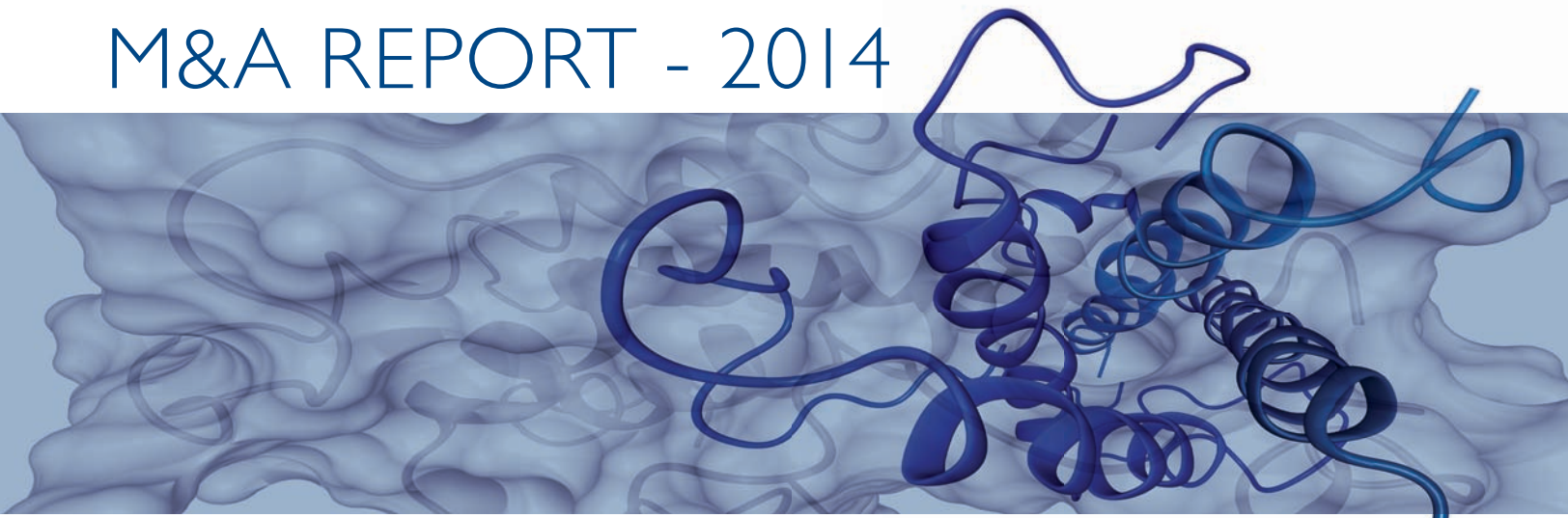
# GLOBAL PHARMA & BIOTECH M&A REPORT - 2014



An IMAP Industry Report

IMAP


IMAP
Conmed Corporation
Surgical devices and equipment for minimally invasive procedures
Utica, NY, United States
Entered into a Sports Medicine Joint Development and Distribution Agreement with
Musculoskeletal Transplant Fdn
Non-profit tissue bank
Edison, NJ, United States
Advised the Buyer
Stada Arzneimittel AG
Leading provider of OTC and generic drugs
Germany
Acquired 100% of the Shares of
Spirig Healthcare AG
OTC & generic drugs unit of Spirig Pharma
Switzerland
Led the Carve-out and M&A Process for the Vendors
Cumberland Pharmaceuticals, Inc.
Manufactures branded prescription products for acute care and gastroenterology markets
Nashville, TN, United States
Acquired Worldwide Rights to Certain Assets of
Kristalose, Mylan Pharmaceuticals
Prescription laxative administered orally for the treatment of constipation
Morgantown, WV, United States
Advised the Buyer
Getinge Group
Healthcare and life sciences products provider
Stockholm, Sweden
Acquired 100% of Business Operations of
Acare Medical Science Ltd
Production of medical equipment
Zhuhai, China
Advised the Buyer
Candoria Holding AG
Holding of pharma companies
Basel, Switzerland
Acquired 100% of the Shares of
Grogg Pharma AG
Owner of Lacdigest®, a medication to treat lactose intolerance
Bern, Switzerland
Advised on Purchase of Company
Vitabalans Oy
Manufacturer of pharmaceuticals, medicines, food supplements & veterinary supplies
Hämeenlinna, Finland
Acquired 100% of Business Operations of
Blanco Pharma GmbH
Distributor of medicines and food supplements
Hamburg, Germany
Advised the Buyer
Grupo Farma
Leading Venezuelan pharmaceutical company
Caracas, Venezuela
Acquired the Pharmaceutical Product Portfolio of
James Brown Pharma
Ecuador-based pharmaceutical company
Quito, Ecuador
Advised the Buyer
Galderma S.A.
World-leading dermatology group
Lausanne, Switzerland
Acquired 100% of the Shares of
Spirig Pharma AG
European dermatology group
Egerkingen, Switzerland
Advised the Seller
Stada Arzneimittel AG
OTC and generic drug provider
Bad Vilbel, Germany
Acquired Majority Control of Wholesale Business of
Spirig Pharma AG
Wholesaler of medicines to doctors and pharmacies
Egerkingen, Switzerland
Advised the Seller
Humana Inc. (NYSE:HUM)
Healthcare insurance and service company
Louisville, KY, United States
Acquired 100% of Business Operations of
Metropolitan Health Networks Inc.
Offers operation of a provider services network (PSN) in the United States
Boca Raton, FL, United States
Advised the Seller
Life Technologies Corporation
Life Science and biotechnology products provider
United States
Acquired 100 % of
BAC BV
Manufacturer of protein purification products
Netherlands
Advised the Seller
Spirig Healthcare AG (STADA)
OTC and generic drug provider
Egerkingen, Switzerland
Acquired the Business Operations of
Spirig Pharma's wholesale business
Wholesaler to physicians and pharmacies
Egerkingen, Switzerland
Advised the vendor throughout the carve-out and sale process
AngioDynamics Inc. (NasdaqGS:ANGO)
Provider of medical and surgical devices
Latham, NY, United States
Acquired
Microsulis Medical Limited
Provider of medical devices
Denmead, Hampshire, United Kingdom
Advised the Seller
Grünenthal Group
Family-owned pharmaceutical company
Aachen, Germany
Acquired Selected Assets of
BIOGEN® LABORATORIOS
Transnational pharmaceutical company
Bogota, Colombia
Represented the Buyer in this Transaction
Smith and Nephew Pte Limited
MNC - Medical equipment manufacturing
London, UK, United Kingdom
Acquired 100 % of Business Operations of
Adler Mediequip Pvt Ltd
Orthopaedic and trauma implants manufacturer
Pune, Maharashtra, India
Advised on Sale of Company
ProConcepta Zug AG
Pharma company
Zug, Switzerland
Acquired the Rights for
Tretinac, owned by Galderma-Spirig
Dermatology product
Egerkingen, Switzerland
Initiated the Transaction and Assisted the Buyer
Silver Peak Partners
Private equity firm
Denver, Colorado, United States
Purchased 100% of Business Operations of
Aamco Medical
Sales and distribution of durable medical equipment
Sandy, Utah, United States
Advised on Sale of Company
Silver Peak Partners
Private equity firm
Denver, Colorado, United States
Purchased 100% of Business Operations of
Tibro Medical
Sales and distribution of durable medical equipment
Murray, Utah, United States
Advised on Sale of Company
Urfar Ilaç Sanayi ve Ticaret A.S.
Pharmaceuticals company
Istanbul, Turkey
Acquired Selected Assets of Business Operations of
Bilim Ilaç Sanayi ve Ticaret A.S.
Pharmaceuticals company
Istanbul, Turkey
Advised on Sale of Company

# Editorial

Christoph Bieri
Chair, IMAP Healthcare Team

## Dear Reader,

The year 2013 was simultaneously thrilling and sobering for the industry. General M&A activity was up. After a long drought, the IPO window for biotech was again wide open, with a record number of companies entering the public spotlight. The fact that the IPO boom was restricted to the US may be interpreted as a sign of American biomedical dominance, or ebullience, depending on the perspective (see our articles on page 6 and 7).

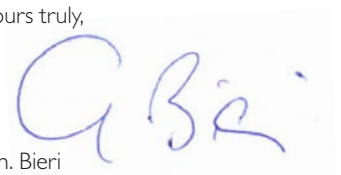
More sobering were the anti-bribery investigations directed towards foreign (and later local) pharma companies in China; these investigations brought inbound deal activity to a standstill and substantially reduced the regional growth prospects of the accused pharma companies (page 11). In India, the skirmish regarding intellectual property in the country continues and new worries about quality and regulatory compliance of its export industry are emerging, although the country still presents enormous growth prospects (page 12).

Historically, the pharmaceutical industry's growth has mainly been driven by innovation. However, it is generally accepted that the huge increase in R&D investment over the last decades did not yield the expected return of new products. Patent cliffs and cost pressure now force Big Pharma to dramatically reshape their R&D efforts, with challenging consequences for their service providers, for example CROs. Our special article on page 14 describes some of the drivers of the global CRO industry and their effects, particularly for mid-sized CROs.

The pharmaceutical industry is continuing its progress in fundamental restructuring. In this environment, acquisitions and divestments are essential means to achieve strategic objectives. With its combination of M&A experience, global reach, local presence and deep industry expertise, IMAP's Healthcare group can provide outstanding support.

Contact us for a confidential discussion of your plans and needs.

Yours truly,



Ch. Bieri

IMAP in Switzerland / Kurmann Partners

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# 2013 – The year in review

## More deals, higher valuations

By number of deals, 2013 was a much stronger year than 2012: there were 615 announced and/or closed transactions involving targets in the biopharmaceutical and diagnostic industry, versus 456 the year before – an increase of 34%.

