

# ***Biotech*** What's next for the business of big molecules?

*How is the biotech industry  
faring in the current  
economic and scientific  
environment?*

2012





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## Contents

	Page
.....	.....
Introduction	04
Where are we now	04
Fluke or first signs of spring?	04
How many millions did you say?	06
Venture funding falls short	06
Big Pharma can't bridge the gap	08
Asia smartens up its act...	09
...but the acid test's innovation	09
Joined-up thinking	11
Playing nicely	11
Patient money	12
Back to school	12
United front	12
Collaborating competitors	13
Swapping notes with the big spenders	13
Package deals	14
Pulling together	14
References	15
Territory contacts	17
Global contacts	18
.....	.....

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# Introduction

The biotech industry plays a major role in the war on disease. So how is it faring in the current economic and scientific environment? In mid-2010, when PwC\* first reviewed the state of the sector – and its achievements in the 30 years since its birth – our verdict was mixed.<sup>1</sup> We had three specific reservations:

- The industry hadn't delivered a significant increase in productivity, measured in terms of new medicines reaching the market
- The business model on which it relied was under great strain; and
- The US was in danger of losing its lead, as the biomedical research base moved east.

But the biotech industry wasn't alone in struggling to translate the discoveries of the past decade into safe, effective, new medicines. The pharma industry was experiencing equal difficulties. Mapping the human genome was one thing; applying the insights the molecular sciences provided, quite another.

So what was the solution? One way forward, we suggested, was closer collaboration. If the biotech and pharma sectors joined forces, they might be able to develop new medicines more effectively and capitalise together on the opportunities arising from the push towards personalised healthcare.

Two years on, there's bad news and good: productivity's still low and money scarce, but a growing number of biotech and pharma companies are collaborating – with patient groups and medical charities, with academia and with each other. And these are real, long-term collaborations, not just one-off licensing deals.

## ***Fluke or first signs of spring?***

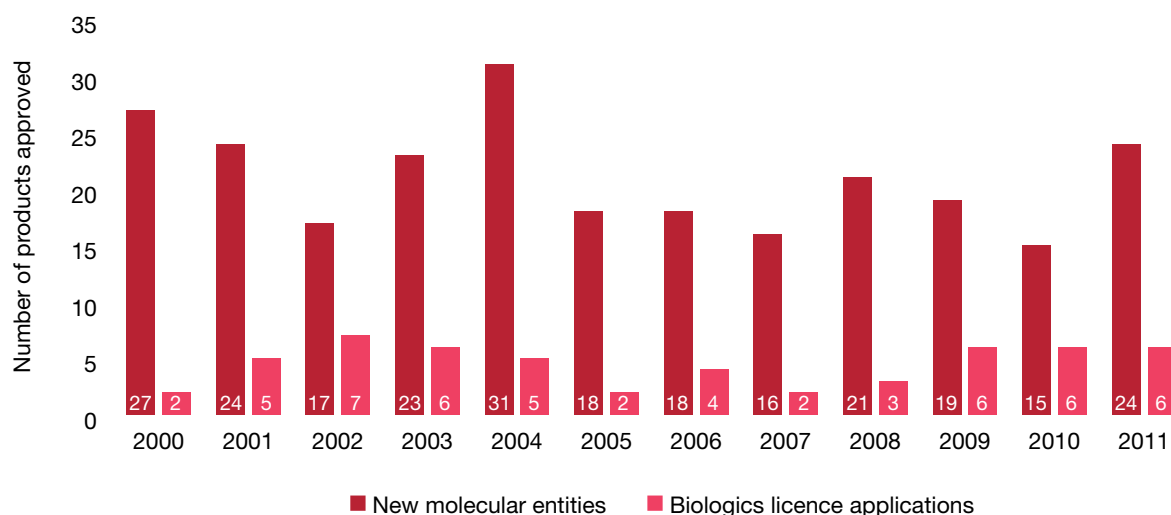
Let's start by looking at productivity. In 2010, we noted that the annual number of medicines approved by the Food and Drug Administration (FDA) had remained broadly constant since 1990, when the impact of the biotech industry first began to show. It typically takes a decade to develop a new medicine, and the earliest biotech companies originated in the '80s. So, if they'd succeeded in improving productivity, there should have been some sign of it by this point.

Today, the evidence is more encouraging. In 2011, the FDA's Center for Drug Evaluation and Research (CDER) approved 30 new medicines – a higher number than at any time since 2004 (see **Figure 1**). Twelve of them were first-in-class therapies.<sup>2</sup> And nine are expected to generate peak sales of more than US\$1 billion a year.<sup>3</sup>

Big Pharma was responsible for more than a third of these new products, but several biotech companies also had noteworthy successes. Massachusetts-based Vertex Pharmaceuticals was behind Incivek, one of two medicines that could transform the treatment of hepatitis C. Human Genome Sciences co-developed Benlysta, the first new therapy for systemic lupus erythematosus in 50 years, with GlaxoSmithKline (GSK). And Incyte crept under the wire at the end of 2011 with Jakafi, the first approved treatment for myelofibrosis.<sup>4</sup>

\*"PwC" refers to the network of member firms of PricewaterhouseCoopers International Limited (PwCIL), or, as the context requires, individual member firms of the PwC network.

