OPINION PIECE

The European biotech sector: Could it achieve more?

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INTRODUCTION

There is a general feeling among investors and other observers that the European biotech sector has not delivered and fund managers complain that there have been very few successes. The author's view is that, although we have not yet reached the heights of the US biotech industry, there have been numerous success stories in Europe. This paper shows that most of the ingredients required for a successful biotech sector already exist in Europe. Most importantly, there is enough cash in Europe to allow companies to bring products to market. The biggest problem is that there is a fragmented equity capital market, which, as well as limiting the pool of capital accessible to individual companies, may also affect the visibility of success. Thus, the success of Actelion and Serono, although known to UK small-cap investors, cannot impact their funds. However, it is time that we stopped complaining about what we do not have and started concentrating on what we do. Companies need to adapt to the realities of the investment environment in Europe. The good news is that we are already seeing some of this reality being taken on board by European companies, where many of them, like the early US biotechs, are aiming at the lower-hanging fruit by picking up products with relatively lower-risk profiles, such as reformulations of existing drugs. This should allow them to start generating their own cash and then take the bigger gambles. Perhaps most important of all and contrary to common belief, as our analysis shows, we do not believe that the amount of cash available to European biotechs is a significant hurdle to achieving success.

Is there enough money in Europe?

The estimated average cost of developing a new drug has risen from US$138m in 1975 to US$800m in 2003 (PhRMA website). Given this cost and the amount of cash that is available to an average biotech company, how can any of them, be they American or European, ever achieve product success? Data presented in this paper show that the average amount of money that successful US biotech companies raised from public equity markets up to regulatory filing or launching a product is significantly lower, at between US$170 and 180m. This quantum of money appears to be available to EU companies.

There is plenty of good science around

The biotech industry requires academic science. This is certainly not in short supply in the USA. The quality and quantity of science in Europe are more than adequate to continue to feed the European biotech industry.

Management is maturing, but. . .

A number of biotech companies in Europe are now in the first or second decade of their lives and there is a recycling of seasoned management into new companies. There is a problem in Europe, however, in that country borders as well as language and cultural differences may hinder the free flow of good management within Europe. This is not a problem in the USA.

Venture capital is flowing

There are now a reasonably large number of European venture capitalists that invest

Venture capital

in European biotechs. Also, there is more interest from US venture capitalists in European biotech.

One big problem is the geographical fragmentation of Europe's capital markets

European investors with a specialist hat on tend to have most of their money invested in the USA, as 80–90 per cent of the biotech investment opportunities are located there. The generalists suffer from geographical limits of where they can invest their money. Thus, a UK generalist small/mid-cap investor is often prohibited from investing in Switzerland or France. Add to this the fact that of the pan-European investors that do exist, most tend to be large-cap investors, and it becomes clear why the pool of money available for small European biotechs is even more limited than the relative sizes of the equity capital markets of Europe versus the USA would suggest.

Equity capital

WHAT FACTORS CONTRIBUTED TO THE SUCCESS OF THE US BIOTECH INDUSTRY AND DO THEY EXIST IN EUROPE?

It is important to try to understand what may have contributed to the success of the US biotech industry. Most people point to the large amount of cash that is available to US companies as a key contributor. Although the fact that US companies have been able to take significantly more cash off the table than their European counterparts is not in dispute, as is argued below, this is unlikely to have been the most significant contributor to success. A combination of good management, great science, a high-risk appetite, available cash as well as experienced venture capitalists (VCs) and a uniform pan-US equity market were all important contributors. It is also important to note that, as shown here, the big money only started flowing in the USA after a number of success stories established the credibility of the industry. Simply by reading early issues of the industry journal *Biocentury*, it becomes clear that there was a lot of soul-searching in the USA in the early 1990s as to the lack of success in the biotech sector, much the same as we see in Europe now (Figure 1). Indeed, it often feels like many of these comments about the US biotech sector in the early 1990s are being recycled now in Europe. This was despite the successes of Genentech and Amgen. It is only when Amgen's Epogen proved to be a much bigger hit than anyone had imagined and a trickle of further success stories began to flow, that investors started to take the sector seriously.

Low-hanging fruit

Much of the early success in the USA was derived from relatively low-hanging fruit. Although not detracting from the difficulty in achieving success with such products as Amgen's Epogen and Genentech's Nutropin, the risks of failure were not as high as they are for new products with completely unproven mechanisms of action. For instance, early success of Genentech was based on the production of human growth hormone (HGH) produced using recombinant DNA technology and cell culture. The question asked was not whether HGH is a molecule that can help children with growth retardation, but whether HGH produced using recombinant technologies is the same as that extracted from human cadaver brains. Thus, the early success of US biotech was mostly based on such developments.