The total value of transactions also increased: the sum of published transaction values was around US$100 billion, much higher than in 2012 (US$67 billion) and within the range of 2011 (US$90 billion), even though 2013 did not see mega-mergers such as the 2011 Sanofi / Genzyme and Takeda / Nycomed combinations. Thus deal activity in the mid-sized segments was particularly strong. A total of 37 transactions had published values in excess of US$500 million, up from 33 in 2012.

Of the 615 transactions, again, only a small fraction involved Western or Japanese pharma companies acquiring emerging markets players, similar to 2012. As in previous years, most targets were located in the US and Western Europe. Transactions with published values in excess of US$1 billion exclusively concerned targets located in these regions (see table below). The two exceptions are the proposed acquisition of South African Adcock Ingram by CFR Pharmaceuticals from Chile (withdrawn in early 2014), and Mylan's acquisition of Agila Specialties, the generic injectable business of Strides Arcolab.

The main deal drivers during the last year were access to new products, tax savings (see article on Western Europe on page 10) and economies of scale.

| | Location of Target | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Range** | **North America** | **Western Europe** | **China** | **CEE** | **India** | **Japan** | **LatAm** | **Other** | **Total 2013** | **Total 2012** |
| More than US$1 billion | 9 | 6 | | | | | | 2 | 17 | 14 |
| US$100 million - US$1 billion | 33 | 25 | 16 | 4 | 2 | | 2 | 6 | 88 | 75 |
| US$10 million - US$100 million | 31 | 32 | 47 | 4 | 7 | 2 | 4 | 12 | 139 | 102 |
| Less than US$10 million | 20 | 21 | 26 | 1 | 4 | 10 | 1 | 14 | 97 | 62 |
| Unknown | 111 | 87 | 8 | 26 | 8 | 9 | 11 | 14 | 274 | 203 |
| **Total** | **204** | **171** | **97** | **35** | **21** | **21** | **18** | **48** | **615** | **456** |

## Moving to emerging markets?

A comparably low number of transactions involved targets in emerging markets, with 44 transactions out of 615 in 2013.

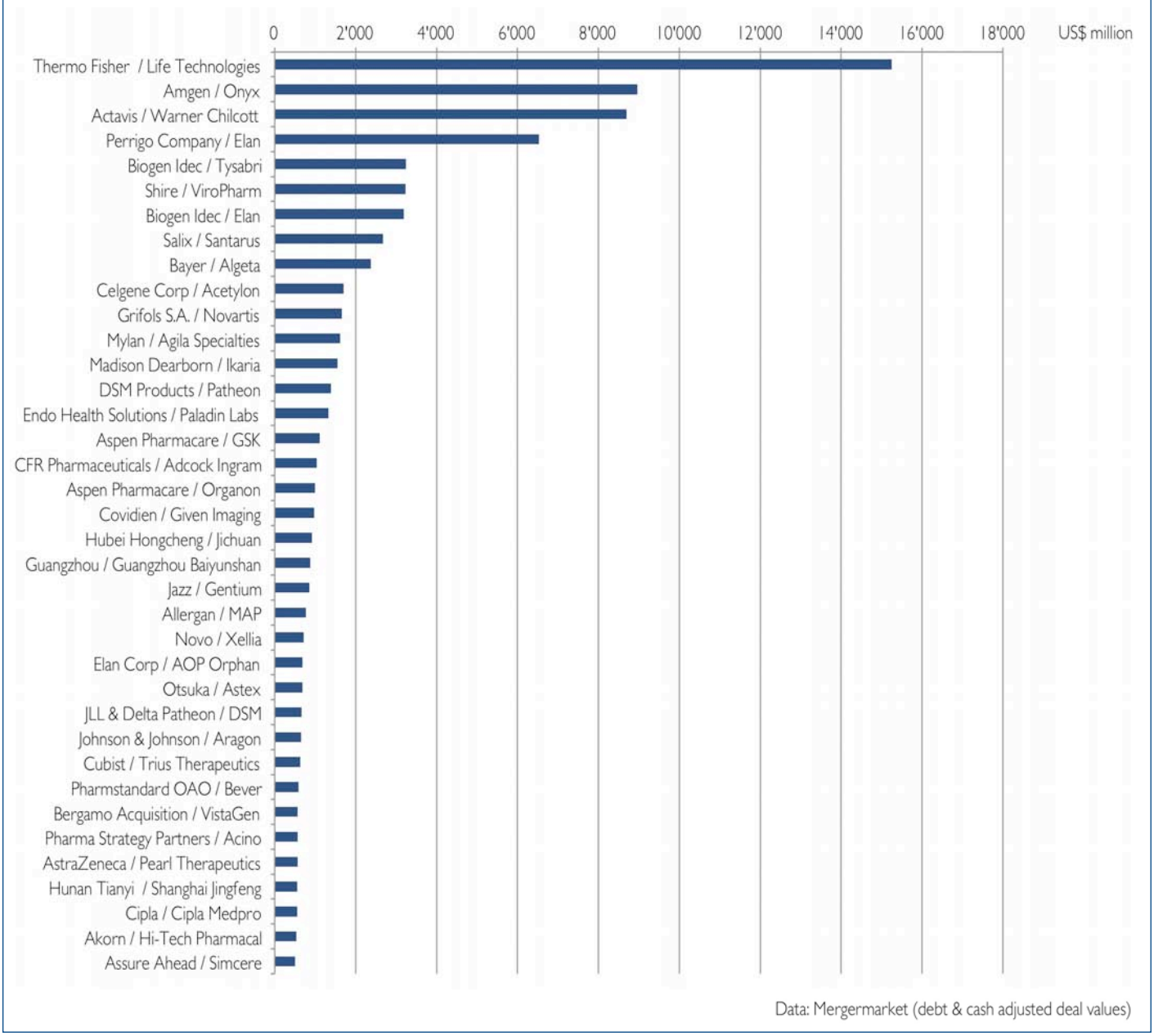
| | Acquiror location | | |
|---|---|---|---|
| **Target Location** | **North America** | **Western Europe** | **Japan** |
| China | 2 | 2 | |
| LatAm | 4 | 5 | |
| India | 3 | 2 | |
| CEE | 5 | 5 | |
| Other | 9 | 6 | 1 |
| **Total** | **23** | **20** | **1** |

## Pipeline transactions with very high valuations

The acquisition of Life Technologies, a supplier of R&D and diagnostic technology, by competitor Thermo Fisher, is the culmination of a decade of consolidation in this industry's sub-segment. The companies had to agree to a number of technology divestments to have the US$13 billion deal approved by the anti-trust authorities. It remains to be seen whether a company at this scale can be innovative; and whether its sheer size gives it a competitive advantage over its smaller peers.

Amgen's acquisition of Onyx, at over US$9 billion, brings the former access to an approved product that will make US$3 billion revenues – in 2021, maybe. What may look expensive on the surface was described by some analysts as "a steal": they point out that Onyx will secure Amgen's long-term growth. This type of transaction – large biopharma company acquires a "one-product" or even a "pipeline-only" firm – is a persistent trend of the last few years. It may also be one of the drivers of the IPO boom, as investors in an IPO can expect that share prices will appreciate in anticipation of a take-over (see article on page 6). However, valuations of "hot" development-stage or one-product companies are so high that some large pharma companies felt compelled to let the market know that they are not willing to pay "just any price".

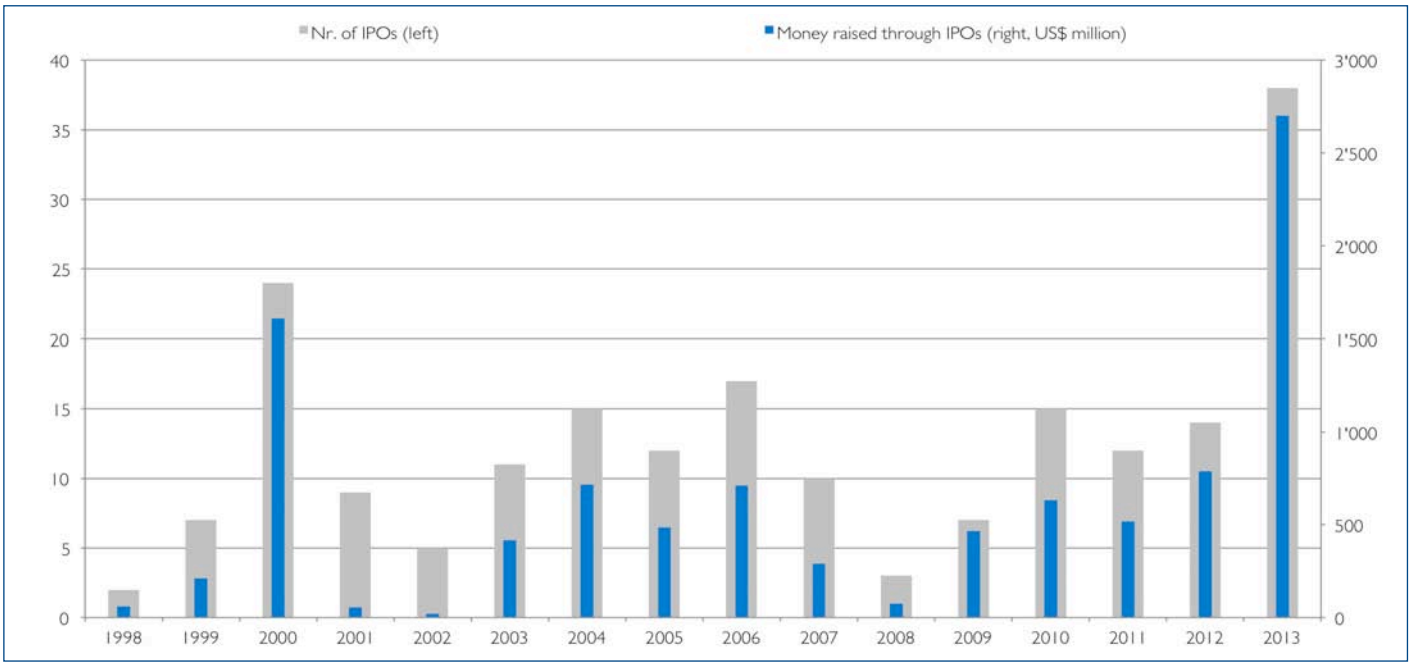
### Deals with deal values over US$500 million




