



**COLLABORATIVE  
DEVELOPMENT  
FINANCING**

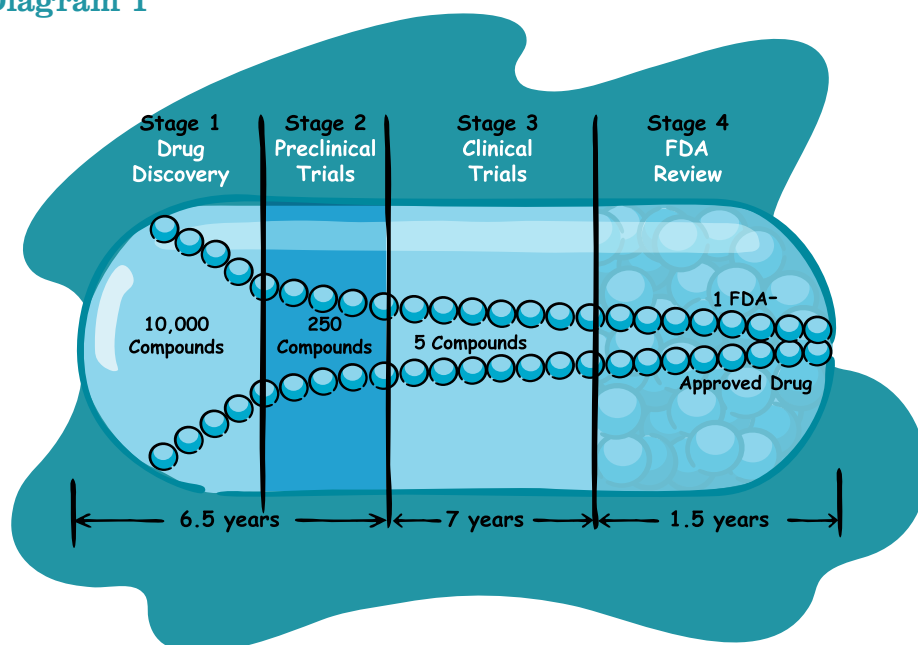
BY  
WARREN NACHLIS  
AND  
WENDY BRASUNAS

## The Growth of the Biotechnology Industry

Pharmaceutical drug development is a risky and very expensive process. According to the Pharmaceutical Research and Manufacturers of America, only one in every 10,000 pharmaceutical products developed in the laboratory actually ever receives FDA approval (see *Diagram 1 below*), and the process from discovery to approval takes an average of 15 years to complete. In 2004, an estimated \$40 billion was spent on drug development in the U.S., yet only around 100 new drug applications (“NDAs”) were submitted to the FDA for approval in that year. Industry estimates the cost of development for a single drug at approximately \$800 million. Additionally, pharmaceutical companies usually incur significant marketing costs before beginning to see a financial return.

Because of the high costs and even higher risks, large pharmaceutical companies have increasingly turned toward investing resources into developing modifications to existing drugs (68 percent of NDAs between 1993 and 2004 were for preexisting molecular entities). As a result, smaller biotechnology companies have stepped in and become the driving force behind some of the most innovative drug development. The biotech industry, now entering its fourth decade, represents a significant market force. Four of the largest biotech companies (Genentech, Amgen, Gilead, and Genzyme) combine for more than \$200 billion in market capitalization and \$30 billion in annual revenue. Still, due to the high risks and costs

**Diagram 1**



Large pharma has long been eager to fund compounds in the later stages of clinical testing, when risk is lower.

