker to co-ordinate the process or, if you don't, plan the process - and the people management process - carefully so as to achieve deadlines, and best of all, after the deal has been done, to ensure that you will have no regrets.

- 0 -