**Figure 1: The number of new medicines reaching the market has picked up**



Source: US Food and Drug Administration

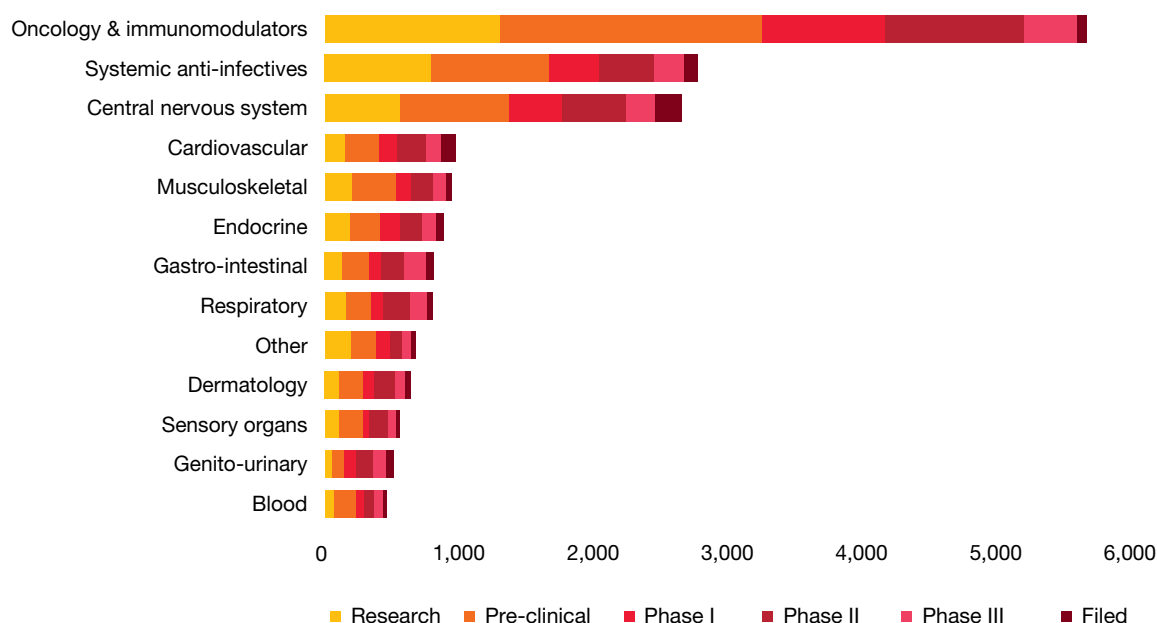
Note: New molecular entities and biologics licence applications approved by CDER

But a few blooms don't make a bouquet, and a closer look at the figures shows that the number of biologics approved by the FDA has stayed the same for the past three years. In fact, it's still slightly lower than in 2002, when seven new biologics were approved. Seen from a historical perspective, then, the picture isn't quite so positive.

There are other issues, too. A recent study of 4,275 medicines moving through clinical trials to FDA approval suggests that the failure rate is actually increasing. Between 2003 and 2010, only one in 10 treatments reached the market, compared with a previous rate of one in five or six.<sup>5</sup> The global pipeline is also becoming more concentrated.

Nearly 31% of the molecules currently in research and development (R&D) cover cancer and autoimmune diseases (see **Figure 2**).

**Figure 2: The global pipeline's getting very narrow**



Source: EvaluatePharma

## How many millions did you say?

And developing a new medicine is still an expensive business, although just how expensive is the subject of fierce debate. In 2006, the Tufts Center for the Study of Drug Development pegged the average cost at \$1.24 billion for a large molecule and \$1.32 billion for a small molecule (based on an estimate of \$802 million in 2000 dollars, uplifted by 64% to reflect rising costs).<sup>6</sup>

But, in early 2011, two academics challenged these figures. They argued that Tufts had committed some serious methodological ‘errors’ and used too small a sample to represent the industry as a whole. The real cost of developing a new treatment, they claimed, was more like \$59 million in 2006 dollars – the equivalent of \$75 million today.<sup>7</sup>

Various other commentators have now joined the battle. In February 2012, for example, a couple of journalists at *Forbes* added up the amount invested in R&D by each of the 12 Big Pharma companies for the past 15 years, adjusted it for inflation, and then divided it by the number of approvals each company secured over the same period. The result? Amgen was a model of efficiency; it spent ‘just’ \$3.7 billion on each of the molecules it launched. AstraZeneca, by contrast, spent nearly three times as much.<sup>8</sup>

So where does the truth lie? Harvard economist Frederic Scherer suggests that it lies somewhere in the middle. Scherer finds fault with certain aspects of Tufts’ analysis. But it’s clear ‘by any reckoning,’ he says, that average costs per approved molecule ‘have risen greatly over recent decades to levels measured in the hundreds of millions of dollars’.<sup>9</sup>

In other words, the biotech industry hasn’t driven development costs down greatly. Yet neither – currently, at any rate – is it bringing in the sort of income the old blockbusters produced. In 2009, five of the 10 top-selling medicines were biologics. And market research firm EvaluatePharma predicts that, by 2016,

there’ll be seven such best-sellers (see **Table 1**).<sup>10</sup> But Humira – the product that will probably head the league – is forecast to generate only 80% of the revenues Lipitor earned in its heyday.

## Venture funding falls short

If the biotech industry’s contribution to productivity is still questionable, what about the business model on which it’s historically relied? We argued two years ago that this model – based as it is on external investment, typically venture capital – was under pressure. Again, the news is mixed.

On the upside, US venture capitalists are back on the scene; venture funding in the domestic biotech sector topped \$4.7 billion in 2011, 22% more than in 2010. On the downside, the total number of deals dipped again, after perking up in 2010 (see **Figure 3**)<sup>11</sup>. And first-round financings fell by 19%; only 98 of the deals struck in 2011 involved start-ups.<sup>12</sup>

What’s more, only 13% of the venture capitalists the US National Venture Capital Association (NVCA) recently polled said they plan to increase the amount they invest in the sector.<sup>13</sup> And, to judge from events in the first quarter of 2012, they meant what they said. There were just 99 deals with a combined value of \$780 million in the three months ending March 2012. That’s little better than in 2009, when there were 94 deals collectively worth \$705 million.<sup>14</sup>

