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# STRATEGIC FOR LIFE SCIEN

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eveloping Life Sciences companies (including pharmaceutical, medical device and biotech companies) are almost universally running out of money. The IPO market is effectively closed. Valuation multiples for acquisitions are plummeting.

A large portion of the publicly traded biotech industry has had its market capitalization decimated. Venture capital firms are re-examining their existing investments and generally reluctant to make new ones. Those that are actively investing are more closely scrutinizing each investment, and when they do decide to fund a company, they have their pick of the bumper crop of companies seeking funding.

Device and pharmaceutical companies are also facing non-economic pressures. Large fully integrated pharmaceutical manufacturers are undergoing tremendous restructuring and cost-cutting efforts driven primarily by upcoming patent expirations and a lack of strong products in development pipelines. For example, in 2012 the following major drugs are scheduled to go off patent: Astra Zeneca's cholesterol drug Crestor; Forest Laboratories' antidepressant Lexapro; GlaxoSmithKline's diabetes drug Avandia; and Merk's asthma drug Singulair.

All of these factors have conspired to force growing life sciences companies to find new ways of leveraging their existing resources. This presents both challenges and opportunities for those in the industry - development stage and mature companies alike. Following is a brief summary of some of the most common arrangements we have been seeing.

## STRATEGIC INVESTMENT

A strategic investment involves one company making an equity investment or preferred debt investment in another company. This equity or debt infusion enables the recipient to fund future R & D efforts. This partnering strategy typically includes additional rights for the investor in either a specific product or category of products being developed by the recipient company. This may include, for example, preferential treatment in future investment rounds or a right of first refusal to acquire or license technology.

This strategy has several advantages. It is a hands-off transaction that is simple to document and can be accomplished relatively quickly. Strategic investments typically involve very low integration between the investor and recipient. This effort may involve appointment by the investor company of one or more members to the recipient company's board of directors, but there is rarely a joint project team or other day-to-day input on the development of the recipient company's new products. The lack of integration and control is also the most significant disadvantage for the investing company the investor has little real control over the direction of the R&D or the company itself.

## ALLIANCES CES COMPANIES

Many large pharmaceutical companies and device manufacturers have their own venture capital arms to facilitate strategic investments. For example, Astellas Venture Management, LLC, the corporate venture capital arm of Astellas Pharma, Inc., is dedicated solely to identifying biotechnology start-up companies with promising early-stage products. Amgen, Eli Lilly, Johnson and Johnson, Pfizer and Takeda have similar venture capital arms.

### **CO-DEVELOPMENT**

A second type of partnership effort can be characterized as a co-development relationship. A co-development relationship typically involves the joint contribution of, labor, intellectual property, capital and other assets.

Many large fully-integrated pharmaceutical manufacturers and large device manufacturers have established teams that specifically identify and nurture co-development relationships. A co-development relationship is formalized when the parties enter into a Co-Development Agreement. The Co-Development Agreement will typically establish a joint project team that includes personnel from both companies who will oversee and contribute to the development of a product or category of products.

A key component of the relationship is the provision of additional capital in the form of an up-front payment, with a number of subsequent milestone payments to keep the project moving forward toward product approval. Co-development agreements may also involve equity investment or preferred debt placement made concurrent with execution of the co-development agreement. Companies with later stage technology to contribute typically have the most to gain from co-development relationships.

Co-development relationships are advantageous for the more established party as they allow phased contributions and access to new technologies to help add to existing product lines or bolster pipelines. Further, their collaborative team-oriented nature can create synergies and efficiencies for companies that have existing expertise in a therapeutic area. For companies possessing a technology that needs additional resources to bring to market, co-development relationships can offer both access to capital and expertise to complete late-stage clinical trials or other later stage hurdles.

There are two primary downsides of entering into this type of relationship. A Co-Development Agreement does not result in the creation of a separate legal entity, therefore both companies may bear liability that results out of the relationship. Consequently, insurance indemnification and other risk allocation obligations should be structured carefully.

Second, if the pairing does result in a successful product, profit and intellectual property may be co-mingled between the co-developers. This can result in difficulties when attempting to untangle the various assets, including intellectual property. Another key challenge is confidentiality and proprietary information. Entering into such a relationship may make secrets harder to guard and can give away certain valuable process information and trade secrets to competitors. In this regard, co-development relationships hedge risk, but also hedge reward.