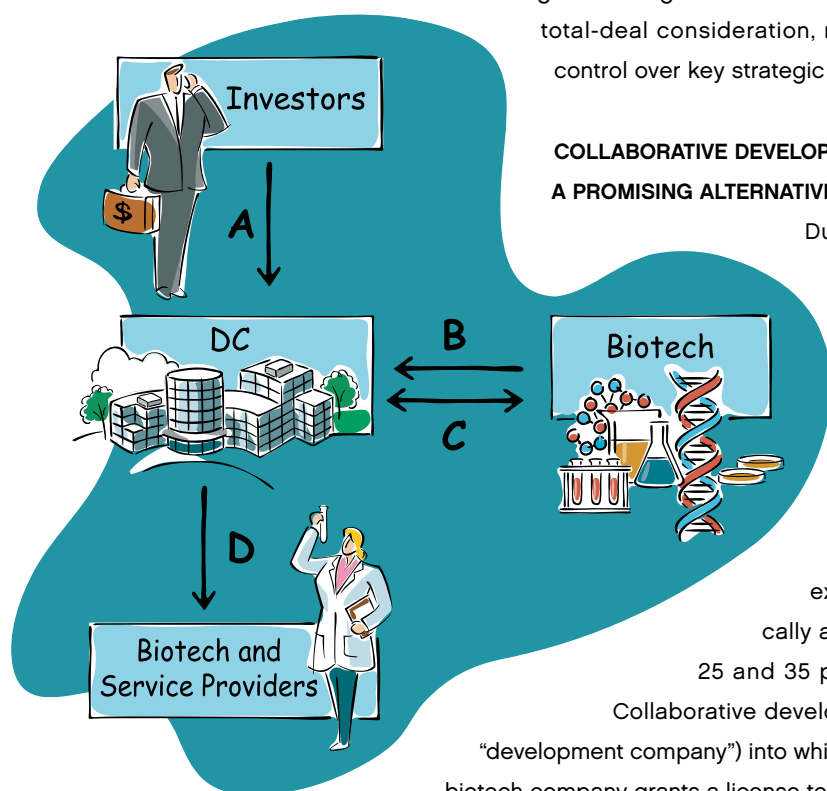
associated with drug development and the emerging technological breakthroughs that can change the landscape of the industry overnight, the biotech market remains highly volatile.

#### DEVELOPMENT-STAGE BIOTECH COMPANIES ARE OFTEN CAPITAL-CONSTRAINED

In contrast to the big four biotech companies mentioned above, a group of smaller, publicly traded biotech companies with market capitalizations between \$50 million and \$900 million each often have a difficult time generating funding for their development pipelines. Often, these development-stage biotech companies find themselves capital-constrained as their IPO cash begins to wane and they have difficulty generating additional capital in the equity markets.

In response to these capital constraints, a common source of funding for development pipelines is partnerships with large pharmaceutical companies. Large pharma has long been eager to fund compounds in the later stages of clinical testing, when risk is lower. However, a recent dearth of attractive Phase III drugs available to the large pharmaceutical companies has increased their interest in licensing drugs at earlier stages of development. Although this seems like a sound economic choice for the biotech company, it can, in fact, be a short-sighted strategic decision that involves giving up control and a large portion of the potential economic upside prematurely. A review by Recombinant Capital of more than 40 large-pharma licensing deals consummated during 2004 and 2005 revealed that deals initiated during preclinical and Phase I development paid an average of about \$16 million upfront, while deals initiated at a more advanced Phase II or Phase III clinical-development stage paid an average of more than \$50 million upfront. Additionally, early-stage licensing deals often result in the biotech company's receiving smaller total-deal consideration, mere single-digit royalties, and near-total loss of control over key strategic assets.

Diagram 2



#### COLLABORATIVE DEVELOPMENT FINANCING—

#### A PROMISING ALTERNATIVE TO LARGE-PHARMA LICENSING DEALS

During the 1980s and 1990s, many of today's largest biotechnology companies (mentioned on page 15) used a type of financing called "collaborative development financing" to fund early-stage promising development programs. With collaborative development financing, a biotech company still licenses its drug in development to a third party in return for financing, but does so in such a way that the biotech company has an exclusive right to buy back the licensed drug (typically at a compounded annual rate of return of between 25 and 35 percent) further down the development pipeline.

