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Winning The Due Diligence Process

Keys to a Successful Transaction

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The biomedical industry has grown explosively since Genentech, the first commercial biotechnology company, was founded in 1976 – to the point where there are thousands of biotechnology and biomedical companies. This large number of companies and their commercial potential has attracted investment capital from venture capitalists and private equity firms and the interest of large pharmaceutical companies focused on building their product pipelines.

Although venture capital investment and big pharma's interest has never been greater, the investment dollars are spread among an increasingly large group of companies. Many factors affect whether an investment is made or an M&A deal is struck. But no VC firm or pharma company makes an investment or enters into a partnership or alliance without conducting extensive due diligence.

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There are only two outcomes to the due diligence process – pass or fail. Failure carries a very high penalty, including the possible end of the company. Careful planning, preparation and commitment of the time and resources to this process can often make the difference between success and failure.

Simply put, due diligence is a detailed analysis and investigation of the company's commercial, legal and financial status. Although much of successfully navigating the due diligence process is common sense, a surprising number of companies commit serious errors that could be avoided with greater preparation and understanding of the process. Failing any part of the due diligence process could cause your company to miss a vital capital infusion or a game-changing M&A opportunity.

This article serves as a primer on successfully completing the due diligence process, addressing important points that are often overlooked and lead to serious mistakes during due diligence.

Planning

Don't wait until the due diligence meeting is scheduled to accumulate and organize the due diligence material – that's too late. Once a company decides to seek an investor or partner, planning for the due diligence audit should begin immediately. First, due diligence binders should be created containing detailed information for the 12 subject areas of due diligence (see Table 1). Provide as much of the information electronically as possible and consider establishing an electronic virtual data room where all information can be accessed remotely, protected by appropriate firewalls. Generally, the process of gathering all of this information will highlight areas where gaps exist. The process of obtaining and organizing the due diligence information takes a minimum of several weeks.

Financials

Financials for a biomedical company are often given short shrift because the top line typically doesn't materialize until a number of years out. But the financials show how carefully a company is managed and the level of their contingency planning. In addition to historical information, provide five years of detailed projections, including a balance sheet, P&L and cash flow. Financial projections should be attractive but very attainable.

Particular attention should be given to the assumptions and resulting sensitivity analysis with a range of outcomes depending on optimistic, realistic and pessimistic assumptions for clinical outcomes and duration. Investors don't like to write

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big checks for unexpected financing needs, particularly when milestones aren't being hit. But, if provided with realistic scenarios, they are more liable to support additional financing at a reasonable valuation.

Detailed interim financials on a monthly or quarterly basis should be provided so prospects can track the burn rate and ensure the company is meeting planned goals. Budgeted expenses should be very detailed and broken out by subject area including, at a minimum, General & Administrative, Research and Development and Pre-clinical and Clinical expenses. Clinical expenses should be further broken out by product area, and a sensitivity analysis performed to see what impact the number of trial patients or cost per patient has on expense.

We all read about the many failures or delays of clinical trials. If prospective investors or corporate partners might have to write future checks, they want to know how big they are going to be. Some pharma companies use elaborate models and Monte Carlo simulation (an elaborate modeling technique) to simulate different clinical scenarios and related expense and future timing for product commercialization. Based on these outcomes, different valuation techniques and probabilities are used to estimate a company's value and resulting investment proposal.

A company must be reasonably conversant with these techniques and able to provide the necessary input in order to pass the due diligence process. (See "How Much is Your Company Worth" in the January, 2007 issue of *BioBusiness News*, or contact the author for a reprint.)

1. Corporate Books and Records
2. Regulatory Filings
3. Federal Grants
4. Financial Information
5. Employee Materials
6. Contingent Liabilities
7. Contracts, Agreements, and Other Arrangements
8. Intellectual Property and Proprietary Rights
9. Plant, Property and Equipment
10. Insurance
11. Sales and Marketing
12. Miscellaneous

Table 1. Due Diligence Scope

References

All prospective investors or M&A partners check references, some much more than others. Again, planning can avoid unpleasant surprises. Every potential reference – personal, business, academic or professional – should be called and permission requested to give their name as a prospective reference. Common courtesy requires that references be called before giving out their name.

The other reason to call is to determine how positive, or negative, the reference will be. Companies are sometimes blindsided by unexpected negative references. Review sample questions with the reference as a courtesy, and subtly probe to determine how the reference might answer prospective questions. Of course, the preparatory call must be done carefully, so that prospective investors will not feel that the reference call has been "rehearsed."

Depending on how the reference reacts, form a view on whether the subject will make a suitable reference. The investor or M&A prospect can then be steered to the most relevant and helpful references.

Tell the Truth

This may seem like obvious advice, but an amazing number of company officers exaggerate, shade the truth, or try to characterize neutral or bad news as positive. Prospects see right through these attempts at "managing information," causing the management team to lose credibility. Prospects are in the business of taking risks when they believe the upside potential outweighs the downside risk. But prospects are not willing to take risks on management who are not trustworthy or do not communicate honestly. Once management loses their credibility, it's the death knell for any investment or M&A deal.

Showcase Your People

Due diligence is an opportunity to showcase your people. Typically, the due diligence process involves days or weeks of time spent by prospective investors or M&A partners in the target company's offices. It physically brings together both groups. Make sure you let your management team and employees demonstrate their abilities and acumen. Too often biomedical ventures rely on the genius of one or two scientists or entrepreneurial pioneers. Successful biomedical companies must develop competent disciplines and managers in multiple areas. Investors are willing to replace one or two key employees, but are not willing to replace an entire management team. So show off your management team and let them build investor confidence at every opportunity.

Role of the Chief Financial Officer

CFOs sometimes come across as glamorous or as sales and public relations oriented. Investors don't want glamorous CFOs. They want a CFO who knows where every penny is buried and who can be relied upon to honestly communicate what is actually happening from a financial standpoint. During presentations or due diligence meetings, the CFO should come across as the authority on all the numbers, demonstrating command, not glamour.

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Work Through Lunch

Conveying the right work ethic is an important part of passing the due diligence audit. Your prospective investors or partners want the maximum pay-off from their investment. Obviously, the best investment is in great science, a huge market and a strong management team. But satisfying all three elements is rare. Inevitably, there are trade-offs. Average science or an average market, but a superior management team can work. Great science or a large market, with a mediocre management team rarely works.

Part of being a great management team is not only "working smart" but "working hard." Investors love to see their investees working nights, weekends and long hours. So, make sure you convey that work ethic during due diligence.

Consider Using a Professional Adviser

The due diligence process is incredibly time consuming and disruptive to your business and is just one element of successfully completing a company's initiative, whether that be M&A, a capital raise or a strategic alliance or partnership. A professional adviser can take over much of the responsibility and time commitment necessary to complete the assignment, by finding the right M&A partner or investor, guiding you through the due diligence gauntlet, negotiating fair documents and successfully closing the transaction. ■

Note: A detailed due diligence check list is available from the author.

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