Data: Mergermarket (debt & cash adjusted deal values)

# Global deal drivers

## Booming IPO market – but only in the USA

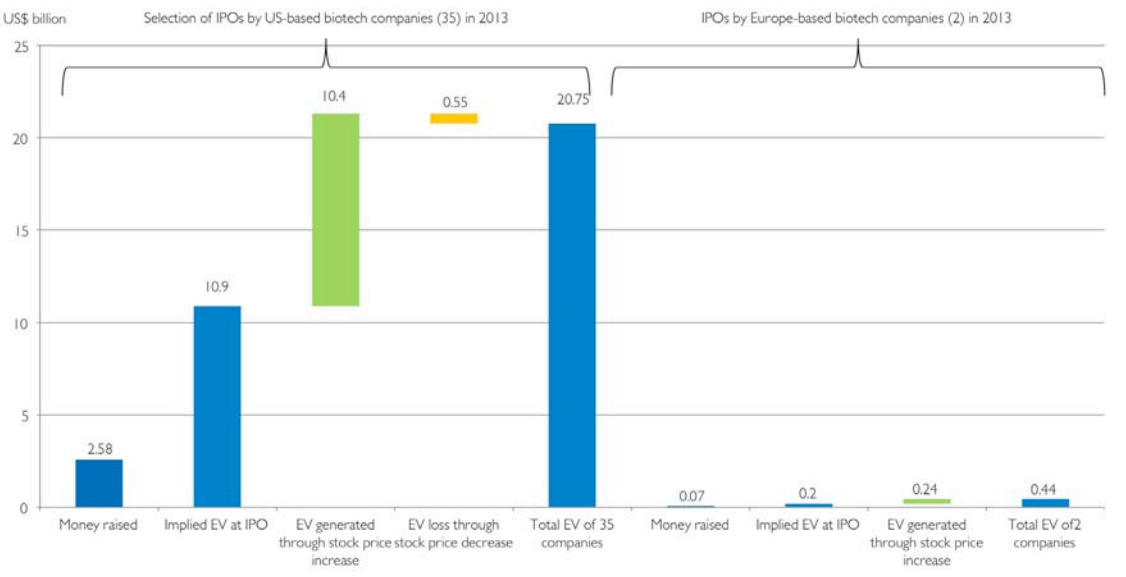



In 2013, we witnessed the comeback of the biotech IPO. Thirty-seven biotech companies went public last year, raising more than US$2.7 billion in the process. This is the highest number of biotech IPOs since at least 2000.

Several reasons have been cited for the sudden popularity of biotech IPOs. On the one hand, the IPO boom was a general phenomenon not restricted only to biotechs. The general trend was fueled by the benign stock market environment and the consequent higher risk appetite of investors; as well as the Jumpstart Our Business Startup (JOBS) Act in the USA, which makes it easier for a small company to go public. On the other hand, biotech IPOs were of particular interest because of the sector's perceived superior performance and a "recycling factor," where large funds wanted to reinvest cash generated by previous exits from other biotech companies.

As per January 17 2014, the aggregate enterprise values (EV: market capitalization less cash at hand) of the 37 companies that went public in 2013 amounted to just above US$20 billion. Approximately US$10.4 billion was "generated" after the companies went public by share price appreciation, offset by an aggregate of US$550 million of losses of share valuations since the first trading day. Needless to say, none of these companies has significant revenue – their valuation is merely based on the anticipation of the success of their development programs. Hence their valuation reflects just "hope."

There is a dramatic difference between IPO markets in Europe and in the USA (see graph below); this puzzles many observers. The reasons for these differences may be manifold (see also the following opinion piece).




Data: KP research

## Opinion: Is the IPO market in Europe dead for biopharmas? *by Benoit Bouche*

In 2013, only two European biotechs – namely, Cardio3Biosciences and Erytech – went public, raising approximately US$70 million; while 37 US companies raised a total of US$2.7 billion through IPOs, i.e. 38 times the proceeds.

Is the pharmaceutical market in Europe 38 times smaller than the USA's? Or is the scientific community 38 times weaker, filing 38 times fewer patents than their US counterparts? Obviously not. So what happens and what lessons should investors and entrepreneurs take home?

Several potential explanations have been brought forward; but they do not survive closer scrutiny:

***Markets are not as efficient in Europe.*** A never-demonstrated cliché that is even harder to claim while NYSE and Euronext have merged.

***A weaker economical context.*** The US economy could well be better positioned than Europe as a whole to rebound but the statistics show that the issue we are discussing is much more a specific biotech issue than a global one. Europe indeed proudly released a total of 278 offerings, raising US$36 billion in 2013; numbers that are not that far from the 222 IPOs raising US$55 billion in the US during the same period.

***A cultural gap.*** True, in Europe, becoming public is not a "must-do" for a company once it reaches a decent size, as may be the case in the US. A number of German and French economists even claim that closely-held, private firms outperform public companies. But this cannot be an answer for the UK, which had no biotech IPOs in 2013 although listing a company there on the AIM is an easy, cheap and routine decision.

We see other problems which are root causes of the large gap in success: the much-weaker venture capital industry; lower quality ventures; and the inherent and distinct network effect – a virtuous cycle that is broken in Europe.

***A weaker VC industry:*** In the last decade, the venture capital industry suffered much more in Europe than in the US. With fewer exits to manage, European local VCs do not have the deal flow to feed capital markets. The remaining successful VC firms active in Europe are truly global, and happier to see their companies (re)locating to renowned US clusters, where they will find staff, new ideas, synergies and frequent contact with deep pocket investors.

***Lower quality ventures:*** Biopharma ventures are too small in Europe. We believe that if the same companies were US-headquartered, they would very likely be ineligible for an IPO there. European-based ventures are often not international enough, lack a sufficiently broad IP portfolio, and lack a solid, experienced management structure. Further, biopharma ventures are less aggressive here: one reason for the lower number of IPO-worthy biotechs is that M&A activity driven by biotech ventures is underdeveloped, that growing via inorganic initiatives is not an element in these companies' strategies.

***Virtuous cycle broken:*** The smaller pie in Europe breaks the virtuous cycle fueling the entire biotech venture and IPO industry. Fewer deals make Europe less attractive to the advisors whose signature is sometimes a mandatory condition for IPO investors to listen to a pitch. A harder path to an IPO as a potential exit makes Europe less attractive to VCs for investment. And the entrepreneur, looking at it, may well prefer to bring their idea to the US to find a better ecosystem.

There is no doubt that successful US IPOs have been a discussion item in the board meetings of European biotechs. And you can be sure that 2014 will see a significant increase in the number of filings – hopefully not too late to fully benefit from the wide-open IPO window, as was the case in the late 90's before the genomics bubble exploded. It will take more work, however, to bring the European market back to a virtuous cycle.

**Benoit Bouche, with IMAP in France (Societex),**
has advised on a large number of IPOs in Europe.
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## Biosimilar market takes shape

Much has been written about regulatory uncertainty around biosimilars, the "me-too" or "copy-cat" biotech drugs. How the market would shape up was also largely unclear. The development costs for biosimilars are now estimated to range between US$40 million and US$250 million per molecule; and the time to market six to nine years – timelines and risks that are far outside the scope of generic drug manufacturers. The large investment requirement limits the number of potential competitors. Merck & Co. closed down a dedicated biosimilar unit, instead focusing on partnerships. However, as the high-profile failure of the Lonza / Teva partnership shows, it is difficult to develop compelling strategies.

Partnerships between originators and generic drug firms or new entrants appear to be a working formula. Today, Novartis' subsidiary Sandoz, Hospira (in partnership with Celltrion), Teva and Actavis (in partnership with Amgen) have biosimilars on the market (which is yet restricted to outside the US). Samsung, which announced partnerships with Merck & Co. and Biogen Idec in 2013, seems to be on track to develop a sustainable position as the only new entrant.

Alvotech is a new company run by Robert Wessman, formerly the CEO of Actavis, who announced an investment of US$250 million in a biosimilar plant in Iceland late last year; it remains to be seen if this venture achieves success similar to Actavis'.

We expect that the number of biosimilars per orignal biotech drug will typically be low, and also anticipate that the pressure of biosimilars on originators will be relatively modest – which also means that the patent cliff of biologics is not as steep as for chemical drugs.

# Global deal drivers

## Shaking up R&D

As many statistics have shown, in R&D, big money does not mean big results. The depressing productivity of Big Pharma's R&D units is one of the most lamented problems of the last ten years. No wonder that the big companies are trying to shake things up.

