

The Biotech Funding Crisis: Cutting the Gordian Knot

by Martyn Postle and David Schulman

According to legend, in 333 BC a youthful Alexander the Great and his army came upon a complex series of knots in the town of Gordia on their way to engage Persia in combat. As the story goes, whoever was able to undo the Gordian Knots would go on to conquer Persia. After unsuccessfully trying for some time to untie the knots with his hands, Alexander the Great drew his sword and sliced through the knots. The lesson: difficult problems sometimes require innovative responses.

Problem: Biotech Funding Crisis

Many promising biotechnology companies were experiencing grave difficulties in securing adequate capital to fund new drug development even before the New Economy/technology valuation meltdown that began in the public equity markets in early 2000. Since then, prospects for raising capital have only worsened as a general matter. This has led some industry participants, the authors included, to characterise the fundraising landscape for biotechnology companies as something akin to a nuclear financial winter. Only the most promising companies have avoided this dilemma. While the Amex Biotechnology Index has appreciated by over 40% for the first half of 2003, the gains are off of historically low equity trading prices and are subject to the general concerns that 2003 may not have experienced the last of the bear market.

The reasons for the relative dearth of capital for biotechs are both well-known and understandable:

- Long lead times between the identification of promising compounds and any ultimate product regulatory approval and market launch, often as long as 8 to 10 years for successful drugs.
- A renewed investor focus on positive cash-generative businesses, particularly since the public equity market declines in 2000, and therefore away from many biotechs that do not have interests in significant marketed drugs.
- A recent decline in the number of approved drugs by both the FDA as well as European product regulators, and a perception that product regulators have become more cautious and less expeditious in their review processes (new drugs approved by the FDA fell from 53 in 1996 to 17 in 2002).
- The biotech business model, where the biotech conducts mainly its own research, but relies on a pharma company partner to conduct the more expensive late stage clinical development and commercialisation. Unfortunately for biotech, although research is relatively cheap when compared to development, it is also the area of highest risk and project attrition.
- The pharma business model, where consolidation has created much larger pharma companies that are setting much higher hurdle rates for potential commercial success before they are prepared to take the fruits of biotech research into clinical development.

This makes investment opportunities in most biotechs a relatively unattractive proposition for traditional pools of capital such as secured bank lenders and most private equity funds.

Possible Solutions to the Biotech Funding Crisis

While there are no simple, “one size-fits-all” solutions to this funding problem, there are several approaches that should be considered as a means to attract and even lower the cost of capital for biotechs. Although not as dramatic as Alexander the Great’s approach to the Gordian Knot dilemma, these approaches are already achieving desired capital-sourcing solutions. As discussed more fully below, these are:

- (a) The consolidation of the array of biotechs into fewer, more focused players with relatively lower administrative overhead and operating leverage.
- (b) The raising of venture capital from unorthodox sources such as large pharmaceutical companies.
- (c) Under appropriate circumstances, the negotiation of complex product alliance deals with large pharmas that provide the biotech with financial liquidity in a variety ways.
- (d) Acquisitions of non-core marketed products from pharmas, which may serve as temporary “cash cows” for biotechs as they continue through the development stage.
- (e) Securitisations and outright true sales by those fortunate biotechs of streams of royalty payments from out-licensed marketed products.

Whilst option (a), consolidation, has started to gather pace in the UK, the authors believe that more biotech companies should be investigating whether options (b) through (e) would provide them with a better strategic solution.

(a) Biotech Consolidation

Executing a strategy that combines two or more biotechs will be fraught with many hurdles, not least of which will be company-to-company valuations that underpin share-for-share splits to shareholders, and thorny governance issues. Nevertheless, if the merger hurdles can be overcome, then the consolidated biotech will be better positioned to share resources (especially where one of the merger partners has a larger pool of cash), cut costs, and reduce operational leverage. Recent examples of this include, in the UK, the combination of Celltech and Oxford Glycosciences, and British Biotech first with RiboTargets and now with Vernalis. Biotechs should continue to carefully evaluate this “mass with cash” option.