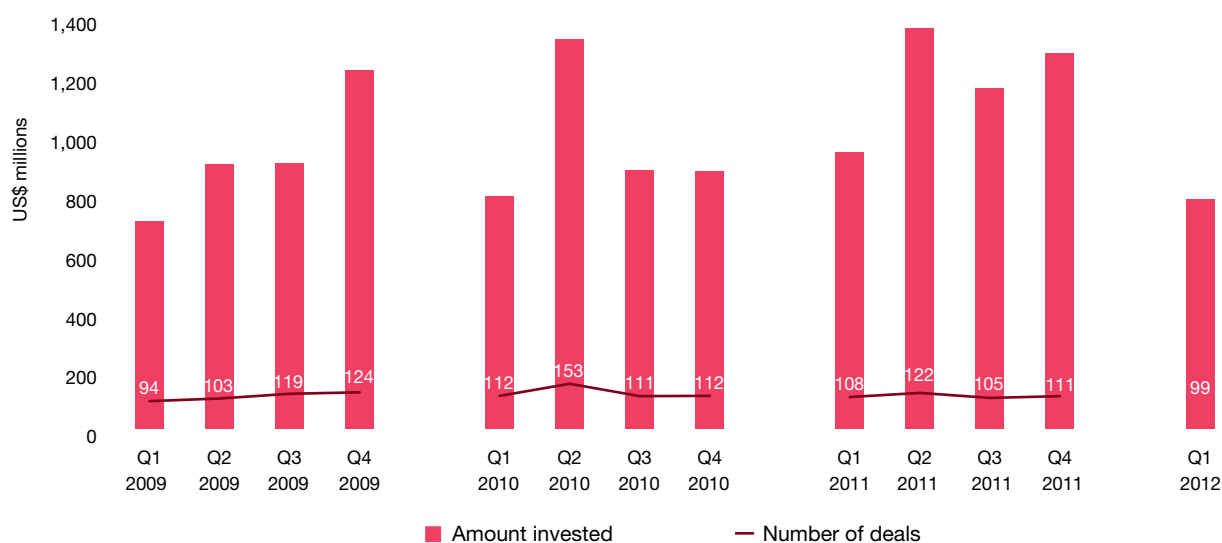
It’s harder still to get venture capital in Europe and Asia. In 2011, venture funding in the European biotech industry dropped to \$1.2 billion – down from \$1.4 billion the previous year – as the Eurozone’s problems cast a shadow over the entire region.<sup>15</sup> And, in Asia, venture backing plays a much smaller role. In the first half of 2011, Asian biotechs raised only \$81 million, a fraction of the venture funding raised in the US and Europe.<sup>16</sup>

**Table 1: Top of the pops**

Top 10 drugs in 2009 (global sales in US\$ billions)		Top 10 drugs in 2016 (global sales in US\$ billions)	
Lipitor	12.0	Humira	9.7
Plavix	9.1	Avastin	7.6
Seretide/Advair	8.1	Rituxan	7.7
Enbrel	7.3	Crestor	7.5
Humira	6.7	Enbrel	7.2
Remicade	6.5	Seretide/Advair	7.0
Avastin	6.2	Januvia/Janumet	6.8
Diovan	6.1	Herceptin	6.5
Rituxan	6.1	Remicade	6.1
Crestor	6.1	Prevnar 13 (conj. vaccine)	5.8

Source: EvaluatePharma

**Figure 3: US venture funding is still scarce for first-timers**



Source: PwC/National Venture Capital Association MoneyTree™

Things may still pick up: 36% of the US venture capitalists the NVCA surveyed hope to invest more heavily in European biotechs, while 44% have their eyes on Asia. But even if they do spread their wings, it's obvious the industry won't be awash with cash. The same NVCA survey shows that 39% of US venture capitalists intend to cut the amount they invest in life sciences firms over the next three years – some of them by as much as a third.<sup>17</sup>

Why? Primarily because there are better opportunities elsewhere. As **Table 2** shows, the biotech sector delivers much lower returns than those that can be obtained from many other sectors. Indeed, in the past five years, it's typically delivered a pooled gross internal rate of return that's less than a third of the return from investing in information technology.<sup>18</sup>

Realising a return has also, of course, become much harder. In 2011, there were only eight initial public offerings (IPOs) in the US biotech sector, and they raised only \$517 million – a far cry from the 19 IPOs that fetched more than \$1.2 billion in 2007.<sup>19</sup> In short, venture capitalists aren't likely to pile back into the industry while the economic outlook remains so uncertain.

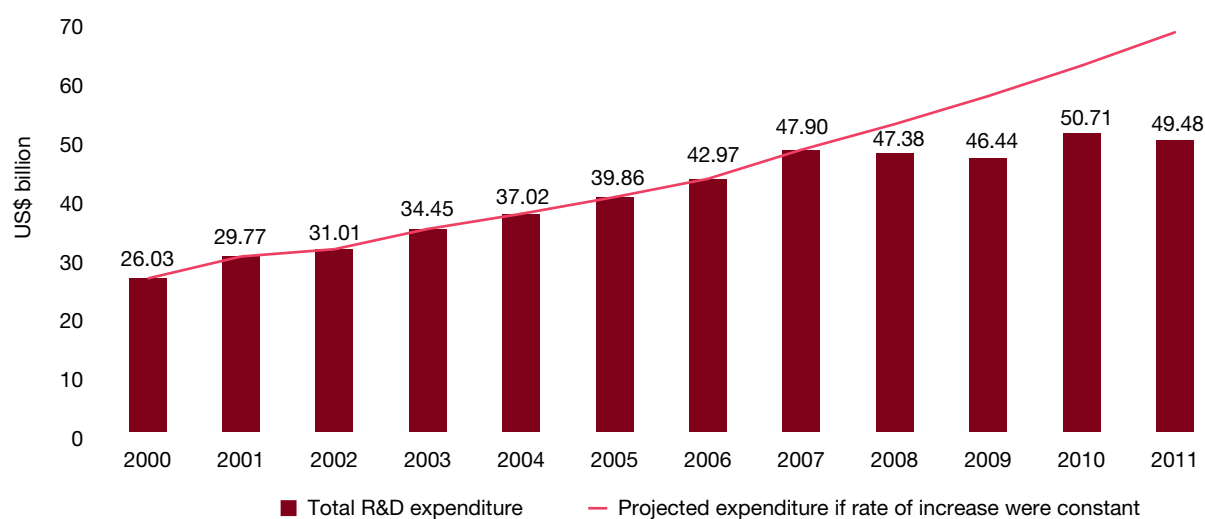
**Table 2: The biotech sector offers lower returns than many other sectors**