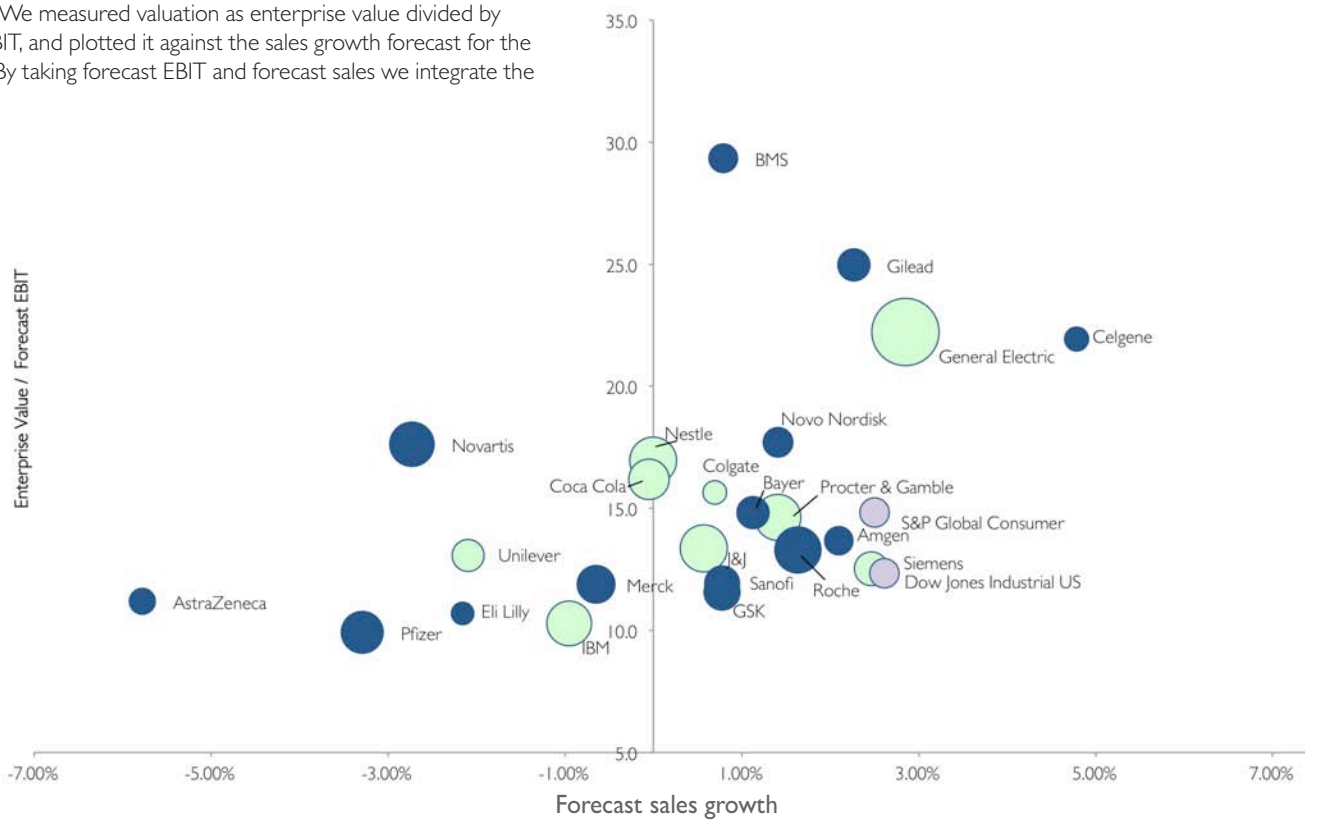
The last year has seen a number of announcements of restructurings of R&D units, most dramatically at Merck and AstraZeneca. As industry observers point out, the general trend seems to be to move R&D jobs from legacy locations out to the large hubs in Boston (MA), San Diego (CA), San Francisco (CA), Shanghai (CN) and Cambridge (UK).

| Company | Chopping away… | … and building up |
|---|---|---|
| **AstraZeneca** | Laying off 1,600 staff; closing major research hub in Alderley Park (UK); relocating 2,500 jobs. Reducing R&D budget by US$1 billion. | Cambridge (UK) R&D center: US$500 million investment; moving staff from Alderley Park (UK). |
| **Pfizer** | Reducing budget from US$9.4 billion in 2011 to US$6.5 to US$7 billion. | Moving Alewife (MA) staff to Cambridge (MA); investing US$100 million, announced in 2011; now with three R&D centers: San Francisco (CA), New York (NY) and Cambridge (MA). |
| **Merck & Co.** | Reducing R&D budget by US$1 billion, in the context of reducing all staff by 20%. | Innovation hubs in London (UK), San Francisco (CA), and Shanghai (CN). |
| **Novartis** | Laying off 500 R&D staff; closing Horsham (UK) and Vienna (AT); biotherapeutics unit in La Jolla (CA); relocating oncology from Emeryville (CA) to Boston (MA). | Adding 175 jobs in respiratory and cancer research in Cambridge (MA). |

## Is there an intrinsic pharma valuation premium?

Acquisitions in the pharmaceutical industry come at very high valuations. If the target has a pipeline of interesting drug candidates or even only one drug candidate, it is sometimes difficult to fend off the impression that buyers overpay. One explanation may be that pharma companies, by virtue of their business in a regulated environment, generally enjoy a high valuation.

A rough analysis suggests this is not true for the large pharma companies in general. We measured valuation as enterprise value divided by forecast EBIT, and plotted it against the sales growth forecast for the next year. By taking forecast EBIT and forecast sales we integrate the stock market's expectation about the future development of the companies in our analysis. Comparing the results of pharma companies with other large industrial corporations does not yield a difference: Most of them trade in the same rough corridor (see graph; bubble size relates to enterprise value). This suggests that there is no intrinsic "pharma valuation premium."



# USA

## Pipeline acquisitions dominate M&A activity

In 2013, M&A in pharma and biotech was primarily focused on pipeline acquisitions with an emphasis on biotech; however, many pharma companies are accomplishing their strategic goals with other alternatives to M&A such as partnering and licensing. High stock market valuations, a strong IPO market in 2013 for biotech companies, and aggressive bidding for some late-stage biotech companies have contributed to an M&A environment with strong valuations but less activity than might be expected. The year 2013 also saw a return to "earn-outs" in a large number of deals which participants have used to bridge perceived value gaps.

## Most notable transactions of 2013

***Amgen, Inc. acquires Onyx Pharmaceuticals, Inc.:*** Amgen, the world's largest independent biotechnology company, completed the cash acquisition of Onyx Pharmaceuticals, a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of cancer patients, in October 2013 for US$10.4 billion, a 44% premium over the pre-announcement closing price. The acquisition of Onyx is an excellent fit with Amgen's strategy to advance innovative medicines that address serious unmet medical needs, and the acquired products and pipeline strengthen Amgen's position in oncology with new treatments in the areas of liver, kidney, breast, colorectal, and thyroid cancer. Additionally, Amgen stands to gain incremental synergies and value from the Onyx product portfolio by leveraging Amgen's worldwide commercial, development, and manufacturing capabilities.

***Johnson & Johnson acquires Aragon Pharmaceuticals, Inc.:*** Johnson & Johnson completed the acquisition of Aragon Pharmaceuticals for US$650 million in cash and US$350 million in contingent milestone payments in August 2013. Aragon was a privately-held pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers. The acquisition strengthens J&J's prostate cancer pipeline and allows the company to extend its prostate cancer franchise after its current drug (Zytiga) goes off patent, with a potentially best-in-class compound that is a second generation androgen receptor signaling inhibitor, ARN-509, in Phase 2 development for castration-resistant prostate cancer (CRPC).

***Cubist Pharmaceuticals Inc. acquires Trius Therapeutics, Inc.:*** Cubist Pharmaceuticals Inc. completed an agreement to acquire Trius Therapeutics, Inc. for approximately US$650 million in cash and contingent value rights on September 11, 2013. On completion of the transaction, Trius Therapeutics will operate as a wholly-owned subsidiary of Cubist. Trius is an excellent strategic fit with its lead product candidate, tedizolid phosphate, having the potential to be an important new treatment in the fight against resistant infections. The need for new treatments to combat drug-resistant bacteria is growing, requiring new medications to help hospitals and their patients combat these infections. Cubist Pharmaceuticals, Inc. is a biopharmaceutical company focused on the research, development, and commercialization of pharmaceutical products that address significant unmet medical needs in the acute care environment.

## Filling the R&D pipeline will remain a key M&A driver in 2014

**Pharma/biotech activity will be active in 2014, with deals focused on pipeline enhancement. Companies will also continue to use partnering and licensing of products where possible to achieve their strategic goals, as well as the divestment of non-core assets. External factors such as healthcare reform, shifts in patent law and regulations, changing relationships with third-party payers, providers and patients will all continue to have a significant influence on the types of M&A activity going forward.**

**We also believe that in 2014 pharma companies will continue to pursue a changing business model, especially with regard to drug development. With the cost of a new drug exceeding US$1 billion and requiring a lengthy, time-consuming approval process, consolidation of early-stage, small, and specialty pharma/biotech companies will become the norm. It is expected that over US$200 billion in drug revenue is subject to expiring patents in 2014, allowing generic manufacturers to replace the key products of many pharma companies.**

Contributed by IMAP in Naples (Florida)

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# Regional insights

## Western Europe

### Tax savings as a key deal driver

Deal activity involving European targets increased in line with the general market, from approximately 114 deals in 2012 to 171 in 2013. However, in contrast to the US, where deals were mainly driven by pipeline access, the motivation of deals involving European targets was largely industry restructuring – and tax.

By using a deal structure called "inversion," US-listed companies can relocate their corporate headquarters and their tax domicile to Ireland in the context of the acquisition of an Irish company. With this mechanism, Actavis (by purchasing Warner Chilcott) could reduce its tax rate to 17%, down from 28% in Switzerland where the company moved after the acquisition of Actavis by Watson Laboratories, and down from the original 37% rate Watson had in the US in 2011. Such tax reductions can justify a hefty premium in an acquisition. Perrigo's acquisition of Elan (at the time of acquisition a royalty-collecting shell) was obviously solely made due to tax considerations. And when Endo Health (USA) designed the acquisition of Paladin Labs of Canada, they did so through an Irish holding that acquired both companies, thereby moving the tax domicile to the island.