### **JOINT VENTURE**

A third general category of partnering effort is the joint venture. A joint venture can BART involve any number of parties but in this arena most commonly involves either: (i) a larger pharmaceutical or device player and a start-up or (ii) similarly sized companies that have complementary technologies. The parties form a new entity, typically a limited liability company, to which each party will contribute some combination of assets, intellectual property and personnel. The joint venture then takes responsibility for ownership and development of a product or category of products using the assets that have been contributed by both parties.

Joint ventures require high integration, but the structure of the joint venture entity itself can be flexible and can be designed to meet the goals mutually agreed upon by the parties. Perhaps the largest benefit of a joint venture as compared to other bio-partnering arrangements is that the separate entity structure generally limits the liability of each individual party to its contribution to the joint venture entity. This separate entity structure of a joint venture affiliation does bring some challenges, however.

A joint venture can be difficult to unwind. Further, governance issues may arise: there are only two ways to structure voting rights in a two-party joint venture: voting is either split evenly between the parties, which can lead to deadlock, or one party holds a majority of the votes which can leave the minority party with less control over the venture. Finally, joint venture collaborations between certain parties may raise antitrust concerns. The Federal Trade Commission ("FTC") has released "Collaboration Guidelines" to assist parties structure compliant joint ventures.

## LICENSE AGREEMENT

A traditional license agreement is the fourth type of partnering effort that device and pharmaceutical companies may consider. Licensing can occur at nearly



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any stage of product development and typically involves up-front payments to a product developer by an entity who will in turn receive the exclusive right to use or market the technology. Upfront payments are also found in the co-development partnering strategy discussed earlier. Licensing differs from co-development in that licensing generally involves less integration and collaboration between the partnering entities.

Entering into a licensing agreement is advantageous for the licensee because fees can be structured to fluctuate with sales success. Further, licensing a product typically costs the licensee less than developing a technology or buying it outright. The licensor benefits from such an arrangement when the licensor lacks resources such as capital or manpower to bring a product to market.

There are drawbacks to licensing. From a licensor's perspective, licensing a product does diminish the profit potential. The licensor also loses total control of the product's form in the marketplace. Similarly, the licensing agreement may prohibit the licensee from altering the technology significantly to fit their needs or may prohibit uses in certain therapeutic areas. Licensing can also, similar to joint ventures, bring up unique antitrust concerns.

The Federal Trade Commission may view an exclusive license as an acquisition of intellectual property, which would make the transaction reportable under the Hart Scott Rodino Act (15 U.S.C. §18a). In 1995, the FTC released guidance that can assist entities structure a compliant licensing agreement called "Antitrust Guidelines for the Licensing of Intellectual Property". This document is publicly available on their website.

## **CO-MARKETING ARRANGEMENT**

Co-marketing a product is the final basic



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type of partnering effort. A co-marketing arrangement is typically entered into with a later stage product. Royalty payments are exchanged for the right to produce and/or sell a product. This type of arrangement most commonly permits both parties to sell a product, sometimes in distinct market segments. Entering into a co-marketing arrangement is an effective method of increasing market penetration when financing for marketing efforts is limited.

The major drawback of this type of arrangement is that co-marketing can be viewed as anti-competitive behavior, particularly when parties share pricing and marketing information. The Department of Justice has, however, approved a variety of co-marketing arrangements so it is possible to structure a co-marketing arrangement without engaging in prohibited anti-competitive behavior.

## CONCLUSION

Strategic alliances and partnering arrangements are one viable strategy a pharmaceutical, medical device or biotechnology company should evaluate during these challenging times. Entering into a licensing arrangement, co-development or co-marketing effort, or a joint venture can provide a company with needed capital and access to the skills necessary to bring products to market or keep research programs viable. Further, partnering can be an effective alternative to an IPO or selling an entity to a fully integrated pharmaceutical company or device manufacturer. The partnering strategies presented in this article are the most basic options in their fundamental forms. Various hybrids of each are possible and can be individually tailored to meet unique objectives. 😰

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