	2006	2007	2008	2009	2010	Average
Information Tech.	19.53	22.45	46.22	59.92	82.97	92.44
Hardware/Systems	-0.31	48.74	16.44	70.51	53.13	75.40
Software/Services	9.85	12.83	25.78	44.52	47.14	56.05
Manufacturing	22.02	5.39	22.01	34.17	50.63	53.69
Media/Comms.	-2.34	4.43	17.41	47.15	56.01	49.06
Chemicals/Materials	-4.98	37.21	4.61	1.49	64.73	41.22
Consumer/Retail	-0.32	-5.35	10.25	41.19	18.59	25.87
<b>Healthcare/Biotech</b>	<b>3.74</b>	<b>7.76</b>	<b>12.01</b>	<b>11.72</b>	<b>27.31</b>	<b>25.02</b>
Industrial	13.73	-16.94	58.53	N/A	N/A	18.44
Financial Services	21.25	-8.05	3.00	14.66	11.73	17.04
Energy	2.18	18.86	6.79	9.24	5.22	16.92
Electronics	-5.76	2.31	5.13	14.59	17.52	13.52
Other/Fund of Funds	-7.41	12.41	-2.98	16.82	11.48	12.13
Environmental	-67.81	4.69	0.05	-1.10	24.25	-15.97

Source: Cambridge Associates

Note: The pooled gross internal rate of return (%) delivered by companies receiving an initial investment in the years 2006 to 2010

**Figure 4: Big Pharma's trimming its R&D expenditure**



Source: Pharmaceutical Research and Manufacturers of America (PhRMA)

Note: Between 2000 and 2007, R&D expenditure rose at a compound annual growth rate of 9.1%. If this trend had continued, PhRMA's members would now spend nearly \$68 billion a year on R&D

## Big Pharma can't bridge the gap

Some of the largest biopharma companies are now trying to fill the gap. In 2011, they collectively contributed \$694 million – nearly 15% of the total venture capital invested in the US biotech sector that year.<sup>20</sup> Three firms have also topped up the pot with new funds. In September 2011, MSD (known as Merck in the US) launched the Global Health Innovation Fund and Merck Research Venture Fund, with \$250 million each to invest.<sup>21</sup> Then, in March 2012, GSK and Johnson & Johnson teamed up with Index Ventures to create a \$200 million fund for backing early-stage biotech companies.<sup>22</sup>

It's too early to evaluate the success of this last fund. But MSD has already put \$37 million into a digital pharma marketing company and two diagnostics providers, via the first of the two funds it set up.<sup>23</sup> It's also made four fund-to-fund investments through its Research Venture Fund and tied up with Flagship Ventures to find suitable biotech candidates.<sup>24</sup>

Yet Big Pharma's in no position to pick up all the slack. Most of the leading players are under pressure themselves, as their earnings from aging medicines

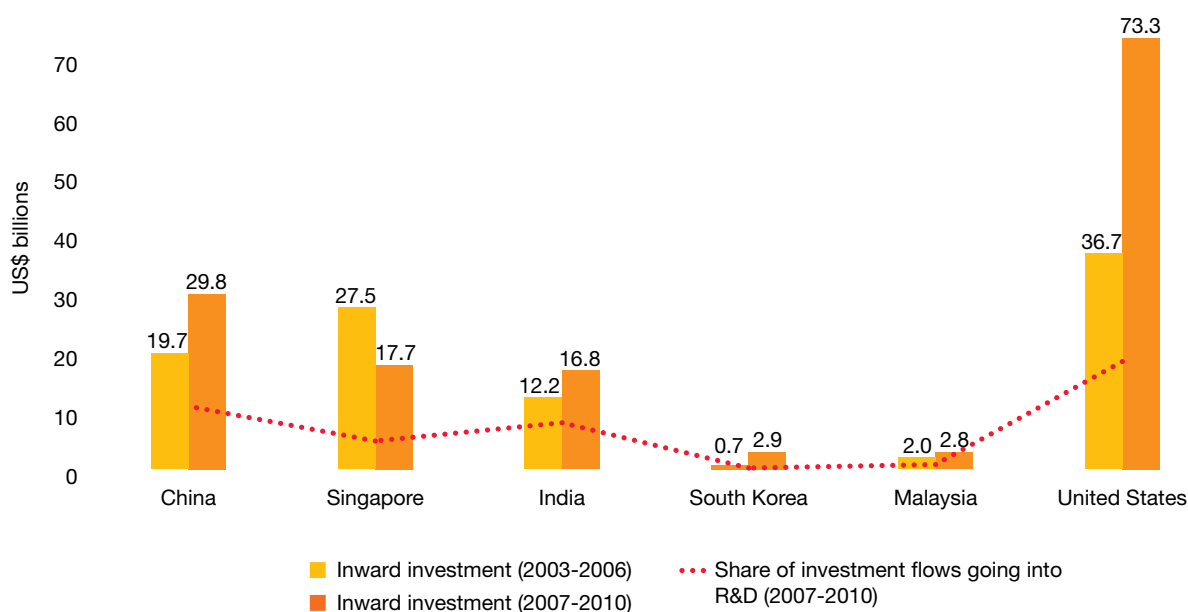
tumble over the 'patent cliff'. Witness the fact that the members of trade body Pharmaceutical Research and Manufacturers of America (PhRMA) cut their R&D expenditure by 2.4% in 2011 (see **Figure 4**).<sup>25</sup> That's the third such drop in the past five years and the equivalent of an 8.5% fall in real terms since 2007.<sup>26</sup>

At least one biopharma firm has now pulled out of the venture game altogether. Executives at Biogen Idec, which began life as a biotech start-up itself, believe there are better ways of supporting innovation, such as sponsoring university research. And they say the usual argument for becoming a corporate venture capitalist – that you get preferential treatment when it's time to buy a new technology – is essentially a myth, or should be, because the backers owe it to their shareholders to strike the best deal for all concerned.<sup>27</sup>

These trends imply that the business model on which the biotech industry has relied is indeed very vulnerable. The 'ivy-league' candidates will still be able to attract venture funding, but there won't be enough cash to sustain the entire sector.