### Most notable transactions of 2013

***The acquisition of Gentium (Italy) by Jazz Pharmaceutical (Ireland since recently)*** valued Gentium's defibrotide, a drug used to counter liver problems after hematopoietic stem cell transplants, at close to US$1 billion. The deal is particularly notable as Gentium is the only European biotech company acquired in a sizeable transaction in 2013. Gentium's defibrotide had a long and bumpy road to market approval. It is used to treat adverse consequences of hematopoietic stem cell transplantations.

In August 2013, Mr. Reinhard took over as chairman of Novartis, succeeding the iconic Mr. Vasella, and shortly after announced a comprehensive strategy review. Since then, the market has been buzzing with rumors about potential disposals. The first tangible result was the ***divestment of the blood transfusion business to Grifols of Spain,*** for US$1.7 billion. The OTC, diagnostic, vaccine and animal health businesses have been put forward as being in play as well. It is generally assumed that there will be further divestments until mid-2014.

Another notable transaction, although not in the core of pharma, was ***the combination of the pharmaceutical business of Dutch DSM with Patheon of Canada.*** This JV creates a large contract manufacturer for the pharmaceutical industry, with 23 production sites and more than 8,000 staff worldwide. The deal is symptomatic for a general consolidation and realignment process in the industry segments that provide services to pharmaceutical companies (see also the in-depth analysis of the CRO industry later in this report).

### More break-ups to be expected

**We believe that the break-up of conglomerates – such as the split of Abbott Laboratories in 2011, and the spin-off of Pfizer's animal health business to Zoetis in 2012 – will continue to be a fundamental driver of transactions. For example, we expect Novartis to dispose of further businesses, and Pfizer to complete the work and spin-off its generics division. GSK and J&J are other candidates for spin-offs, as well as Teva, Mylan and Actavis.**

**Contributed by IMAP in Switzerland:**

Kurmann Partners
Christoph Bieri (christoph.bieri@imap.com)

# Central and Eastern Europe

## A strong year for M&A in the region

The level of M&A activity in the CEE region was exceptionally high in 2013, with overall 41 transactions compared with 27 in 2012 and more than 50% growth. The total volume of disclosed transactions was EUR995 million. Whereas in 2012 just four deals were closed in Poland, in 2003 there were 13 transactions, making the country the leader in this segment; followed by Russia with 11 deals and the Czech Republic with five transactions. Romania has seen three transactions, Ukraine two and in Slovakia, Hungary and Estonia each, just one transaction closed. Out of 41 transactions, 60% were domestic transactions and 40% cross-border ones. The most active international buyers or sellers were from US (four transactions), France (three) and Canada (two).

Regarding the sub-segments, the most active dealmaking was in the pharmaceutical segment with 39% share on all transactions, followed by hospitals and medical centers with 29% share, while medtech companies, distributors and laboratories had about 10% share each. Private equity funds participated in nine transactions, or in 22% of all transactions, well below last year when they participated in almost 50% of all deals.

## Most notable transactions in 2013

The most notable transactions involved Servier (France), Gardenhills (Russia) and Penta (Czech Republic).

***Les Laboratories Servier SAS,*** a France-based pharma company engaged in R&D for drugs, bought the remaining 49% share in Hungarian publicly-traded company EGIS Pharmaceuticals, engaged in R&D, manufacturing and selling pharmaceuticals products. In a voluntary public offer the price represented a premium of 33% and the value of the delisting was about EUR358 million and P/E multiple was 11,2x based on 2012 EGIS net income.

***Russian-based company GardenHills OOO,*** owned by Roman Avdeyev, co-owner of Credit Bank of Moscow, bought 100% share in VeroPharm OJSC, the listed Russian pharma company manufacturing generic and oncology drugs. Majority stake was bought from another Russian-listed company, Pharmacy Chain 36.6 OAO, operating a beauty and health retail chain, which aimed to use proceeds from the sale to reduce its debts. The total deal value was EUR261 million and P/E multiple was 7.8x based on Veropharm 2012 net income figures.

***Penta, a Czech Republic-based private equity firm,*** together with NEUCA SA, a Polish pharma products distributor and retailer, acquired ACP Pharma S.A., a Polish company engaged in wholesale and distribution of pharma products, from Mediq NV, a listed Dutch international retail and distribution company for pharma and medical supplies. Penta acquired the retail business and Neuca wholesale. Penta, which owned Dr. Max, a pharmacy chain, became the second-largest on the Polish market, operating 300 pharmacies.

The total deal value is EUR102 million. Penta also bought majority control of EMC Instytut Medyczny, the largest Polish chain of private hospitals, through public offer (68% stake) for EUR21 million, valuing the company 1.2x sales, 16.5x EBITDA and 215x earnings. A third Penta investment was in Slovakia, where for EUR20 million they bought a Slovak company owning four local hospitals, Nemocnice a Polikliniky, valuing the company at 0.8x sales.

## Deal activity likely to return to lower levels in 2014

**After the year of heavy M&A activities we expect moderation in dealmaking in 2014. As there are a limited number of possible large transactions, M&A activity will concentrate on small and mid-sized deals in sectors where scalability and economy of scale is important: outpatient and medical centers, hospitals, pharma retail, distribution and laboratories. Healthcare facilities particularly – like hospitals – are mostly underinvested and need throughout the CEE region large investments. There is a pressure from health insurance companies to rationalize payments and reduce costs as healthcare budgets are constrained due to high unemployment rate in some countries and due to growing healthcare costs; while insurance does not increase as overall growth in salaries of contributors/insured is still limited. So, as many small regional hospitals are still in public ownership and some in red figures, there is a pressure on municipalities and governments to find a strong partner to ensure local accessibility of healthcare services. The biggest potential offered is in Poland due to regulation and highest copayments/out-of-pocket expenses covered by patients.**

**Contributed by IMAP in Czech & Slovak Republic**

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# Regional insights

## China

### M&A activity hampered by regulations, bribery investigations

It was a rather uncomfortable year in 2013 for the sector's executives and M&A professionals. First, China's regulators did not allow any new IPOs on the two local stock markets for the entirety of 2013, thus limiting capital-raising opportunities. Second, an avalanche of investigations and allegations of bribery started with the raiding of GSK's Shanghai office in July 2013. The latter heavily impacted total market growth, which turned out to be 10-15% compared to more than 20% in previous years, as MNCs froze all marketing budgets after July 2013.

The bribery investigations also had a negative impact on sales performance (some multinationals sold less than in 2012) as well as on price policies. Moreover, the investigations changed the perception of China abroad: in many cases, foreign companies aiming to acquire or partner up with local firms cannot justify the risks in the current climate. Consequently, inbound pharma deals dropped to 20 in 2013 from 26 in 2012, while the total deal value in 2013 was around US$1.2 billion; the lowest on record since 2011. Reflecting the tougher environment, Actavis Inc., the world's second largest generics maker, announced in early January 2014 that it would pull out of China (the world's largest generics market) and focus its investments on more profitable markets. In turn, Actavis will sell its JV in Foshan to Zhejiang Chiral Medicine.

Despite a difficult environment and a closed IPO market, valuations did not necessarily scale back; however, they were driven by domestic buyers. Our statistics, based on 99 announced deals including both domestic and foreign parties, yield a median P/E multiple of 17.9x, a median revenue multiple of 2.4x, and a median EBIT multiple of 15.2x.

### Where were the inbound deals?

The only noteworthy inbound transactions in 2013 were ***Eli Lilly's animal health division buying a 20% stake in China Animal Healthcare*** for US$100 million in April 2013; and Boehringer Ingelheim sharing a US$81 million investment with Zhangjiang Biotech and Pharmaceutical Base Development Co. into a cGMP CMO facility in Shanghai.

On the domestic deal front, consolidation is the name of the game. In May 2013, Tongjitang Chinese Medicines was acquired by Winteam Pharmaceutical Group at a price of up to US$393 million. That deal was a substantial profit for Tongjitang's CEO, who, along with Fosun Pharma, took the company private two years earlier at a price of US$138 million. Also in May, Sinopharm acquired 57% of Winteam for US$252 million. With this deal, Winteam has become the Traditional Chinese Medicine arm of Sinopharm. In July 2013, Sinopharm bought 20% of the drug maker China National Accord Medicines, worth US$696 million, helping Sinopharm to further implement its strategy of being a vertically integrated player.

In July, ***Shanghai RAAS acquired Banghe Pharma*** for US$290 million. Both companies are makers of blood plasma derivatives, and further strengthen the domestic player landscape for albumin supply, which has been somewhat dominated by international players.

Both Sinopharm and Cardinal Health continued to consolidate the drug distribution landscape. Cardinal Health acquired six local drug distributors for a total of US$120 million and also bought Baiji Xinte, a privately-held pharmacy retail chain with 19 stores across China. Other domestic pharma companies continued a trend that started in 2011, buying into hospitals and clinics; as in the example of Gansu Duyiwei Biological Pharmaceutical, which invested into three hospitals in Sichuan; and Kangmei Pharmaceuticals, which bought two hospitals in Tonghua.

### China needs to say yes…

There were two global deals where Chinese authorities had to provide their approving nod. In August, Chinese regulators greenlighted Baxter International's US$4 billion purchase of Gambro AB without special conditions. Thermo Fisher, to complete its acquisition of Life Technologies for US$13.6 billion, had it much harder. Chinese authorities said they would approve, but with the condition that Thermo Fisher would dispose its 51% stake in a vaccines JV in China, that it would sell its cell culture and gene adjustment units, and that it would lower the prices on two products in China.

