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Biotechs: Show Me the Money

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Money makes the biotech world go around. However, quicker circulation of that cash is driving both trends in new investment in start-ups and the approach of investors to exits. Increasingly, to get funded, new companies need to demonstrate a fast track approach that will allow the company to hit key milestone events swiftly, and those milestones may well be revenue generation events or even profitability. Existing companies are increasingly taking advantage of the concern found in larger pharmaceutical companies that their development pipelines are not sufficiently advanced to replace products that will lose patent protection. M&A and licensing deals between big pharma and biotechs have taken off and the competition for those deals has allowed investors and companies increasingly to bang the table and ask big pharma companies to “show me the money.”

New Deals

Who is investing? The answer in the US and the UK is that for pure drug research and development plays, fewer venture capital (VC) houses are interested. For example, Apax Partners has made its intention clear that it will not look at new research & development (R&D)-focused life science companies. They are not alone. The sums required to be invested cannot command the desired rate of return and the payback period can be too long. Certain funds are increasingly focused on more classic private equity plays in the healthcare sector, chasing classes of assets that can support a leveraged structure.

A number of funds which have been active in the sector are effectively fully committed to their existing portfolio of investments. However, a number of key players are continuing to invest. Abingworth, Schroder Ventures, Atlas Ventures and Advent Ventures, for example, have all been able to raise new funds and remain active in the space. There is money available for the right technology/business plan. The prospect of near term or immediate revenue can be an important factor in attracting investment. Merlin backed Derms Development in its acquisition of Crawford Pharmaceuticals, which is a leading supplier of treatments for dermatological conditions. Derms, following the acquisition, completed a number of deals including the acquisition of a majority stake in French company ACM to increase the revenue base.

One area that has attracted investor interest is speciality pharma, with new companies being formed and funded to take product rights and build salesforces in particular territories. Warburg Pincus has formed Archimedes Pharma to create a pan-European speciality pharma business through a roll up of certain European pharmaceutical businesses. Archimedes has effectively been given a line of equity to make acquisitions as products/companies become available. The single investor approach also provides greater flexibility, as management can avoid the down time spent in dealing with new investor syndicates and discussions on valuation and preferences. Warburg is, however, not the only investor to spot the opportunity in this area. Advent Ventures founded Speciality European Pharma in 2006 with a mission to acquire, develop, register and commercialise speciality therapeutic products for the European market. In the USA in 2006, Essex Woodlands established EUSA Pharma (EUSA) with a US\$53 million funding. EUSA subsequently acquired Talisker Pharma which included two development stage central nervous system (CNS) products. EUSA recently announced

the acquisition of OPI, an integrated biopharmaceutical company, and obtained financing of US\$175 million from a financing led by 3i.EUSA's aim is to build a portfolio of products in the field of pain and critical care and to create a balanced company in the EU and the USA. Another newly formed business is Acacia Pharma which is a hospital-based pharmaceutical company. Acacia's model is to develop its own products and also to establish sales in the UK in the short term through product acquisition. In turn the revenue will support the product development of Acacia's own products. The focus of these companies will be to produce revenue generating businesses which are not dependent on the long development cycle of R&D-driven companies and which should be an attractive proposition for exits either through M&A or an initial public offering (IPO). Each of these companies has been established around a management team that has a proven track record of success.

To the extent that R&D-focused companies are being funded, the sorts of companies being funded are those where the technology and products have been incubated within an institution for a long time. An example might be the Series A round of Amsterdam Molecular Therapeutics, which raised €22 million in November 2006 in a funding round led by ABM AMRO and including Advent, where for several years AMT's technology and products had been incubated within the Amsterdam Medical Centre.

Exits

VC exits generally come in the form of initial public offerings or M&A transactions of portfolio companies. According to Ernst & Young's annual report on the state of the venture capital industry (*Transition: Global Venture Capital Insights Report 2006*), the US and Israel have seen increasing M&A activity in recent years, while Europe has experienced an increase in IPOs. This trend has not, however, been seen to apply to biotechnology companies of late even in Europe. Although IPOs have historically funded late stage trials and product launches, there appears to have been a recent decline in the number of VC-backed biotechs achieving an IPO exit both in the US and Europe.