**Figure 5: The US still attracts the bulk of all foreign direct biopharma investment**



Source: Jones Lang LaSalle

### Asia smartens up its act...

What, then, about our next hypothesis: that the research base is moving east and the US is losing its lead in biomedical research? Some of the patterns we identified in 2010 have continued. The number of students completing doctorates in the physical and biological sciences is still soaring in China, for example.<sup>28</sup>

The returnee trend seems to be accelerating, too. Unfortunately, there's no hard data on reverse migration. But the Chinese Ministry of Education estimates that, in 2010, 134,800 overseas Chinese students went back after getting a foreign education. That's more than double the number who returned in 2008.<sup>29</sup> And recruitment consultancy Kelly Services predicts that as many as 300,000 Indian professionals working abroad could go home by 2015.<sup>30</sup>

The emerging Asian economies are also still ramping up their investment in biotech R&D. The Indian government plans to spend \$297 million in the coming financial year alone. Much of that money will go on setting up a new national bioinformatics centre and

several inter-institutional centres for translational research.<sup>31</sup> Meanwhile, the South Korean government has put about \$5 billion into two biotech clusters in Osong and Daegu, and is now actively promoting the development of a domestic biosimilars industry.<sup>32</sup>

Singapore – which already has a thriving biotech base – has pledged to invest another \$2.8 billion (in US dollars) on biomedical R&D by 2016.<sup>33</sup> Malaysia aims to sink nearly \$3 billion of public and private funds in the sector during the second phase of its national biotechnology plan.<sup>34</sup> And China dwarfs them all; in mid-2011, Beijing announced that it intends to spend more than \$300 billion on science and technology in the next five years, with biotech one of seven top priorities.<sup>35</sup>

These efforts are bearing fruit. Between 2004 and 2009, the number of listed biopharma companies in Asia climbed from 276 to 370, and their combined revenues nearly tripled from \$27.4 billion to \$73 billion.<sup>36</sup> At least two Indian and five Chinese biopharma firms have now joined the 'billion-dollar club,' with several Malaysian firms close behind.<sup>37</sup>

Many of the big multinationals have also been setting up Asian R&D hubs. In fact, R&D accounted for 31% of the 653 cross-border biotech and pharma investments that fDi Markets recorded in Asia from 2004-2011.<sup>38</sup> China, Singapore, and India attracted most of this money, although the US still gets the biggest share of all foreign direct biopharma investment (see **Figure 5**).<sup>39</sup>

### ... but the acid test's innovation

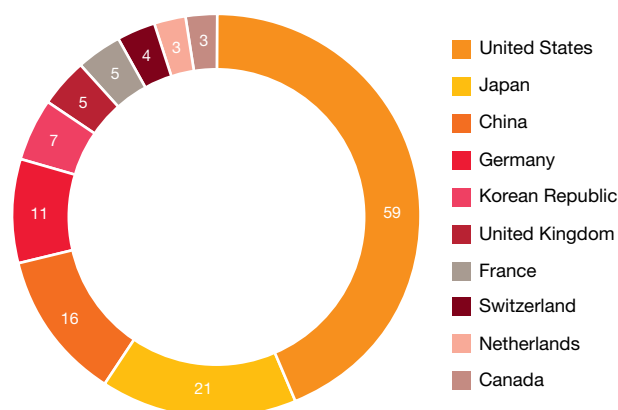
Even so, between 2007 and 2010, Asia's top five biopharma players collectively brought in \$70 billion. Yet they continue to lag way behind the leading developed economies in terms of innovation. The number of biotech patent applications originating in the US is far higher than in any other country (see **Figure 6**).<sup>40</sup> But it's not just the number of applications that counts, it's also their quality – and here, too, the US reigns supreme.

Internationally recognised patents are generally a better test of innovation than those that are only recognised in the inventor's country of origin. In 2010, 42% of all US inventors and 37% of all Japanese inventors who applied for patents in any field of technology filed abroad. So did 40% of those based in India, although the number of applications was much smaller. But more than 95% of the applications Chinese inventors submitted were filed domestically.<sup>41</sup>

That's not all. One researcher – reasoning that most of the medicines developed worldwide are marketed in the US, and that FDA approval is therefore a good global benchmark – looked at the location of every listed inventor of a pharmaceutical patent in the FDA Orange Book between 2000 and 2009. Sixty percent of them were based in the US, and 31.5% in just seven other countries. Only one inventor lived in India, and only two in China (see **Figure 7**).<sup>42</sup>

Of course, this doesn't mean the US – or any other developed country with a strong record of biotech R&D – can