### Rebound of M&A activity expected in the near future

**We expect 2014 to be China's rebound year in pharma / biotech. GSK's bribery allegation will come to a conclusion in the second quarter of 2014, clarifying the situation; whilst scrutiny on sales practices is certainly here to stay. Apart from Actavis, no major pharma MNC or international company has retreated from China since July 2013. The multinationals remain acquisition-hungry in China. The acquisition objective may be less on securing sales capacity than expanding production capacity and extending their local registration and regulatory teams.**

**Valuation expectations may be slightly adjusted to lower, more reasonable levels, and provide a better opportunity for buys. China opened its IPO market again in January 2014, and China aims at listing 300 more companies this year, along different sectors.**

**Contributed by IMAP in China**

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# India

## Strong increase in transaction values

The year 2013 witnessed a total of 30 M&A deals in the pharma and biotech sector (inbound, outbound and domestic). While maintaining the same number of deals as in CY 2012, total deal value increased from US$1.7 billion in 2012 to US$2.5 billion in the current year. On the private equity side, a total of 14 deals were consummated in 2013, aggregating to US$427 million of investment, as opposed to 14 deals with US$180 million of investment last year. This implies a more than doubling of average deal size.

Domestic and inbound M&A deals are yield valuations in the range of 18.0x - 20.0x LTM EBITDA, higher as compared to other sectors. With strong industry fundamentals and international players trying to get a toehold in the Indian market, overall the sector remains a "seller's market."

## Notable deals

The three most prominent deals in India in 2013 were Mylan's acquisition of Agila Specialties, Emcure's purchase of BMS' chemotherapy brand, and Cipla's buy-out of Cipla Medpro in South Africa.

*US-based drug maker Mylan Inc. acquired the India-based Agila Specialties* injectables drug division of Indian-listed company Strides Arcolab Ltd., for a total consideration of US$1.75 billion. The transaction was consummated at an LTM EV/Sales and EV/EBITDA multiple of 7.0x and 21.0x respectively. Agila produces drugs across nine manufacturing facilities in India, Brazil and Poland, eight of which have been approved by the USFDA. The acquisition of Agila provided Mylan with a broad product portfolio of more than 300 filings approved globally and marketed through a network covering 70 countries, including 61 ANDAs approved by the USFDA.

The deal holds significance as it was a big ticket inbound acquisition (ranked 3rd in the Indian pharma market) amidst regulatory challenges around FDI and scrutiny by international drug regulators.

*India-based Emcure Pharma acquired worldwide rights of BiCNU from Bristol-Myers Squibb* for US$10 million. The product is a chemotherapy agent indicated for treatment of brain tumors, multiple myeloma, Hodgkin's disease and non-Hodgkin's lymphoma. Under the agreement, Emcure acquired marketing rights and authorizations, trademarks, and the technology and know-how related to the product. The acquisition is expected to increase Emcure's presence in the global oncology market segment and serve as an anchor product in building the company's full service oncology franchise. The deal highlights a renowned product/brand acquisition for building strong presence in a particular therapeutic area while also gaining wide geographical presence.

*Cipla Ltd., based in India, acquired Cipla Medpro South Africa Limited,* for an aggregate consideration of US$512 million. The acquisition of the third-largest South African firm helped Cipla further strengthen its position in the African continent. At the time of this transaction, Cipla was looking for acquisition opportunities. It was actively seeking to expand its existing partnerships in emerging markets and also entering into new deals through joint ventures and acquisitions in key markets like Turkey, Morocco, Brazil and Nigeria. Cipla Medpro turned out to be an appropriate opportunity. The deal asserts continued outbound acquisition of quality assets by Indian pharma companies.

### India remains an attractive market to enter

**The upcoming Indian parliamentary elections in May 2014, heightened scrutiny by international regulators, overhang of FDI policies (where any foreign investment in an existing pharma unit needs to be approved by the Foreign Investment Promotion Board (FIPB)) and a price ceiling as per the New Drug Price Control Order 2013 (DPCO) may result in a slight tapering off of inbound strategic deal activity in the midterm. Still, with inbound strategic buyers in a "wait and watch" phase, private equity investors will continue to show interest in the sector**

**Long-term prospects of M&A activity remain bright as the Indian pharma market – both domestic and exports – remains fundamentally strong. The country is one of the fastest-growing pharma markets in the world, has one of the highest numbers of USFDA-approved plants outside of US (169 in number), has the highest share in the number of ANDAs filed with the USFDA (c.40% of total filed in 2013) and has the highest number of DMF filings with the USFDA (c.47% in 2013). With these credentials, Indian pharma assets remain a lucrative investment opportunity for foreign strategic buyers.**

**Contributed by IMAP in India**

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# Regional insights

## Latin America

### The process of consolidation in the pharmaceutical industry is advancing

The winners are the national competitors, often taking advantage of protective measures by their governments. In the generics business in particular, the leading international companies Teva and Sandoz have not succeeded in beating national champions. A late entry into this fastest growing segment of the pharmaceutical market has proven to be expensive and risky, as Sanofi had to learn following the acquisition of Medley in Brazil.

In general there is a tendency towards caution among international and Latin American corporations when it comes to acquisitions. In the last few months, lower purchase prices and an increasing number of stalled or completely aborted transactions have been observed. The most prominent case – which was accompanied by great media fanfare – is most likely the sale transaction of the Brazilian industry giants Aché. The exaggerated purchase price expectations of one section of the shareholders and the rumoured unwillingness to sell of another section are suspected as reasons for the termination or interruption of this transaction. Overall, there are also external factors such as the cooling of the economic climate in Brazil, which prompt investors to think twice.

### Government focus shifts to securing drug supply

In the past, governments often implemented simple measures in order to strengthen the competitiveness of national over international competitors. The primary concern of governments is meanwhile no longer the sourcing and securing of jobs, but the sustainable supply of their populations with latest-generation drugs at an acceptable quality and price. Another aspect is the declared intention of large countries like Brazil, to get their own industry to produce biosimilars at affordable prices. The PPP programme and government-privileged biotech ventures, such as the Bionovis joint venture of EMS, Aché, Hypermarcas and União Química suggest that the political will to protect and promote the domestic industry will not allow the international marketers of "Biosimilars" much room to maneuver, unless they make their expertise available to local competitors, in order to secure even just a little piece of the pie.

Large regional competitors such as Roemmers or Tecnofarma, who built up a strong regional presence in the nineties and noughties, appeared cautious in 2013. Likewise the international pharmaceutical corporations kept a low profile last year. More activity was observed among the medium-sized players from Latin America, North America and Europe. The Canadian Paladin acquired the Binotal activities (ampicillin) from Bayer in Mexico. Gedeon Richter took over the majority share in Next in Brazil after they had held a minority stake for several years. Eurofarma bought Refasa in Peru as a part of their internationalisation strategy. Gruenenthal doubled their Latin American turnover through the acquisition of Andrómaco in Chile and the product portfolio of Biogen de Colombia. Catalent acquired the Brazilian Relthy and thus expanded their expertise and production capacity in the growth business of capsules and vitamins.

### Growing global aspirations

The attempt by CFR (Recalzine) to take over the South African Adcock Ingram may have attracted the most attention, but it has not led to success. The action of the publicly listed CFR must also be seen as an attempt to build profitable volume in emerging markets outside the region, since reasonable targets in Latin America are strategically and pricewise becoming increasingly difficult to find. IMAP expects more mergers between medium-sized players, both within Latin America and between Latin American and American or European pharmaceutical companies. The focus will probably lay on companies with strong brands but a thin development pipeline.

Pressure to consolidate is likely to increase in the field of pharmaceutical distribution, both at wholesale and pharmacy level. IMAP expects larger transactions in the coming years; acquisitions by international logistics groups are conceivable, as are mergers among smaller, regionally active wholesalers. Among pharmacies, an increase in chain-linked outlets has been seen for a while now, thus making these acquisition targets increasingly attractive for powerful national and international investors. Vertical integrations within the sales channels, whereby wholesalers enter into the pharmacy business and vice versa may happen in a few cases too.

### IMAP expects deal activity to remain similar to 2013

**At the moment it is unclear whether the pressure on currencies in Argentina, Brazil, and – less prominently – in Colombia, is more of a deterrent or an incentive for strategic and financial investors. The relative stability in Mexico should ensure sustained buying interest. It remains to be seen whether the successful defensive front of medium-sized national pharmaceutical companies in Mexico seen thus far will continue to be able to withstand the temptations of powerful foreign investors from the Americas or from overseas.**

**Contributed by IMAP in Switzerland**

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# The CRO market shake-out

## After a long phase of growth, consolidation is looming

Outsourcing of R&D activities – from drug discovery through to data management of late-stage clinical trials – has been one of the key trends of the pharma industry in the last decades. The CRO market grew with double-digit annual rates to a respectable US$25 billion. General wisdom – and many analysts – predict further growth at similar rate. However, our recent analysis of the market suggests that overall growth will be much slower in the mid-term and that there will be a massive shake-out among smaller and mid-sized CROs.