Similarly, the biological functions of erythropoietin and interferon-alpha were well understood. What Amgen and Biogen did was to produce these hormones using biotech manufacturing technologies. The product development risks were far lower than they would have been if these were completely new drugs with unproven mechanisms of action. Looking at the other success stories also

'A year ago the biotech sector appeared to be headed for blockbuster product successes and the kinds of returns investors dream of. But an unbroken string of product failures and the specter of drug price controls have shaken investor confidence and prompted several Wall Street analysts to reexamine the underlying assumptions that once had made them bullish on the industry.' 15th March, 1993.

'Over the course of the past year, we have seen product development failures wreak havoc with the capital markets and watched equity values evaporate across the industry. Something is clearly wrong in an endeavor where companies can achieve billion-dollar valuations without any products, when even under the best of circumstances, the rate of failure is well-documented and far outweighs the probability of success.' 12th April, 1993

'investor skepticism continues to ring loudly across the sector, witnessed in recent days by the hammering of MedImmune when it dropped a non-primary indication for RespiGam, and the plunging of Cortech shares below cash value following its well-managed but disappointing sepsis trial.' 1st August, 1994.

Figure 1: A view on the US biotech sector in the early 1990s
Source: *Biocentury*

reveals that these companies did not take the risks that biotech companies generally have to take today. Medimmune started life by selling an acquired product (CytoGam) from Connaught Labs. Even its own first product, RespiGam, was purified antibodies from human plasma, hardly a biotech product. Centocor started by selling diagnostic products and Genzyme acquired a biochemicals business from Whatman in the UK, which brought with it a diagnostic manufacturing facility and marketed products.

The author's aim is not to belittle the very significant achievements that these companies have made, but to show that the US biotech pioneers all started either by manufacturing known molecules using biotech methods or by first selling non-biotech products (Table 1). Nevertheless, they almost all eventually moved on to the more familiar ground of producing new drugs targeting new potential disease targets.

Management

US biotech companies have had access to seasoned management for a very long time. Many of these managers were

Table 1: Potted history of US biotech majors

Company	Date incorporated	IPO date	First own product to market	Date of launch	2001 sales
Amgen	1980	1983	Epogen (erythropoietin)	1989	US$4600m (partly through JNJ)
Biogen	1978	1983	Intron-A (interferon-alpha)	1986 through Schering Plough	US$1447m
Genentech	1976	1980	Protropin (growth hormone)	1982	US$250m (combined sales of three products)
Medimmune	1987	1991	RepsiGam	1996 (after failing to win approval in 1993)	US$516m (sales of follow-on product, Synagis)
Centocor	1979	1982	Diagnostic for rabies infection	1982	This product is now irrelevant. Centocor later developed an antibody called ReoPro which now has sales of US$431m
Genzyme	1981	1986	Immiglucerase (naturally occurring enzyme)	1981	Cerezyme, the recombinant form of the enzyme sold US$569m.

Source: company data and Nomura estimates.

schooled through the first few biotech companies in the US (whether successful or not) and are experienced in running small R&D-led businesses. This is something that has only recently been seen in Europe.

Risk

Risk appetite and lack of fear of failure

In the 1980s, an European scientist moving from academia into the pharma industry would have been viewed extremely negatively by colleagues, let alone one capitalising on a piece of science by setting up his/her own company. This was never a problem in the USA, and indeed was highly encouraged. On top of this, management with a company or product failure to its name is not shunned by US investors; indeed a failure is often viewed as an important part of the seasoning process for management.

Experienced VCs

There was a dedicated band of US biotech VCs which supported and nurtured biotech companies early on. These VCs provided not only capital but also management expertise and networking capability.

Significant 'home market'

Many US biotechs were, and continue to be, able to retain marketing rights to their 'home market' that allows them to build significant businesses once products reach the market.

Cash and capital markets

The USA has the largest equity capital markets in the world, being almost three times the size of all the European equity markets put together. There is also no question as to the fact that there has been more cash available to US biotechs than to EU biotechs. But, as is shown below, on a per company basis, cash is not an issue in Europe.

Science

The biotech industry requires academic science. This is certainly not in short supply in the USA.

DO WE HAVE THE RIGHT INGREDIENTS IN EUROPE?