**Figure 6: US scientists apply for more biotech patents than scientists in any other country (thousands)**

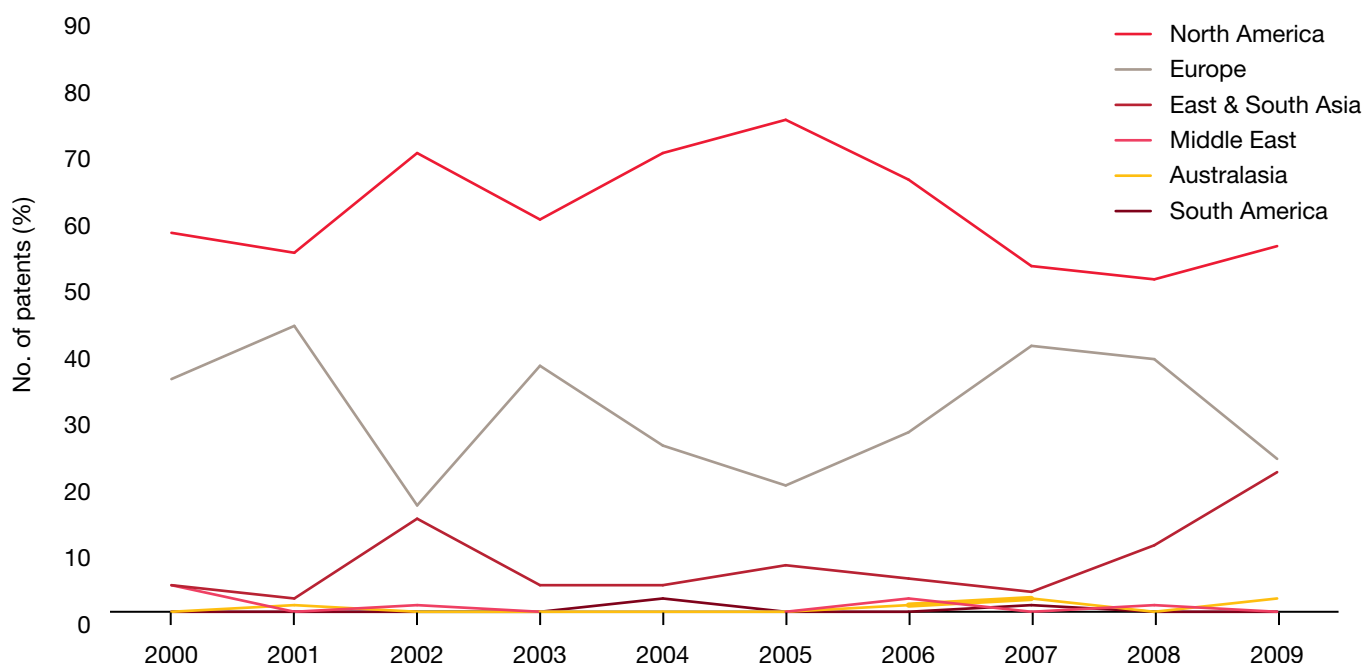


Source: World Intellectual Property Organisation

Note: The top 10 countries generating biotech patent applications between 2005 and 2009

afford to be complacent. By the end of 2010, there were 187 novel investigational drugs undergoing clinical trials in China, and 39 of them are covered by US or European patents, suggesting they have global potential.<sup>43</sup> China's standing as a source of innovation could soon improve, then, but the US looks likely to stay in pole position for some time to come.

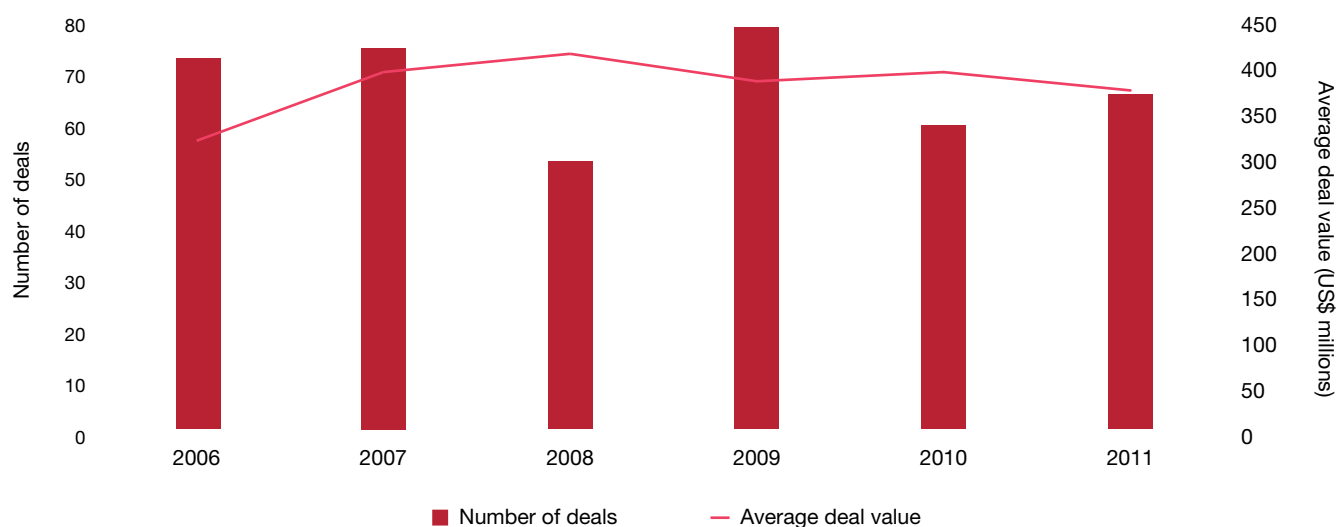
**Figure 7: Most biopharma invention still originates in the US**



Source: Yali Friedman, "Location of pharmaceutical innovation: 2000–2009"

Notes: (1). Data for 2000 only cover January to June; (2). Where inventors from more than one country co-developed a patent, each country was assigned a proportionate share of the credit.

**Figure 8: The number of biotech-pharma alliances is creeping up again**



Sources: Burrill & Co., Windhover

Note: All deals between biotech and pharma companies exceeding \$20 million. Data for 2011 are projected from the figures for the nine months to 30 September 2011

## Joined-up thinking

So two of the three concerns we expressed in 2010 still look valid. But, fortunately, there've been other major developments in the intervening two years as well. The 'biotech-ification' of Big Pharma has continued, just as we predicted. The trend towards collaboration has been even more pronounced. In 2010, we identified three particular forms of collaboration:

- Pre-competitive discovery federations – where public and private institutions pool their resources to overcome bottlenecks in early-stage biomedical research
- Competitive development consortia – where rival biopharma companies form syndicates to develop the most promising molecules in their combined portfolios; and
- Service-provision alliances – where biopharma companies and service providers join forces to offer healthcare packages for patients with specific diseases.

We cited a few instances but remarked that they were rare. Today, there are many more collaborations – and some of them hint at the emergence of new business models.

## Playing nicely

Take the way biotech and pharma companies are starting to come together. In 2011, there were an estimated 65 alliances worth more than \$20 million. That's still lower than before (see **Figure 8**).<sup>44</sup> But some of these partnerships have been structured much more creatively.

