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Successful Life Science Collaborations Require Flexibility

Law360, New York (February 21, 2013, 11:57 AM ET) -- It goes without saying that the process of getting innovative new medicines to patients is a long, complex and expensive undertaking. One of the ironies of the life sciences industry, however, is that small companies — the ones that don't always have the time, money or global capabilities to develop and launch a new medicine on its own — are the source of much of the innovation in it.

Strategic partnering, therefore, is important. For emerging companies, it can provide capital, expertise and global reach that could prove challenging to build independently. For established companies, it can provide access to innovation and leverage existing capabilities in drug development and commercialization. Given the complementary objectives of parties entering into strategic alliances, it stands to reason that these arrangements should be universally successful.

But they're not. In fact, most strategic alliances fail to meet the objectives of the parties at the time they were entered into. This isn't just because the risk of failure in drug development is high. It's because, during the life of the alliance, the strategic objectives of the parties can evolve to a point where the terms of the alliance no longer advance those objectives. It's because the regulatory, competitive and reimbursement landscapes for biological and pharmaceutical products are changing and the economic terms of the transaction may no longer be as attractive. It's because M&A activity and portfolio prioritization exercises can result in good product candidates not being "good enough" to survive in a restructured organization.

In nearly 20 years of advising both licensors and licensees of biological and pharmaceutical products, I have come to appreciate that the companies which get the most value out of collaborative relationships are the ones that continue to pay attention to the parties' strategic objectives long after the ink on the contract is dry, that maintain regular, open dialog at the senior-most levels of the organization as to what is working and what isn't, and that aren't afraid to put the contract aside and think about new and better ways to achieve the parties' individual and collective goals — even if it means a complete restructuring of the relationship.

Restructuring a collaborative relationship doesn't signify failure. Rather, it creates an opportunity for each party to focus its financial resources and intellectual capital on places where it can create the most value. To wit, BiogenIdec and Elan announced earlier this month that they planned to restructure their collaboration to develop and commercialize Tysabri (natalizumab), a treatment for multiple sclerosis.

This collaboration began in 2000 and, over the course of the last dozen years, the parties overcame challenges that would put a strain on even the most healthy of relationships — M&A activity, safety concerns with the product, and litigation between the parties over certain contractual rights. During this period, the prospects of the parties' product portfolios continued to evolve as well — BiogenIdec continued to grow its multiple sclerosis franchise and established its market leading position in this field, and Elan increasingly focused its portfolio toward treatments for neurogenerative diseases such as Alzheimer's and Parkinson's disease and away from autoimmune diseases such as multiple sclerosis.

Notwithstanding the challenges that BiogenIdec and Elan faced during the course of their relationship, they remained focused on opportunities to create the most value for each other, their respective shareholders and, ultimately, for patients. In their restructured relationship, Elan agreed to provide BiogenIdec with complete strategic and operational control over the commercialization of Tysabri, enabling BiogenIdec to leverage its expertise and commercial infrastructure in the field and to obtain an increased share of downstream revenues. In return, BiogenIdec committed to a significant up-front as well as additional downstream payments that provide Elan a substantial opportunity to invest in other research and development programs that can diversify and de-risk its overall portfolio, while also giving Elan a meaningful, albeit smaller, financial interest in Tysabri's future success.

Similarly, last summer, Infinity Pharmaceuticals restructured its global strategic alliance with Purdue Pharma and Mundipharma. After a productive four-year collaboration, Mundipharma wished to alter the financial terms of the relationship, and Infinity concluded that having global development and commercialization rights for IPI-145, its inhibitor of PI3K delta and gamma, were more valuable than having a source of research and development funding.

The parties restructured the program in a manner that returned ex-U.S. rights to IPI-145 to Infinity and gave Purdue a stake in the product's success through increased equity ownership in lieu of product rights. Creativity in restructuring this relationship has proven worthwhile for both parties — Infinity's market capitalization has more than doubled since regaining those product rights, and entities affiliated with Purdue have an unrealized gain in their equity ownership that roughly matches their R&D investment in Infinity over the term of the alliance.

In drafting and negotiating strategic alliance agreements, it is easy to focus attention solely on potential risks and to legislate contractually how those risks will be addressed. It is much more difficult to form relationships — particularly those that create incentives for roles and responsibilities to evolve as circumstances change — and therein lies the opportunity to add value. Because every transaction is different, there are no "magic drafting bullets" to achieve this objective. But there are general principles for negotiating these arrangements that, if followed, can promote opportunities for the parties to get the most out of them, even if their strategic priorities change.