The analysis presented below suggests that most of the ingredients important for the growth of the US biotech exist in Europe.

Management

This may have been a problem before, but is not anymore. A number of biotech companies in Europe are now in the first or second decade of their lives and there is a recycling of seasoned management into new companies (Table 2). There is a problem in Europe, however, in that country borders as well as language and cultural differences may hinder the free flow of good management within Europe. This is not a problem in the USA.

European investors have generally had a very negative view of managements of companies that have failed or have had a significant product failure. This of course is acceptable if the failure is entirely the management's fault, or if the management had painted a very rosy future for the company, which had then turned out to be based on unreasonable assumptions. But given the fact that the majority of drugs fail, it is not surprising that there are a large number of biotech companies that have endured drug failures in Phase II or III. Unfortunately in Europe, we are only just coming to terms with the fact that drug failures are part and parcel of the life of a biotech company.

Risk appetite and lack of fear of failure

The perceived wisdom is that the risk appetite of US investors is higher than their European counterparts. However, there is no solid evidence behind this claim.

Experienced VCs

There are now a reasonably large number of European VCs that invest in European biotechs. Also, the level of interest from US VCs is rising.

Significant 'home market'

This is where European biotechs are disadvantaged. Compared with Europe,

Table 2: Management histories of selected private European biotech companies

	Chairman	Chief Executive Officer	Financial director	Business dev.
Arakis (UK)	Michael Redmond: managing director of Fisons Pharmaceutical	Dr Ken Cunningham: vice president of European affairs for Alza Coporation	Peter Keen: co-founder of Merlin Biosciences and Chiroscience	Dr Julian Gilbert: commercial development director of PolyMASC
Arpida (Swiss)	Dr Andre Lamotte: founder and investment manager of New Medical Technologies (VC)	Dr Khalid Islam: ex. Hoechst Marion Roussel	Harry Welten: director of corporate finance at UBS Warburg	Martina Weiss-Radtke: licensing director at BTG
Astex (UK)	Dr Peter Fellner: CEO of Celltech	Timothy Haines: president and CEO of Intervascular Inc.		Dr Martin Buckland: vice president of Business development at Elan
Newron (Italy)	Rolf Stahl: CEO of Shire Pharmaceuticals	Dr Luca Benatti: head of molecular biology at Pharmacia	Christophe Bourrilly: founder of OncoMethylone	Marco Caremi: director of business development at Schwartz Pharma
ProStrakan (UK & France)	Harry Stratford: founder and former CEO of Shire Pharmaceuticals	Dr Wilson Totten: director of R&D at Shire	Adrian Gardner: managing director of Lazard corporate finance	Enrico Bastianelli: product manager for Procter & Gamble

Source: Nomura and company websites.

the USA is a uniform marketplace, which does not suffer from the same fragmentation seen in Europe. The regulatory environment, pricing and reimbursement policies and language differences within Europe present formidable barriers for a small company trying to establish its own salesforce. The European drugs market is complicated by national barriers and even pharmaceutical companies sometimes find this difficult to deal with. However, there is nothing to stop European biotechs from setting up operations in the USA. Indeed, given that it is the largest market for drugs, this is a necessity. However, this is an option only worth exploring once the company is close to a product launch.

Cash and capital markets

There is no question that the European capital markets are not as amenable to the cash-hungry biotech model as the USA is. But as we will show in the next section, there is a lot more cash than is generally believed to be the case. However, there are two main issues that present important hurdles to European biotechs:

- Looking over their shoulder. The success of the US biotech sector has created a situation where there is constant comparison of the relatively nascent European sector to the mature US sector.

- Not really 'European biotech'. European investors with a specialist hat on tend to have most of their money invested in the USA, as 80–90 per cent of the biotech investment opportunities are located there. The generalists suffer from geographical limits of where they can invest their money. Thus, a UK generalist small/mid-cap investor is often prohibited from investing in Switzerland or France. Add to this the fact that of the pan-European investors that do exist, most tend to be large-cap investors, and it becomes clear why the pool of money available for small European biotechs is even more limited than the relative sizes of the equity capital markets of Europe versus the USA would suggest. A US generalist investor based in California has no problem investing in a biotech company 3,000 miles (4,800km) away in New York, whereas a UK-based investor cannot invest in a biotech company in France, only 300 (480km) miles away.