The deal Forma Therapeutics struck with Roche subsidiary Genentech is a good example. In June 2011, Forma handed over worldwide rights to one of its early-stage cancer medication programmes. In return, Genentech paid an upfront lump sum and will make additional milestone payments, if Forma meets certain scientific and commercial criteria.<sup>45</sup>

There's nothing novel about such terms. What sets the deal apart is the fact that Genentech also bought an option to acquire any resulting compound outright, rather than licensing it in and paying royalties. So, if Forma succeeds, it will be able to sell the compound and deliver a return to its investors without going public or getting acquired. That means its venture backers can keep growing the company and benefit fully from any subsequent sale.<sup>46</sup>

Forma isn't the only biotech exploring new ways of realising value without turning to the capital markets or a trade buyer. Antibody specialist Adimab has built a business based on selling access to its high-tech platform for discovering new human antibodies, instead of getting into drug development itself. Nimbus Discovery has adopted the same approach.<sup>47</sup>

Quantice Pharmaceuticals has taken a slightly different tack. It's sold Celgene an exclusive three-and-a-half year licence to its platform for analysing genetic variations in individual patients' tumours. But the \$45-million package includes a stake in the company and an exclusive option to buy Quantice at a later date. So Quantice has effectively given its venture backers an immediate return on their money, as well as making sure it's got capital to grow.<sup>48</sup>

Meanwhile, Warp Drive Bio, which aims to discover new products by analysing the genomes of plants, animals and wild organisms, has given Sanofi – one of its three venture backers – a non-exclusive option to buy the company. But the deal cuts both ways. Warp Drive Bio will retain the rights to many of the assets it develops unless Sanofi exercises the

option. And, if it reaches certain milestones, it can force Sanofi to buy it at a predetermined price.<sup>49</sup>

So, even if the stock markets are still depressed and trade buyers are sparse, the biotech industry's actively pursuing new business models – although the pressure's on to deliver. As *FierceBiotech* reporter John Carroll recently noted, “Big Pharma's trigger finger is getting increasingly itchy when it comes to killing unwanted or unsuccessful collaboration pacts”.<sup>50</sup>

### Patient money

Some biotech and pharma companies are also looking for new allies, and several have turned to patient advocacy groups as a source of funding. Vertex got \$75 million from the Cystic Fibrosis Foundation when it was developing Kalydeco, for example. It repaid that trust in January 2012, when it won FDA approval for the first medicine to target the mutated gene that causes cystic fibrosis. It will also pay the foundation a share of the proceeds from all sales.<sup>51</sup>

Similarly, Amylin Pharmaceuticals has joined forces with the Juvenile Diabetes Research Foundation to fund a series of clinical trials on the effectiveness of a combination therapy for Type 1 diabetes.<sup>52</sup> And, in April 2012, the Michael J. Fox Foundation agreed to pay for further testing of a therapy developed by Sanofi that might treat the mental symptoms of Parkinson's disease.<sup>53</sup>

The ‘venture philanthropist’ model, as it's been called, is now spreading outside the US. In March 2012, Britain's Wellcome Trust launched a \$310-million fund to invest directly in healthcare and life sciences companies.<sup>54</sup> Cancer Research UK has also teamed up with a European venture capital firm to create a nearly \$50-million fund for boosting the development of new cancer treatments.<sup>55</sup>

These moves mark a profound shift. Medical charities and patient organisations have long supported basic research, but they're now moving down the pipeline – and the biotech industry's ready to play with them.

### Back to school

There's been a significant rise in the number of alliances with academic institutions, too, although this is largely a Big Pharma trend. Pfizer's gone ‘back to school’ in a big way. In May 2010, it linked up with Washington University School of Medicine in St Louis to identify new uses for existing compounds.<sup>56</sup> Then, in November 2010, it started building a translational research network that now includes 20 US universities and academic medical centres.<sup>57</sup>

Other industry giants have also been dusting off their textbooks (see **Table 3**). Between January and September 2011, there were 30 new biopharma alliances with academic bodies, nearly double the total for 2010.<sup>58</sup> And the pace shows no sign of slowing. In early 2012, for example, Eli Lilly signed Cambridge University up to its ‘Open Innovation Drug Discovery Platform’, bringing the number of participating European institutions to more than 60.<sup>59</sup>

### United front

Several new precompetitive federations for grappling with ‘big data’ have simultaneously emerged. The Pistoia Alliance is one such instance; it draws on the ‘crowd’ wisdom of pharma and informatics experts from a wide range of organisations to devise and document best practice in R&D.<sup>60</sup> And Sage Bionetworks is an open-source forum where computational biologists can pool their data and brainpower to crack particularly difficult problems.<sup>61</sup>

The US National Institutes of Health (NIH) has also just embraced crowd-sourcing in an effort to ‘teach old drugs new tricks’, as Health and Human Services Secretary Kathleen Sebelius put it. The NIH's National Center for Advancing Translational Sciences and its industry partners Pfizer, AstraZeneca, and Lilly are tapping the nation's ‘brightest minds’ to test various compounds that have been studied in humans but shelved, to see whether new uses can be found for them.<sup>62</sup>

**Table 3: Big Pharma's calling on the profs**

	Academic institution	Therapeutic focus
AstraZeneca & GSK	Manchester University	Inflammatory diseases
Bayer	University of California San Francisco	Translational research
Gilead Sciences	Yale School of Medicine	Novel molecular mechanisms for cancer
Johnson & Johnson	10 academic “superstars”	Multiple
Merck & Co.	Sanford-Burnham Institute	Alzheimer's disease & major psychiatric disorders
	University of Southern California	Health science
	University of North Carolina	HIV
	University of California San Francisco	HIV
Novo Nordisk	Oxford University	Rheumatoid arthritis & other autoimmune inflammatory diseases
Roche	University of California Los Angeles	Genomics
	University of Geneva & Institute of Bioinformatics	Translational research
Sanofi	University of California San Francisco	Oncology, aging, diabetes & inflammation
	Columbia University	Diabetes
	Stanford University	Early-stage research
	Weill Cornell Medical College	Tuberculosis
	University of California San Diego	Acne

Source: PwC

Note: Key biopharma alliances with academic institutions in 2011

## Collaborating competitors

It's not just non-competitive or pre-competitive partnerships that are flavour of the month, though. Co-development pacts between rival companies have become equally popular, especially in the oncology arena. AstraZeneca and MSD kicked off in 2009, when they agreed to share the cost of testing a combination therapy based on two compounds they'd developed separately. Today, there are at least four more such arrangements.