Recent Trends in the US

Some commentators believe that the increased M&A activity in the biotech sector in the US during 2005 and 2006 will continue in 2007, and that there will be at least 30 biotech IPOs this year – a level last seen in 2004. This is despite the fact that there were only 18 IPOs in 2006 and 17 in 2005 – almost all of which were priced at or below the bottom end of their pricing range. A key fact, however, is that in Q2 2007 of \$12.5bn raised by the sector, only eleven percent came from IPOs, bringing an average of \$51.2 million in proceeds. M&A activity, on the other hand, had 51 deals through May of 2007, with 18 of those valued at \$100 million or more. Although Sirtris Pharmaceuticals successfully went public in March this year, other recently planned biotech IPOs, such as BioVex's \$45 million offering, have been shelved. Most recently, both Prestwick Pharmaceuticals and Voyager Pharmaceutical Corp. cancelled planned offerings, citing poor market conditions. The increase in the minimum size requirement for an offering, compared to the late 1990s, and the increased cost and burden arising from Sarbanes-Oxley may be contributing factors to this depressed IPO trend. The key issue, however, is the large fall in pre-money values, making it more attractive for investors to seek an M&A exit with the higher valuations they command.

Recent Trends in the UK

Despite the recent success of the Alternative Investment Market (AIM) generally, AIM cannot be considered a mature market for biotech. As of the end of April 2007, there were only forty-three biotechs from a total of 1,639 companies listed on AIM. Of these, eleven listed in 2005, fifteen in 2006 and only two so far this year. European biotech portfolios may suffer more than their US-based counterparts given that Europe has fewer large biotechs. In the current climate, it is only relatively mature companies—those with promising Phase II results or those in Phase III—that are likely to succeed in the public market.

On the other hand, there appears to be a current trend toward a greater number of trade sales in the UK biotech market. Larger biotechs are increasingly looking to acquire smaller entities for new products to boost their development activities and global research infrastructure, while such transactions offer target companies access to wider distribution channels. Since December 2005, there have been a number of biotechs that have taken the M&A exit rather than the IPO route, including KuDOS Pharmaceuticals and Arrow Therapeutics, which were both acquired by AstraZeneca; Domantis Ltd., acquired by GlaxoSmithKline; Oxxon Therapeutics, acquired by Oxford BioMedica; and Paradigm Therapeutics, acquired by Takeda Pharmaceutical. The Domantis

acquisition for £230 million in cash was one of the largest acquisitions in terms of size for a private biotech. The good news for investors on each of these exits was that the acquirer paid cash upfront to secure ownership of the company and the underlying assets. This has allowed the investors to return cash to limited partners. The M&A cash exit is very attractive to investors as an IPO exit will usually involve investors locking up stock on the IPO for a set period to comply either with the rules of the relevant exchange or the requirements of a sponsor and, in addition, sign up for an orderly market restriction for a period following the end of the lock up. An IPO is often not a real liquidity event for a financial investor. The willingness of pharmaceutical companies to offer cash to acquire biotech has been driven by their desperation to fill their own R&D pipelines, with the competitive tension that this naturally causes. Valuations have been driven up by the competition amongst pharmaceutical companies who are looking to secure access to a particular product. In a less competitive situation the terms of an M&A deal can be engineered to give the buyer downside protection by linking deferred consideration to milestone events. The transaction can look like a licence deal but gives the buyer control of the corporate vehicle. However, in a competitive situation venture investors will want to maximise the size of the upfront payment.

The majority of small to mid-size biotechs are typically engaged in on-going R&D with one or more licensing agreements in place with larger pharma companies. This structure makes pre-IPO valuation difficult, with financial advisers typically implementing valuation metrics below the level that the VC investor anticipates or desires. Accordingly, public markets are increasingly perceived as a strategic financing source rather than an exit event—a potential alternative to a series C or D financing round—enabling the VC investor to keep the company progressing, while providing the potential to achieve a cash exit at a later date.