Science

The quality and quantity of science in Europe are more than adequate to continue to feed the European biotech industry. There are now many universities in Europe that are either associated with biotech incubators or have their own incubator in-house. There is plenty of help at hand for academics to protect their intellectual property and there are groups of angel investors and early-stage VCs that found and seed companies. However, the situation, although better than before, still has a long way to go.

ARE THERE ANY EUROPEAN SUCCESSES?

Given the sentiment of many European fund managers and the fact that they continually compare European biotech companies to their US counterparts, one may be forgiven for thinking that there have not been any success stories in Europe. This is far from the reality. Granted, we do not have an Amgen or Genentech in Europe, but we do have Serono, Actelion, Shire and Qiagen, not forgetting Amersham and Celltech. The problem is that the success of UK's Shire does not affect a generalist investor in Switzerland, and a UK investor does not see an impact from the success of Switzerland's Actelion. Fixing this problem is not the job of biotech companies or their investors. What we need is a change in investment policies of funds. Indeed, we believe that even if there was a unified European stock exchange, which is often suggested as a major need, this problem will not be solved until there is a change in the structure of funds.

IS THERE ENOUGH CASH FOR THE EUROPEAN BIOTECH SECTOR?

Many European biotech management teams complain that US companies are more successful because they have more cash handed to them. This section shows that the amount of money raised by individual European companies should be sufficient to allow them to get a product to market.

The US biotech sector has received US$113.6bn (VC, IPO, post-IPO and debt financings; Figure 2) since the beginning of 1994. Given the common view that European biotech is the much poorer cousin of the USA, it is perhaps surprising to find that over the same period US$27.2bn has been invested in the sector. This is not a sector that has much difficulty in accessing capital.

Of this US$27.2bn, 26.6 per cent has been invested by VCs (compared with 17.7 per cent of the total in the USA). This shows that based on this metric, the European biotech sector is still in its adolescent phase relative to the USA, with many private companies yet to be pushed into the public arena. Another

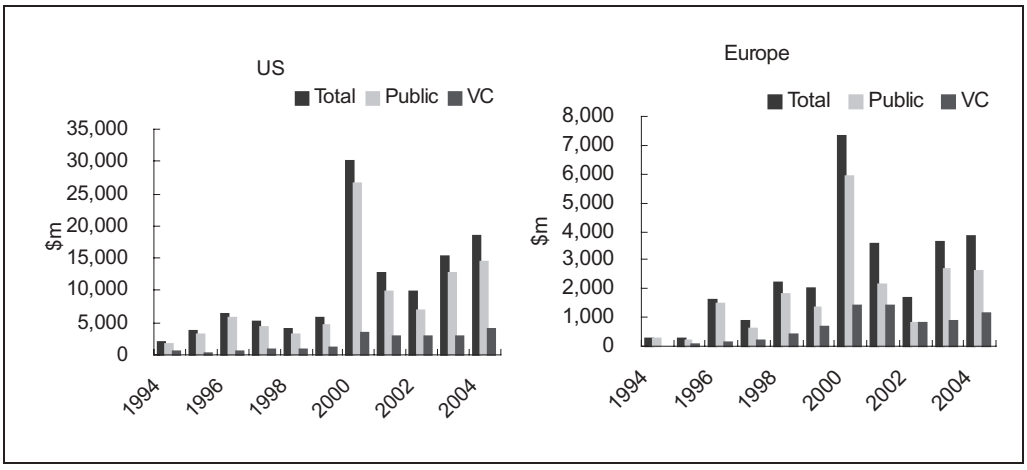

Figure 2: Annual amounts of cash invested in private and public companies in the USA and Europe
Source: Nomura and Biocentury

Total investment

interesting point is that of the total invested in European and US biotech since 1994, 73 per cent and 76 per cent, respectively have been invested since the start of 2000. Also, the amount of money invested in public and private companies in Europe in 2003 is equivalent to the figure invested in US biotech in 1995 (Figure 2). This would suggest that, in terms of investment, Europe is currently where the USA was eight years ago.

Availability of cash in Europe

In summary, the data suggest that there is plenty of cash available in Europe, even though it is not as high as that in the USA. So the question is not whether there is enough cash around, but is it enough to allow European companies to get a product to market?

How much cash does it take to get a first product to market?

Table 3 presents data regarding the amount of cash raised from public markets by the older generation of the US biotech companies by the time their first major product was launched. Perhaps rather surprisingly, the data show that the average amount of money that public investors had to part with before seeing a product launch from their investee companies was about US$180m. This figure is not to be taken as the amount of money required to bring a product to market, as many of these companies not only had private cash invested in them but also most likely received cash from pharma partnerships and, in some cases, other product or service revenues. But it does represent the amount of money raised from public markets before a product launch.

