Corporate Partnership: Lifeline For Biomedical Start-Ups

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Entrepreneurial biomedical companies that lack the resources or expertise to get their innovative products to market can benefit from teaming up with an established corporation. Knowing the options in financial arrangements and the essential steps to take before signing an agreement can smooth negotiations.

If you're an entrepreneur planning to start a drug delivery company, a biopharmaceutical company or a medical device company, you may want to pursue a partnership with a well established corporation after you have proven the feasibility of your technology. Like many biomedical start-ups, your company's technology may have broad applicability and offer too many potential uses for you alone to capitalize upon in a timely fashion. Furthermore, if your company's resources are limited, you could benefit from the support and credibility of a corporate partner that has the resources and market presence.

Partnerships between young, emerging companies and established corporations have a proven history of success. For example, Genentech entered into a licensing and marketing agreement with Eli Lilly for cloned human insulin in 1978, just two years after the company's founding. Under the terms of the agreement, Genentech received up-front licensing fees, payments keyed to interim product development milestones, and royalty payments that began accruing after the product was introduced into the marketplace in 1983. These funds helped the company finance the development of products it now markets itself, such as human growth hormone and tissue plasminogen activator.

Another biomedical company, ALZA Corporation, waited longer to call on the assistance of corporate partners. The company was founded in 1968 but did not begin to achieve success until it started licensing its drug delivery technology to numerous pharmaceutical companies throughout the world. Today, with a market capitalization (shares outstanding times price per share) in the $2 billion range, ALZA now has development and licensing agreements with dozens of pharmaceutical companies. In addition, the company has taken major steps toward marketing its own products.

To help you evaluate the wisdom and timing of corporate partnerships for your company, this article provides:

- An analysis of four major strategic reasons to work with a corporate partner.
- A review of various types of financial arrangements that are possible.
- A description of ten important issues to consider when negotiating with a prospective corporate partner.

When Corporate Partnering Makes Sense

The medical start-up that is considering a corporate partnership is typically motivated by one or more of four basic strategic reasons:

I. The Opportunity to Capitalize on Your Technology – Start-up companies sometimes develop technology that has a broad range of potential uses, not all of which match their own strategic objectives. And yet, a start-up must focus on a well-defined product and marketing strategy to avoid dissipating resources before the company is successful.

If the base technology can be used in products that do not fit the company's strategy, the start-up may want to consider a product development contract or a transfer of technology to another company that has the resources and the strategic fit. In some cases, the start-up will want to transfer the base technology to the larger partner so that the partner can develop and manufacture products. In other cases, the start-up may elect to develop and manufacture products for the corporate partner.

II. Regulatory and Clinical Support – Another good reason for an entrepreneurial company to seek a partner is inherent in the regulatory product-approval process. The costs of drafting a protocol acceptable to the FDA, recruiting clinicians, conducting clinical trials, and preparing results for regulatory approval may be too steep for a new company to bear, especially considering the five-year or longer time-to-market for pharmaceuticals. In such cases, the start-up may identify a partner that has experienced regulatory and clinical departments with the capacity to conduct clinical trials and help obtain regulatory approval. In return, the corporate partner may want the right to sell and distribute the products.

III. Manufacturing Expertise – Manufacturing can represent as great a hurdle as obtaining marketing approval from regulatory agencies. Most start-ups rely on novel technologies for their strategic positioning, and although many develop manufacturing capabilities to use the base technology, others may find it financially impossible to do so. Perhaps the manufacturing process requires a single expensive piece of molding or testing equipment or a costly specialized manufacturing facility or technology, such as fermentation or cell culturing. In such cases, the start-up may be able to find a partner with the needed manufacturing capability and excess capacity.

IV. Access to Selling and Distribution Channels – Assuming that the manufacturing problems have been solved, the challenges of getting the new product to potential customers may lead to a partnership focused on commercialization. Many start-ups cannot afford to invest heavily in marketing, selling and distribution needed to effectively cover the thousands of hospitals, specialist physicians, surgery centers, clinics, etc. scattered throughout the country. The cost of a direct sales force large enough to address targeted markets may be so great that the wisest solution is to market, sell and distribute through the established channels of a corporate partner. For international marketing, such a partner is essential because of the enormous complexities that result from differing government regulations, differing languages, unfamiliar cultural variables and geographic separation.