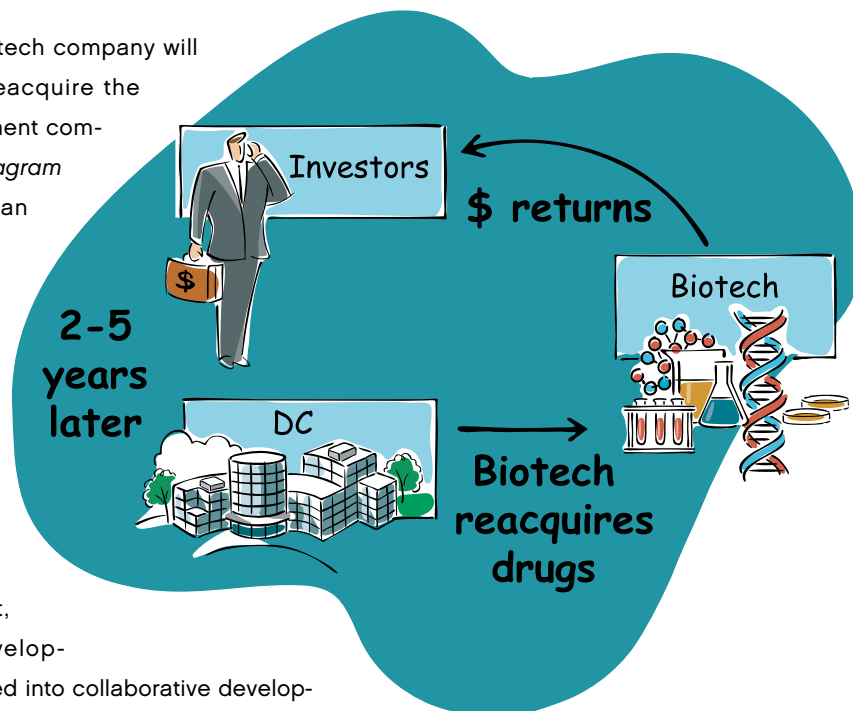
Collaborative development financing works by creating a company (a "development company") into which the financiers place the funding and to which the biotech company grants a license to the intellectual property and other assets related to the drug under development. The development company administers the development process through contracts with the biotech company (i.e., the licensor) as well as the necessary clinical-trial service providers and pays all parties market price for their services.

Within a predetermined time period, usually before the drug completes Phase III trials, the biotech company has the option to reacquire the product under development at a fixed price based on a fixed rate of return on the capital provided by the financiers. On the other hand, if the trials fail, and the drug does not make it to Phase III, the investors lose their contributed capital but retain the rights granted to the development company as they would in a typical licensing deal. The upside for the investors is that these deals also typically include warrants to purchase stock in the biotech company that will likely have some value even if the drug under development ultimately fails, but which will become very lucrative for the investors if the drug makes it to the market.

Diagram 2 on page 16 illustrates the steps of a collaborative development financing transaction. In step A, the investing company funds the development company with the amount of capital agreed upon as the upfront amount. Step B illustrates the biotech company licensing the intellectual property and programs to the development company. Step C demonstrates the biotech company's option to acquire the development company within a specified term (usually two to five years). In step D, the development company initiates and oversees contracts with the biotech company and other clinical-trial service providers for development of the compound.

**Diagram 3**

If Phase II trials are successful, the biotech company will likely exercise its exclusive right to reacquire the licensed drugs back from the development company for the predetermined cost. (See *Diagram 3 at right.*) The investment company can utilize its warrants to purchase stock in the biotech company. Unfortunately, as with all pharmaceutical financing, the risk is high, and if the drug fails in the trials, the financiers will lose the contributed capital.



Symphony Capital LLC (“Symphony”), a private equity firm dedicated to funding biopharmaceutical development, often invests using collaborative development financing. Since 2004, it has entered into collaborative development financing deals with Guilford Pharmaceuticals Inc.; Exelixis, Inc.; Isis Pharmaceuticals, Inc.; Dynavax Technologies Corporation; and Alexza Pharmaceuticals, Inc.