One criticism of the data in Table 3 might be that it is based on the costs of product development almost two decades ago. It is possible that not only did these pioneer companies pick the lower-hanging fruits (such as recombinant growth hormone and erythropoietin in the case of Genentech and Amgen, respectively), but also that the costs of developing biotech drugs was lower then. To address this question, the same analysis was conducted on relatively younger companies (Table 4). The data show that the average amount of money raised from the public markets before getting a product to regulatory authorities (not product launch as was the case in the above analysis) is US$168.4m. This is not significantly different from the figure calculated using the pioneer biotechs. Again it is important to note that, especially in this case, this is not the total amount of money required to get a product to regulatory authorities. Many of the companies in the table have shared the

Table 3: Amount of public money raised by old US biotechs before launch of first major product

Company	IPO date	Amount raised at IPO (US$m)	IPO and subsequent cash raised (US$m)	Cash raised before first product launch (US$m)	First major product
Agouron	1987	6.3	220.3	220.3	1997 Viracept
Amgen	1983	40.0	3594.8	194.8	1989 Epogen
Biogen	1983	57.5	356.8	356.8	1996 Avonex
Celgene	1987	11.0	1234.3	97.9	1998 Thalomid
Centocor	1982	23.1	948.2	432.7	1995 ReoPro
Cephalon	1991	59.4	3340.6	195.4	1999 Provigil
Chiron	1983	19.2	2511.5	42.1	1986 HBV vaccine
Genentech	1980	3.1	3049.9	80.0	1985 Protropin
Genzyme	1986	27.4	1841.3	71.9	1991 Ceredase
Gilead	1992	75.0	1401.5	200.5	1996 Vistide
IDEC	1991	45.0	1449.4	95.9	1997 Rituxan
Immunex	1983	16.5	1460.9	108.9	1991 Leukine
Liposome Co	1986	15.0	203.4	160.8	1995 Abelcet
MedImmune	1991	23.1	832.9	266.6	1998 Synagis (1991-CytoGam)
Median			**1425.5**	**177.8**	
Mean			**1603.3**	**180.3**	Standard deviation = $108.6m

Source: Nomura, Biocentury and Thompson Financial.

Table 4: Amount of public money raised by newer US biotechs before getting a product to regulatory review

Company	IPO date	Amount raised at IPO	IPO and subsequent cash raised	Cash raised before first product filing	Cash balance at first filing	Total public cash used until first product filing	First major product
Amylin			867.1	210.5	93.5	117.0	2005? Symlin
BioMarin	1999	67.3	425.2	208.9	114.8	94.1	2002 Aldurazyme
Cell Therapeutics	1997	30.0	527.8	116.8	23.9	92.9	2000 Trisenox
Cubist	1996	15.0	485.6	407.4	243.1	164.2	2003 Cubicin
Icos	1991	36.0	978.3	386.1	194.9	191.2	2001 Cialis
Imclone	1991	35.0	930.4	430.4	281.5	148.9	2001 Erbitux
Medicines Co.	2000	110.4	285.2	110.4	110.4	110.4	2000 Angiomax
MGI Pharma	1991	16.5	523.9	523.9	282.0	241.9	2005? Dacogen
OSI Pharma	1986	13.8	822.2	687.2	321.9	365.3	2004 Tarceva
Trimeris	1997	33.0	327.4	218.8	61.1	157.7	2002 Fuzeon
Median						153.3	
Mean						168.4	Standard deviation = US$79.0m

?These products are still undergoing regulatory review.
Source: Nomura, Biocentury, Thompson Financial.

cost of product development with pharmaceutical partners. On the other hand, it is unlikely that all of the money that these companies have raised from public markets has been invested in only one product. It is also important to note that the amount of cash that the companies had on their balance sheets at or near the time of the regulatory applications has been subtracted from the total estimate of the public cash raised to that point.

Can European companies get this quantum of cash on an individual basis?

Having established how much money successful US biotech companies raised before getting their main products onto the market, it is perhaps fair to ask whether this quantum of cash is available to individual European biotech companies. Table 5 suggests that individual European companies can indeed raise sufficient money that should allow them to get a product to market.

Which companies could launch significant products over the next five years?