Communicate What You Learn During the Negotiation Process

All too frequently, the individuals who negotiate a collaboration agreement are not those who operationalize the relationship after it is signed. This is an opportunity lost.

During the negotiation process, the parties will share information about the strategic importance of the relationship, or the company's long-term objectives, that provide valuable insights as to how the arrangement may evolve during its term. While many of the things discovered during the negotiation process can be addressed in the contract, others may be inappropriate to address in that manner but should be memorialized as items to monitor over time.

To ensure that potential future risk areas are understood and monitored, I recommend to clients that a member of the negotiating team participate in the ongoing governance of the collaborative relationship. In addition, I generally meet with my client's operations team after the contract is signed to review the material terms of the contract, why they were negotiated in the way that they were, and what the key risk areas are. This will enable the parties to identify potential issues and diverging interests at an early stage, when it is easier to address them quickly and collaboratively.

Focus On Incentives Rather Than Penalties

Emerging life sciences companies often speak, not always in jest, about how long it takes "big pharma" to make decisions or achieve milestones. Whether or not there is any truth to this generalization, this kind of rhetoric necessarily leads to vigorous negotiation over diligence standards ("commercially reasonable" vs. "reasonable best" vs. "best" efforts), what each of those standards means in practice, and what happens if those standards aren't met.

Framing the negotiation in such a manner, around the potential for inadequate performance and the results of the ensuing breach, does not necessarily invite productive conversation regarding performance solutions. How often am I asked whether a party's allegedly lackluster performance is "commercially reasonable?" Frequently. But how often do we discuss whether a licensor would accept a smaller milestone payment if its licensee achieves a performance milestone sooner than anticipated? Not very often. Focusing negotiations on incentives for exceptional performance sets a positive tone and can highlight the parties' strategic priorities much more effectively than parsing a diligence clause in a contract.

Insist On an Escalating Internal Dispute Resolution Process

Many collaborative relationships have a governance/decision-making structure with one or more working groups or committees that manage the operations of the alliance. Ideally, both parties are empowered to participate meaningfully in collaboration governance, and that decision-making processes for the collaboration align with those that each party already has in place for its other programs. While senior executives from each party need not, and in many respects should not, get involved in the day-to-day operations of the collaboration, it is important that a strong relationship between these executives be established and nurtured during the course of the relationship.

In addition, I advise clients that, in the event of a dispute at a committee level, this dispute be elevated to these senior executives for discussion prior to seeking the services of an outside mediator, arbitrator or litigator. First, such an escalation procedure creates an incentive for the operating committees to craft a compromise approach. After all, who wants to admit to their boss (or their boss's boss) that an impasse has been reached? Of course, escalation is often necessary, and escalation to senior executives — particularly executives with a strong, long-standing relationship — will force a discussion of strategic priorities and potential solutions before the parties avail themselves of third-party dispute resolution, after which time the damage to the relationship could become irreparable.

Have a Mechanism To Get a Program Back/Make Sure Each Party Is Compensated for Value Created

Finally, make sure there's an opportunity for one of the parties to pursue the partnered program, even in the event of changed circumstances. Termination clauses of collaboration agreements are often litigated because the value that each party contributes to the partnered program during the course of the relationship is not adequately addressed in "results of termination" section.

As the BiogenIdec/Elan and Infinity/Mundipharma restructurings demonstrate, there is a price at which both parties would be willing to agree to a fundamental change in the relationship. This could take the form of a fixed payment, residual royalties, “tail” research and development funding, or a combination of all three, and it could represent either a fraction or multiple of the value of the program depending upon the circumstances of termination.

Addressing the consequences of various termination scenarios, such as upon a change-in-control, acquisition of a competing product, or equivocal clinical data, in a collaboration agreement can set the stage for future discussions about the optimal structure for advancing the collaborative program under other circumstances. These discussions can easily result in value-creating opportunities for both companies and, ultimately, for patients.

The inherent uncertainty of the drug development process makes it impossible to ensure the success of any collaborative endeavor. However, by creating the right incentives and promoting transparent and open communication, the likelihood that it will have a happy ending, regardless of the data, increases substantially.

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