Economy and convenience are not the only advantages of taking on a corporate partner for marketing purposes. A partner with a reputation for selling high-quality products and providing good service can lend substantial credibility to an unknown medical company. Some potential customers have an aversion to buying from start-up companies, particularly when purchasing expensive items.

On the other hand, if you have a limited product line and sell through a single corporate partner, you may be perceived as having just one customer: your partner. This may narrow your options to sell your company or take it public in the future. As an alternative, you might sell through a distributor and retain the flexibility to create your own sales organization when sales increase and your product line expands.

Alternative Financial Structures for Partnerships

Once you've established that a corporate partnership could benefit your company, you need to decide what kind of partnering relationship you want. Of the many types of financial agreements and terms that can be negotiated, most fall into one of the five following categories, each of which has its pros and cons.

I. Development Contract – Under a development contract, the start-up company may develop technology for a partner under a fee-for-service development agreement. The corporate partner usually wants rights to the technology developed and may agree to pay future royalties based on product sales. The start-up may negotiate the right to use the technology it develops in products that are outside the purview of the contracting partner. For the corporate partner, this fee-for-service arrangement provides the opportunity to acquire needed technology at a negotiated price from a technologically strong start-up. The start-up, for its part, benefits from a cash infusion from the partner, while possibly reserving specific rights to the technology it develops.

II. License – The start-up company may be able to negotiate an up-front licensing fee to pay for accrued expenses, such as development costs and patent filing fees, and may also negotiate royalties on product sales. The objective would be to guarantee the start-up a source of cash and provide the corporate partner with an incentive to commercialize the technology as soon as possible.

By granting a corporate partner a license to certain technology and product applications, the start-up can earn an ongoing stream of revenues without excessive expenses. License fees are usually higher for technology that is patented and lower for trade secrets and non-proprietary know-how. To the corporate partner, royalty payments represent an expense only if the product sells, making the royalties a variable cost.

The prospective corporate partner will usually try to secure an exclusive license and will often object to sharing rights with the start-up company. However, for the start-up, signing a co-exclusive license offers several advantages, including the ability to keep its options open. With co-exclusive rights, the start-up can adjust its strategic focus over time to include the licensed technology and/or product applications.

In addition, co-exclusive rights may enhance the start-up's acquisition value to a potential purchaser.

III. Equity Investment – As an alternative to development contracts and licensing, a corporate partner can make an equity investment in the start-up company in return for certain rights. For the start-up, this approach means an immediate infusion of capital. For the corporate partner, an equity investment means that it can capitalize on the increasing value of the start-up. Accordingly, the corporate partner may want a seat on the board of directors in order to monitor and influence the start-up more effectively.

One potential problem from the partner's perspective is that above certain percentages of ownership (usually 20 percent), an investing company may be forced to use the equity method of accounting, reporting its percentage of the start-up's profits or losses. Since start-up companies usually generate losses for several years, this factor may discourage some corporate investors. At 50 percent or greater ownership, a corporation must consolidate the profits or losses of the start-up company into its own financial statements.

From the start-up's perspective as well, there are potential problems in an equity relationship. The existence of a corporate investor may cause third parties who might be interested in acquiring the start-up to assume that the equity partner has a right-of-first-refusal on an acquisition. In some cases, a corporate partner may in fact want to negotiate terms so that it can acquire the start-up at a future price, usually based on a formula including sales and profits. As a quid pro quo for this type of "call" option, the start-up may negotiate a "put" in the form of an option to sell to the corporate partner at a formula price in the future.

IV. Joint Venture – One other major financial structure creates an ongoing relationship between the parties. The corporate partner and the start-up may agree to contribute technology, cash, people, or other assets to a third entity structured as a joint venture to develop, manufacture, and market products. Ownership in the joint venture is usually commensurate with the value of the assets transferred to it, with both parties gaining from any increase in value of the jointly owned entity.

Before agreeing to a joint venture, the two organizations must agree to a structure for managing the venture. Who will run the company? Who will occupy key management positions? The parties must also agree to an exit strategy, deciding whether the joint venture will eventually sell shares to the public or be acquired by one of the partners.

V. Outright Sale of Technology – This last financial alternative differs from the others in that it creates no continuing relationship between companies. The start-up company simply sells a portion of its technology or a product to a corporate partner. This option makes sense only if the technology or product is not compatible with the start-up's long-term strategy.