Because the biotech company's buyout option price increases linearly over time but the value of the biotech company's stock (and associated warrants) increases exponentially as the drug under development moves successfully through the development process, the development company has significant interest in increasing the value of the drug during development. In contrast to traditional licensing transactions, the biotech company and its shareholders have the potential to keep a greater share of the accrued value in a

*continued on page 37*

## Collaborative Development Financing

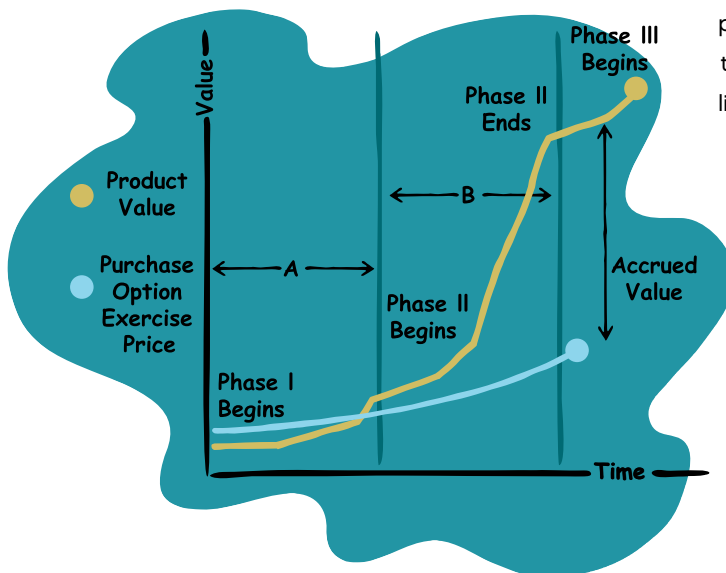
continued from page 17

successful product. As Diagram 4 (below) illustrates, the purchase option exercise price increases steadily, while the value of the developing drug—and as a result, the value of the biotech company's equity—can increase quite rapidly in the later phases of development. Accordingly, in a collaborative development financing deal, the biotech company has the possibility of reaping a much greater piece of its drug's value than it might in a traditional licensing deal with fixed royalties.

In contrast to large pharma, collaborative development financing investors have no interest in retaining the developed products and therefore often are motivated to advocate better and faster development trials even if they require more capital upfront. Additionally, col-

laborative development financing allows the biotech company to maintain control over strategic decisions during the development process. This also differs from traditional licensing deals.

Diagram 4



### DEVELOPMENT-STAGE BIOTECH COMPANIES' NEEDS AND DESIRES MAY INCREASINGLY BE MET BY COLLABORATIVE DEVELOPMENT FINANCING

Licensing transactions in any form can help biotech companies achieve necessary objectives as they struggle to bring their emerging technologies into the market. Such objectives might include generating capital, efficient commercialization, market growth, and assistance in taking their drugs through the regulatory approval process. Additionally, development-stage biotech companies are often looking to keep a hand in the strategic decisions regarding their drugs' development. For a

development-stage biotech company with some appealing early-stage pipeline potential but limited resources for developing this pipeline, collaborative development financing can provide capital and as much additional support in terms of marketing, regulatory, or technology assistance as the parties structure into the deal. The collaborative transaction can accomplish this without divesting the biotech company of its decision-making role in the development of its drug and without the biotech company's relinquishing much of the economic upside related to a developing product. It is likely that as collaborative development financing transactions make a comeback in the investing community, biotech companies and biotech investors alike will consider such deals an appealing alternative to traditional licensing transactions. ▶▶

#### WARREN L. NACHLIS

New York || 1.212.326.8364 || [wnachlis@jonesday.com](mailto:wnachlis@jonesday.com)

#### WENDY L. BRASUNAS

New York || 1.212.326.3901 || [wlbrasunas@jonesday.com](mailto:wlbrasunas@jonesday.com)