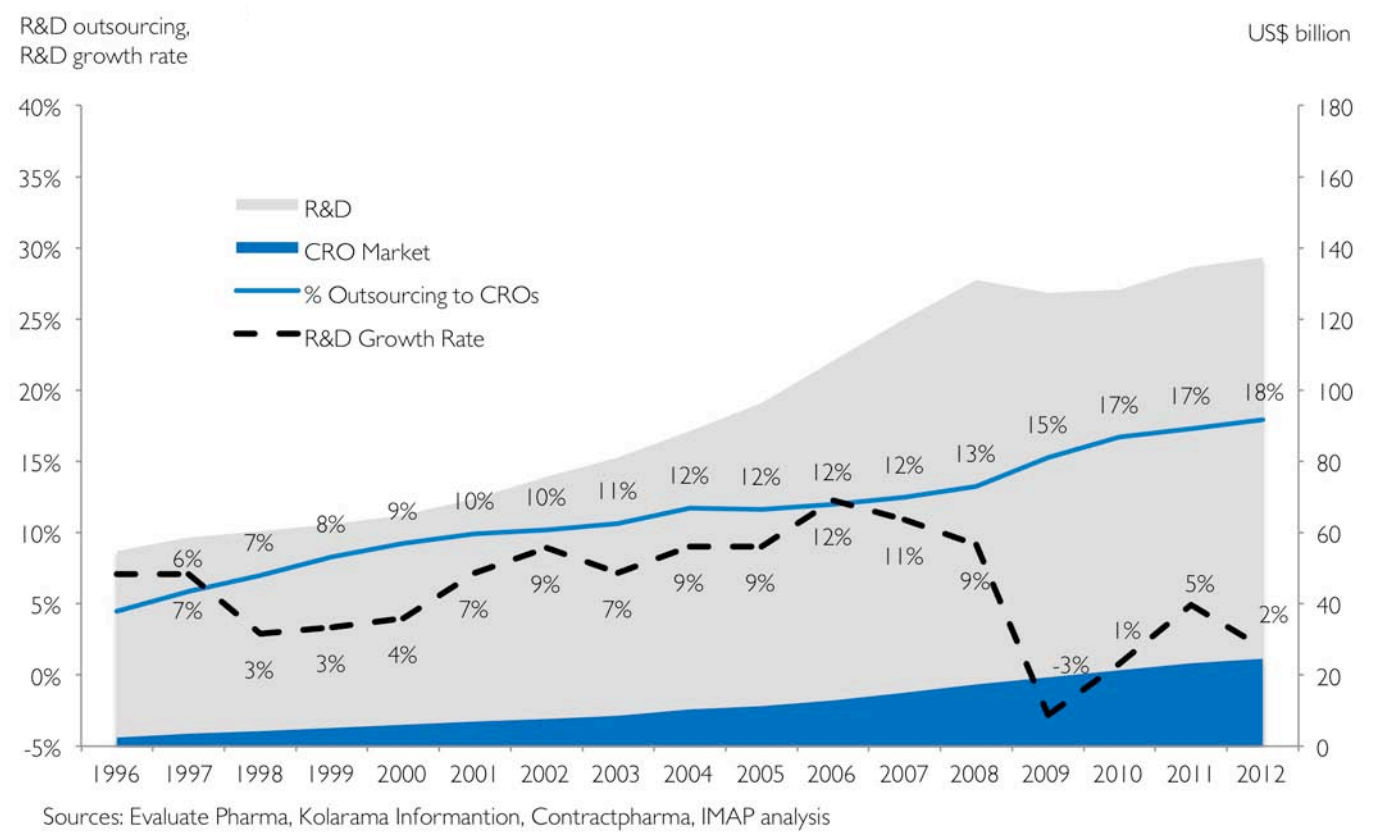
Our rationale is based on the obvious but fundamental observation that the addressable market of CROs relates to the size of the aggregate R&D budgets; R&D budgets relate to the profits of the pharma companies; and the profits again to the original products (not generics) sold by pharma companies in developed countries.

It is generally accepted that pharma revenue growth in the coming years will be mainly driven by generics and emerging markets, which generate very low profits compared to original drugs. As global sales of original drugs stagnate, funds available for R&D will only grow slightly. If the CRO market was to grow faster than the R&D budgets, this would mean that the share of work outsourced would grow substantially, which is unrealistic given the historic pattern, as graph 1 shows.

We expect the pharma R&D growth rate to remain at a very low level as global sales of non-generic drugs stagnate and generate fewer funds available for R&D. This obviously will have a negative impact on the CRO industry in the mid-term.

### Estimated historical R&D growth, outsourcing and CRO market

*graph 1*




Sources: Evaluate Pharma, Kolarama Informantion, Contractpharma, IMAP analysis

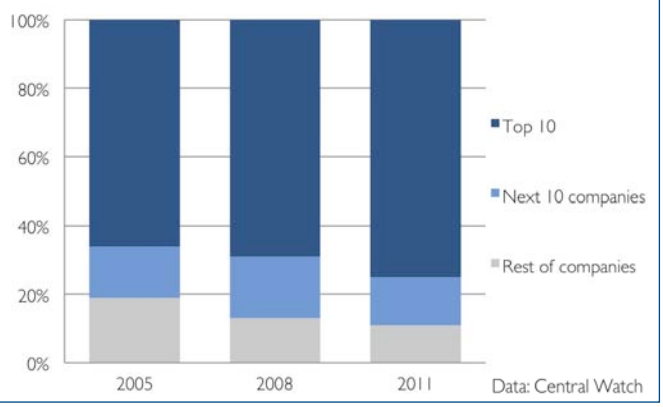
The CRO industry is limited by the total pharma R&D spending (gray: size of the cake) and the outsourcing percentage (blue: size of the piece of the cake). The industry has been growing fast (blue area) thanks to the trend towards outsourcing pharma research (blue line). Also, the total pharma spending was rising steadily (gray area) until 2009, when the R&D growth rate dropped (black line).

# The CRO market shake-out

## Big players are squeezing out medium-sized CROs

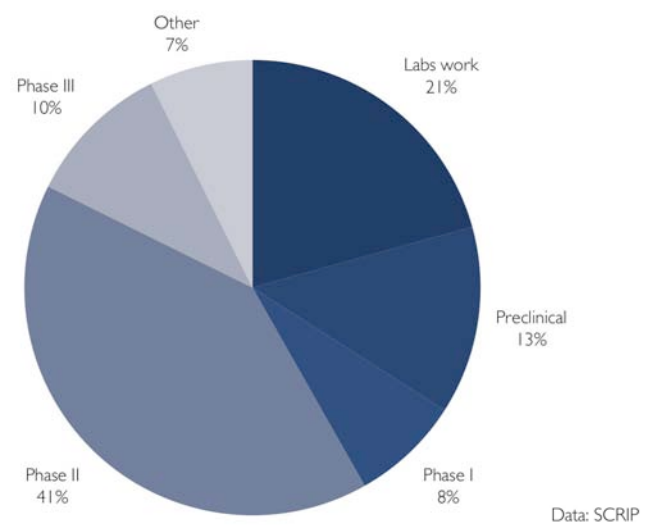
A maturing of the CRO industry will further drive consolidation. Even in the high-growth environment of the past decades, medium and small companies have lost market share to the large players (see graph 2). For the individual smaller CROs this meant that they would not grow, but could still survive. However, about 45% of small- and medium sized CROs either merged, have been acquired or went bankrupt between 2007 and 2012.

### Market share by company size *graph 2*




The mechanisms that favor large CROs are different for preclinical, Phase I, and Phase II-IV studies (see graph 3 for market shares). Preclinical CROs are characterized with high infrastructure costs in which scale and operating at full capacity are important. Operational effectiveness is measured by revenue per unit of lab space. Consequently, a few players like Charles River, Wuxi and Harlan dominate an already-consolidated market. The same revenue profit mechanism is found with Phase I service providers, however, consolidation has not progressed as far here. Phase II-IV service providers are pure consulting firms, driven by client relations, people, and brand; their key indicators are revenue or profit per employee.

### Global CRO market by phase *graph 3*

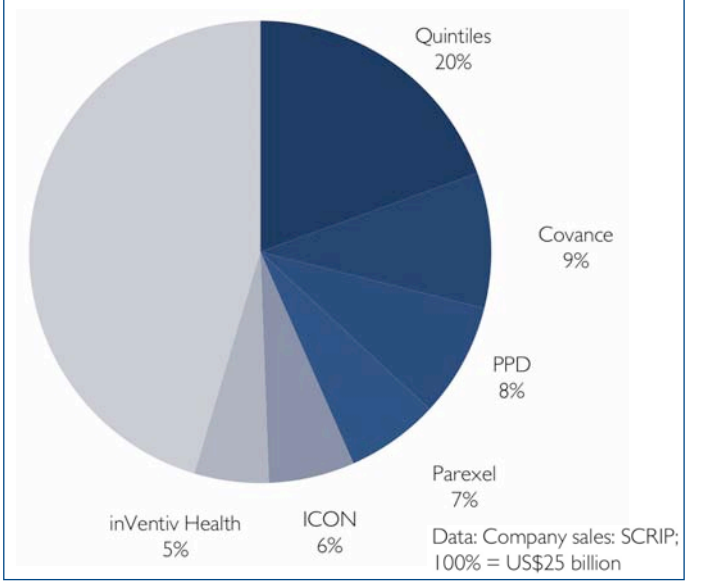



For the reasons outlined below we expect the top players like Quintiles, Covance and PPD (see graph 4) to grow further, while medium-sized and smaller players will further retract. This will happen mostly organically except in cases where they need access to new technology or scarce expertise. The top players already have the critical mass and do not need to resort to M&A to increase competitiveness.

One reason why big is better is the ability to better manage costs and risks. Clinical research projects take a long time, which makes project cost controlling an essential success factor for the CRO's profitability. Most CROs operate at margins around 10%. If a project does not work out as expected (cost overruns, liabilities), this margin drops dramatically. Big CROs are more diversified and they have better systems to manage costs and risks.