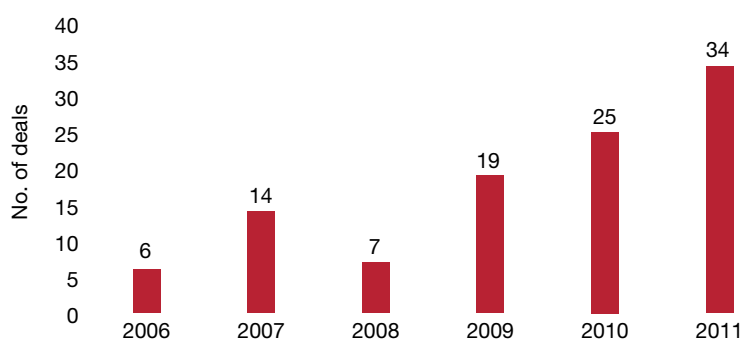
Novartis and Amgen are jointly investigating a therapy for breast cancer. Novartis has also hooked up with GSK to co-develop a treatment for advanced solid tumours. Bristol-Myers Squibb and Roche are collaborating on a melanoma product. And Sanofi's working with Merck KGaA on a combination therapy for multiple forms of cancer.<sup>63</sup>

This new spirit of cooperation is now spilling over into other therapeutic areas. In May 2011, Roche and MSD struck a deal to co-promote Victrelis, MSD's new treatment for chronic hepatitis C. More unusually, the two companies also agreed to pool resources and study 'novel combinations of marketed and investigational medicines [for hepatitis C] from both organisations'.<sup>64</sup>

There's been a similar surge in the number of alliances with diagnostics providers, both to satisfy public demand for personalised medicine and to address the concerns of healthcare payers reluctant to reimburse costly new therapies that can't be directed at known 'responders'. Last year's crop of approvals included two cancer products with companion diagnostics: Pfizer's Xalkori for the treatment of patients with advanced non-small cell lung cancer that's ALK-positive; and Roche's Zelboraf, for people with BRAF-positive metastatic melanoma.<sup>65</sup>

This trend's obviously set to continue. In 2011, the biopharma industry formed 34 new partnerships to develop companion diagnostics – up from 19 in 2009 (see **Figure 9**). The FDA's refusal to approve leukemia treatment Omapro without a diagnostic to identify the target patient population probably acted as a spur.<sup>66</sup>

**Figure 9: Twinning with diagnostic providers is on the rise**



Source: PwC analysis, using data from Windhover, IDV Technology and company press releases

But diagnostic biomarkers have other benefits as well. They can save a lot of time and money during clinical trials by narrowing down the subset of patients on whom a molecule should be tested and exposing defects more rapidly.

## Swapping notes with the big spenders

The financial pressure from cash-strapped healthcare payers has also led to much more collaboration between biopharma companies and their customers. GSK pioneered this policy; its executives now consult health officials and insurers at least five years before a product is due to leave its labs. But GSK's certainly not alone in talking to the people who hold the purse strings.<sup>67</sup>

In 2011, Pfizer paired up with US health insurer Humana to research the health problems of the elderly. AstraZeneca and HealthCore agreed to work together on a study of how to treat disease more cost-effectively. Sanofi brought in Medco Health Solutions to stress-test its entire Phase I development programme. And several smaller companies are starting to follow suit.<sup>68</sup>

Of course, it's one thing to talk, another to listen – especially when the feedback's not favourable. But some companies are clearly acting on what they're told. GSK is a case in point; the firm pulled a diabetes product mid-way through development because healthcare payers weren't sufficiently convinced of its value.<sup>69</sup>

## ***Package deals***

The number of biotech and pharma companies collaborating with other organisations to tap into demand for personalised healthcare and create new ways of adding value is also on the rise. In May 2010, for example, Pathway Genomics entered into a marketing pact with US pharmacy chain Walgreens to supply direct-to-consumer genetic testing kits. The FDA called a halt to the deal, but it's indicative of the direction in which things are moving.<sup>70</sup>

Other, more successful ventures have since been launched. In January 2012, Proteus Biomedical signed a contract with British pharmacy group Lloydspharmacy to sell pills containing edible microchips that communicate with a disposable monitoring patch worn on the shoulder. The service will cost patients about \$78 a month and the two companies will split any profits.<sup>71</sup>

Meanwhile, GSK has linked up with specialist technology provider MedTrust Online to launch an iPhone app that lets oncologists search for clinical trials by cancer type and automatically identifies the trial centers nearest their patients.<sup>72</sup> And Pfizer has started offering an automated vascular health check service in British pharmacies.<sup>73</sup>

## ***Pulling together***

But perhaps the clearest sign of this new willingness to collaborate is GSK's compact with McLaren, the high-tech engineering firm behind Formula 1 racing. The biopharma industry has traditionally taken the view that it's 'different' from other industries – and so there's little it can learn from them. In September 2011, GSK put old prejudices aside when it embarked on a five-year partnership to enhance its manufacturing, R&D, and consumer healthcare businesses with McLaren's engineering and technological expertise.<sup>74</sup>

In general, then, the last two years have provided fresh grounds for hope. The biotech sector's productivity is still open to question, the business model it's traditionally relied on is shaky, and there's been an undeniable geographic shift in the biomedical research base. But US scientists are as inventive as ever; some biotech companies aren't just tightening their belts, they're finding new ways to get funding and create value; and the biopharma community as a whole is trying to pull together.



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