Assuming that our analysis with regards to the availability of cash to European companies is correct, the next question to address is how many European companies could bring a significant product to market in the next five years? Table 6 provides a non-exhaustive list of biotech companies with products that could generate peak sales of higher than US$200m. Thus, the answer to the above question is quite a few, provided the attrition rate of these products is not 100 per cent.

CONCLUSION: EUROPEAN BIOTECH HAS EVERY CHANCE TO DELIVER

This paper has shown that most of the ingredients required for a successful biotech sector exist in Europe. Most importantly, there is enough cash in Europe to allow companies to bring products to market. The biggest problem is that Europe has a fragmented equity capital market, which as well as limiting the pool of capital accessible to individual companies, may also affect the visibility of success. Thus, the success of Actelion and Serono, although known to UK small-cap investors, cannot affect their funds.

It is time that we stopped complaining about what we do not have and started concentrating on what we do have. This includes a number of success stories, although the blockbuster product with >US$1bn sales may still

Table 5: How much cash is available to European companies?

Company	Cash raised from public markets	Comment
Acambis	£81.6m ($146.9m)	Acambis has also raised a sizeable amount of cash from selling its smallpox vaccine to the US government. We are assuming it is not the first product to market.
Actelion (Switzerland)	CHF260m ($224.1m)	Actelion had CHF218m in the bank when its lead drug was approved (2001). On the other hand, the company had already acquired the product at end of Phase II in 1999 from Roche.
Alizyme	£70.3m ($126.5m)	Alizyme has three products ready to enter Phase III and still has around £20m cash in the bank.
Antisoma	£61.5m ($110.7m)	Antisoma still has around £30m cash in the bank. On the other hand, no account has been taken of about £35m of cash that the company received from Roche.
Ark Therapeutics	£55m ($99.0m)	Ark still has a significant chunk of its £55m raised at IPO in the bank.
Biocompatibles	£243m ($437.4m)	This is the estimated cash that Biocompatibles raised before getting its cardiac stents and contact lenses onto the market.
Cambridge Antibody Technology	£141.3m ($254.3m)	Although this is the amount of money CAT raised before Humira reached the market, CAT was not responsible for the development of the product.
GPC Biotech (Germany)	US$201.4m	GPC in-licensed its lead product, Satraplatin, which is now in Phase III development from NeoTherapeutics of the USA. This compound had completed Phase II trials when GPC gained access to it.
Vernalis	£101.2m ($182.2m)	This is the cash raised by Vanguard Medica and then Vernalis before Frovatriptan was launched. This does not include the cash raised by British Biotech, which merged with Vernalis last year.
Xenova	£75.9m ($136.6m)	This is the cash raised by Xenova only and does not include the cash raised by Cantab and KS Biomedix which were both acquired by Xenova.

$:£ = 1.8; CHF:$ = 1.16.
Source: Nomura.

Table 6: A selected list of European biotechs with products in late stage development

Company	Product	Anticipated launch date
Acambis	West Nile Virus vaccine	2007/8
Actelion (Swiss)	Clazosentan	2007/8
Alizyme	ATL-962 and Renzapride	2007/8
Ark Therapeutics	Cerepro	2006
Arpida (Swiss)	Iclaprim	2007/8
Basilea (Swiss)	BAL5788	2007
Biocompatibles	Drug-eluting beads	2005/6
CeNeS	M6G	2006/7
GPC Biotech (Germany)	Satraplatin	2006/7
IDM (France)	Mepact	2006
Neutec Pharma	Mycograb	2006
Newron (private, Italian)	Safinamide	2007/8
Paion (private, Germany)	Desmatoplase	2008
Protherics	Voraxaze	2005/6
Vectura	AD237	2008/9
Vernalis	Frovatriptan in MRM	2006

Source: Nomura.

be eluding European biotechs (with the exception of Serono). Companies need to make do with what is available to them and adapt to the investment environment in Europe. To change the rules and regulations of European fund managers will take a long time and requires not only structural change but also a change in habits. It is not enough just to create a pan-European equity market, if fund managers continue to have a problem with investing in companies that are not domiciled in their home country. The good news is that we are already seeing some of this reality being taken on board by European companies, where many of them, like the early US biotechs, are

aiming at the lower-hanging fruit by picking on products with relatively lower-risk profiles such as reformulations of existing drugs. This should allow them to start generating their own cash and then taking the bigger gambles. What this means, however, is that the blockbuster products are likely to elude us for longer than would otherwise be the case. But chasing blockbusters, in the author's view, is a fool's game as only rarely have existing blockbusters been identified at a stage of their development when most biotech companies are active.

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