Pharma companies planning a big Phase III study go to the top full-service CROs where they find large capacity on a global scale, with well-standardized procedures. The financial stability of the CRO is also a key criterion for sponsors: no bigger nightmare than a CRO going out of business in the middle of a trial. Smaller CROs cannot compete to get retained for these trials; they may get the unattractive role of a subcontractor to the big CROs, which of course is less profitable and not a sustainable strategy.

### Market share of CROs with revenue more than US$1 billion *graph 4*




It also seems that it is becoming more difficult for small and medium-sized CROs to land deals with Big Pharma even for smaller projects. There is a strong trend for strategic partnerships between Big Pharma and the top CROs. Big sponsors prefer to work with big service providers. "If you're going to be a strategic partner, you have to be a large global player," Goldberg, COO of Parexel, was quoted as saying. "That's why the market share has shifted to the big CROs." A CenterWatch survey found that 80% of CRO professionals expect sponsor use of integrated alliances to significantly increase during the next years.

## Competitive advantages of medium-sized CROs may not be sustainable

Today, medium-sized CROs see their opportunity in competing for mid-sized sponsors. In our talks with small and mid-sized CROs, the executives argue that the giants can be beaten when it comes to flexibility and attention for the customer. Big CROs do not send their best staff to smaller accounts. Staff turnover is another issue: the big players fail to keep their talented and experienced staff more than a few years in the company. The CRO industry experiences a voluntary staff turnover of 12.5% as compared to a 1.5% national voluntary turnover rate in the US. And industry hiring practices make things worse: according to HR Survey Solutions, "65 percent of CROs use sign-on bonuses to lure new talent, yet less than one third (29%) utilize retention bonuses." Additionally, the study found that projected long-term incentive levels are markedly lower for CROs as compared to other industries.

Staff turnover is a problem in a people-driven industry with projects that can last years. The changing teams of the CROs are particularly irritating to smaller sponsors. There are some small and medium-sized CROs which were able to achieve respectable growth rates by exploiting these weaknesses of their big competitors.

We think that these advantages are not sustainable. In fact, big CROs already get a large share of their work from medium and small pharma companies. Their success in this market segment is a question of fine-tuning systems, attitude and business model to also accomodate smaller sponsors. The focus of the giants will shift towards this challenge as soon as the market growth rate drops. Today they are aiming to win the large partnerships with Big Pharma; tomorrow they will have to reach down for the smaller project in order to grow.

Moreover, it is inefficient to manage relationships with a large number of clinical research suppliers for different projects. As did the Big Pharma companies, medium-sized sponsors will also be striving to consolidate their vendor base, giving large CROs another advantage.

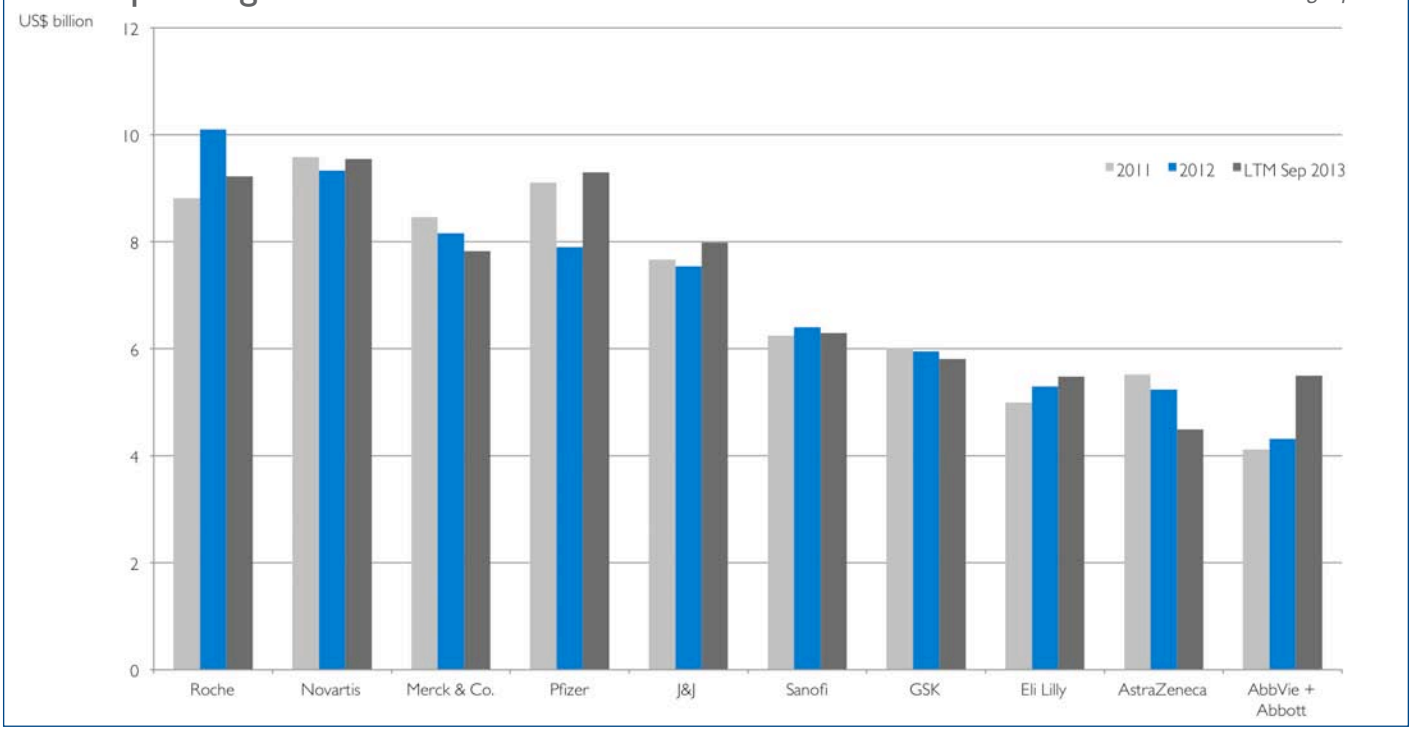
## Focus and innovation to withstand the pressure

To ensure long-term survival, small and medium-sized CROs should focus on defendable niches where they can build a strong position. These niches could be specialization in certain therapeutic areas, like specific oncological indications; or coverage of specific geographies that are difficult to access; or a functional specialization (data collection, trial design, evidenced-based monitoring) where expertise can create value. They may complement their expertise with the application of the newest technology and approaches in the industry such as adaptive trials, evidence-based trial designs, eClinical solutions and others.

Being cheaper and more flexible will not suffice to withstand the changing market. However, small is sometimes beautiful, and focus and innovation are where smaller companies excel.

R&D spending

*graph 5*

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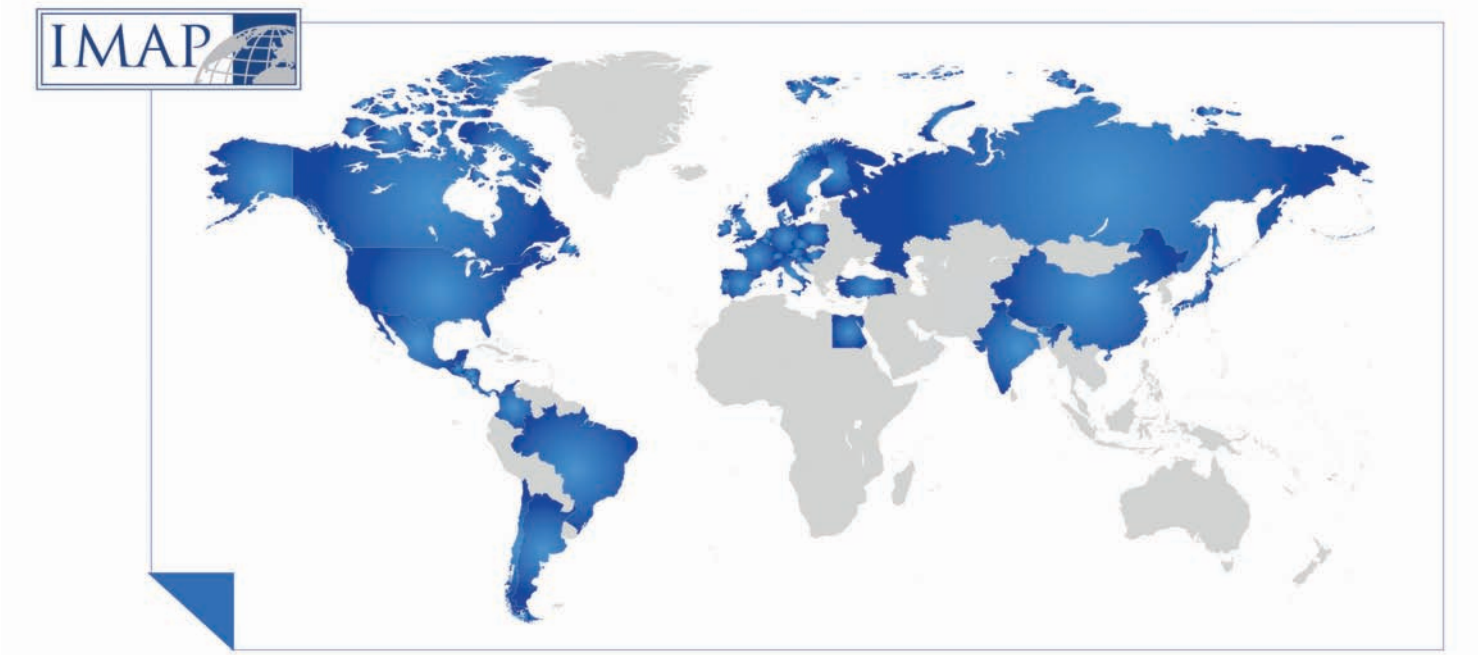


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