(b) Unorthodox Venture Capital

Large pharmas increasingly should represent a promising source of venture capital for biotechs because they are better positioned to understand biotech development risks (unlike traditional sources of capital such as private equity funds). In addition, many large pharmas have a strong need to augment their product pipelines, which are constantly under the scrutiny of investors and financial analysts alike.

While large pharmas are often seen as both customers and competitors of biotechs, a number of industry analysts believe that large pharmas are not well equipped to compete with biotechs in the identification and development of new compounds and, despite large resources, are unable to cultivate the entrepreneurial drive of biotechs engaged in breakthrough research.

Whether or not one believes this argument, what is beyond dispute is that large pharma currently has strong needs for new product that generally is not being met from internal development. Biotech seeks to capitalize on this situation. Under the right circumstances, the need of large pharma to augment its product lines, coupled with its strong cash position and its belief that it can accurately assess biotech investment, can be a compelling match for biotechs searching for capital. What is less clear is how large pharma will approach these investments—

narrowly as if it were a financial investor solely focused on IRRs and multiple returns of invested capital or, more broadly, in terms of potential sources of licensed compounds or, more intangibly, as a source of innovation with unknown commercial potential.

By way of example, GSK has historically made smaller investments in this way (via SR One) and AstraZeneca has recently announced an unspecified collaboration with Advent International, the private equity fund sponsor. In order to for biotech to develop this capital source alternative, it will need to remain realistic about the terms upon which large pharma makes a venture capital investment. While the biotech may wish, under ideal circumstances, to impose restrictions (such as therapeutic-wide non-competes) upon a large pharma that is a minority equity investor, the impulse to treat the large pharma more harshly than a traditional venture capital firm generally should be resisted in all but the most pressing circumstances. Different pharma companies will have different approaches, and often the biotech company will find itself negotiating with different and unconnected groups within the same pharma organisation—often with different agenda and objectives.

(c) Product Alliances

A growing number of biotechs with very promising compounds in later-stage development have been able to enter into alliance agreements with large pharmas. While each deal will vary, the common underlying theme is that the biotech has been able to secure significant immediate and longer-term liquidity with at least several of the following features:

- lines of credit from the large pharma
- equity infusions, particularly in later stage venture capital rounds of financing
- funding of development costs
- funding of detail forces for product co-promotion
- event and performance milestones
- royalties

Importantly, these types of product alliances may serve as powerful validating platforms for the biotech's most promising compounds. One such example is the impact that the deal with Roche signed last November has had on the market capitalisation of Antisoma.

(d) Large Pharma Divestitures

A number of large pharmas are currently reviewing their respective inventories of non-core compounds as well as smaller (and hence relatively less-profitable) marketed products. Particularly in the case of marketed products requiring intense detailing in therapeutic areas that the large pharma no longer views as critical, a divestiture may be advantageous to the large pharma in terms of generating sales proceeds upon sale of a lower profit margin activity. The biotech gains in terms of creating a positive cash generating product around which other small, therapeutically related products may be assembled.

(e) Securitisations and True Sales

Recently, the securitisation market has begun focussing upon ways that will allow a holder (such as a biotech) of rights to receive royalties from marketed licensed drugs to, in effect, sell the right to receive the future stream of royalties for an upfront payment equal to a specified percentage of the discounted value of that future royalty stream. While the securitisation structure typically will favour pooling of a diversified stream of multiple product royalties, sales

of rights to the royalties of a single product are possible. For example, Yale University was able to sell a portion of its royalty stream from AIDS drug Zerit for an upfront payment of \$115 million. As biotechs begin to receive royalties under license agreements, securitisations and true sales should be investigated as possible sources of capital.

Conclusion

The raising of venture capital from unorthodox sources such as large pharmaceutical companies, the consolidation and merger of biotechs, the negotiation of complex product alliance deals with large pharma, the acquisition of non-core marketed products from pharma, and the securitisation and outright true sale of streams of royalty payments from out-licensed marketed products all represent potential and, in certain cases, innovative responses to the current biotech funding dilemma. Like Alexander the Great and the Gordian Knot, biotechs should be daring in their capital fundraising approaches.

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