Steps to Establishing a Successful Partnership

If you are running a start-up company, don't even consider entering a relationship with a corporate partner without first taking the following essential steps:

I. Plan, Plan, Plan – Before beginning negotiations with a potential partner, identify your desired terms (e.g., royalty rate, minimum payments, licensing fee, percentage of equity). List your ideal terms in one column and acceptable terms in another.

Two medical companies entering a relationship must acknowledge that the action makes sense only if both benefit. Each must sacrifice, each will receive something in return, and each must consider the self-interest of the other. Try to understand what your potential corporate partner really needs, and identify what type of deal structure has worked in the past.

Before signing a partnership agreement, talk to the management of other companies with which the corporate partner has worked and find out whether the partner has been diligent, fair, open, honest, and effective.

II. Divide and Conquer – A company with products or technology to license or sell will usually get the greatest value by negotiating rights for each product on a country-by-country basis. You are unlikely to find any one corporate partner that will be strongest for all products or all markets.

III. Consider the Long Term – Plan for at least a three-year relationship when entering into negotiations with a corporate partner. You and the corporate partner must both plan for price increases (unless royalties are based on a percentage of sales) as well as for royalties on additional products developed. In addition, both parties must decide who will own rights to improvements and new products, and who will file for and own future patents.

IV. Negotiate with Decision Makers – If you want to enter into a corporate relationship, make sure you're negotiating with the person having the power to consummate the partnership. If possible, negotiate with the person who will be responsible for implementing any decision that is made.

V. Establish Performance Standards – Make sure any agreement includes performance standards so that both parties can check progress and ensure their goals are being met. Also establish a timetable for the anticipated completion of development projects; a reasonable schedule for successful commercialization; and minimum sales and royalties.

VI. Wait for the Right Moment – Your start-up can gain more from a corporate relationship if you wait for the appropriate time to meet with potential partners. Most corporations will show little interest if the product or technology hasn't been developed or if technical feasibility has not yet been proven. Sometimes a start-up that is in trouble begins looking for partners. This is the worst possible time – deteriorating operations and an immediate need for cash make you vulnerable.

VII. Disclose Incrementally – Generally speaking, neither party should disclose confidential information in initial meetings – they divulge only enough to determine whether there is a basis for future negotiations. If your start-up company and the prospective partner are interested in further discussions, both should enter into confidentiality and nondisclosure agreements before continuing to the next round of meetings.

VIII. Allocate Adequate Resources – Negotiating a relationship with a corporation requires time, an important consideration for a start-up with limited resources. Implementation of the agreement also uses up time as well as other resources. If your start-up cannot afford to devote these resources to the relationship, you probably should not pursue it.

IX. Keep Legal Counsel Involved – Inform your legal counsel of each step in the negotiating process. The services of a good lawyer can be critical to avoiding unfavorable or adverse terms and to helping structure an acceptable agreement. Make sure any agreement reached ensures confidentiality and protects ownership of the technology.

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> The more time spent planning and defining terms up front, the more likely the partnership will be long-lasting and fruitful for both parties.
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X. Plan for Contingencies – Consider what your start-up company will do if the corporate relationship fails. Company management can change, conditions can change, and so can the desirability of the relationship. Define how and under what circumstances you can extricate your company from the agreement. Don't enter a corporate relationship if an unfavorable outcome will destroy your company.

When a Partnership Succeeds

Assuming proper attention is given to the steps I've highlighted in this article, an agreement with a corporate partner can accelerate the growth and enhance the value of a start-up biomedical company. Along with making sound business sense, the exchange of technology or product rights for financial, regulatory/clinical, manufacturing or marketing support can result in the commercialization of products that otherwise might not have made it.

If you're considering the formation of such a partnership, make every possible effort to ensure a solid relationship. Study the various financial structures available and select the one that meets your objectives. Then follow the list of ten essential steps, noting that you must begin with advance planning and end with contingency planning. In all of your planning, the first consideration must be your start-up's survival and prosperity. And remember: it's unwise to bet the company on circumstances and events that are outside your control.

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De Novo Ventures is a lead venture capital investor focusing on the early stage financings (the seed, start-up and first round) of medical companies in the western U.S., particularly in California.

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