The fact that biotech business imperatives are influencing the form of exit is borne out in Ernst & Young's 2006 Report, which highlighted the increase in the median time from initial investment to exit – three years in the mid-1990s to five years in 2006. In biotech investments, this period is now usually seven years or more. The impact of this longer investment period to exit creates a greater emphasis on capital efficiency, staged portfolio financings, milestones and the mitigation of risk. Such a changing exit timetable may also create a need for turnaround strategies and distressed exits.

M&A or IPO are not always the answer. The strong market for the right technology has also placed companies in a position to negotiate fairer terms on licence deals. Pharma are as a result paying a higher price to access technology and often agreeing to shared control of the asset.

Why the Trend Away from IPO Exits?

The move away from IPO exits appears to be driven by lower pre-money valuations. In the US immediately prior to 2000 the average was \$400 million giving plenty of headroom for each of the Series A, B, C and D rounds for each new group of investors to meet their rate of return requirements. The average now is less than \$160 million, and in individual cases is often far less than even this. This gives the venture investors a low return, and in a culture of “last in takes all” often wipes out the founder shareholders and early round investors. The result is less venture investing, a direct consequence of low IPO valuation.

Many factors in the current environment make IPOs an unlikely exit strategy, including:

- market fashion and sentiment, which traditionally influence IPO markets and cannot be relied upon for an objective view of a firm's potential;
- the relatively substantial size and scale of a business needed before it becomes attractive to the market;
- the lengthy timetable involved in taking a company to market;
- high legal and regulatory approval costs in IPO preparation;
- the ongoing costs and regulatory requirements, particularly in the US, associated with operating a public company;
- the necessity for continued growth and “good news” that public markets require to avoid stock illiquidity;
- the necessity for VC shareholders to enter into lock-up periods (typically six to twelve months) leaving them vulnerable to adverse price movements and less control over the business during this period of potential volatility.

It is unsurprising, therefore, that commentators have started to query whether for the classic R&D focused biotech, the Series A/B/C model followed by an IPO will continue to survive. Many believe it

will not, with R&D needing to be funded within institutions longer under other forms of funding.

Partnering Trends

In 2006 there were more alliances between pharma-biotech and biotech-biotech than any year in the industry's history. On one analysis, by Burrill & Company, there was more than \$20 billion in partnering deals raised in 2006 exceeding the \$17 billion raised in 2005. The strong desire by pharma to fill their pipelines has driven demand to a new level and, unlike five years ago, pharmas are now prepared to pay considerable sums for products still at the stages of pre-clinical development or Phase I clinical trials. One analysis estimates that the vast bulk of deals now occur at the discovery or pre-clinical stages; i.e. it is far less common to see deals after the results of Phase II clinical trials or with Phase III clinical trials progressing. Partly this is because valuations have risen so much for a product at this stage that there is every incentive for the pharmaceutical company to strike a bargain at an earlier point in the product development cycle. This does, however, increase the returns available at the earlier stages. According to Burrill, in 2006 the average total upfront payments for Phase I candidates increased by more than seventy percent to \$20 million with significant payments on royalties even being achieved at the pre-clinical/investigational new drug application (IND) phase.

Of the 831 industry-wide alliances forged in 2006 there were a significant number of deals between smaller companies focused on regional rights and expansion into strategic territories. An example might be the deal between UK company, GW Pharmaceuticals, licensing its cannabinoid product, Sativex, for the North American market to Otsuka in early 2007. The companies are increasingly able to slice and dice terms so as to carry out a deal for income but also retain value, for example, a regional market such as Europe so that they can enhance further deal-making including M&A.

There are a number of examples where the price being paid by pharmaceutical companies on a partnering transaction gets to be so high in a competitive situation that the deal flips to an acquisition of the entire company on the basis that very little more cash outlet is required to achieve a much broader asset purchase including all the follow-on products.

Outlook for 2007 and Beyond

The biotech industry is currently engaged in a healthy M&A cycle, with many companies being able to achieve far better valuations from larger pharmaceutical companies seeking to bolster their pipelines than from public investors via IPOs. It is likely that M&A transactions in the UK, as with the US, will continue to drive the general exit strategy for VC investors in small biotech companies. More rarely investors will support a company for the long haul, using partnering income to underpin the finances of the biotech.