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Taking the Pulse of the Global Lifesciences Industry

December 2014

Thank You

We would like to thank all of the Lifesciences specialists who presented and contributed at the CMS Global Lifesciences Forum, as it is with their help and support that we bring you this insightful report.

CMS Lifesciences sector group

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Introduction

Lifescience specialists from across the world gathered in Amsterdam for the annual CMS Global Lifesciences Forum on 10 November 2014 to discuss the future of the industry. This report summarises some of the key legal issues our clients are facing in the sector, including regulatory, fundraising, and development opportunities in new markets and technologies.

Executive summary

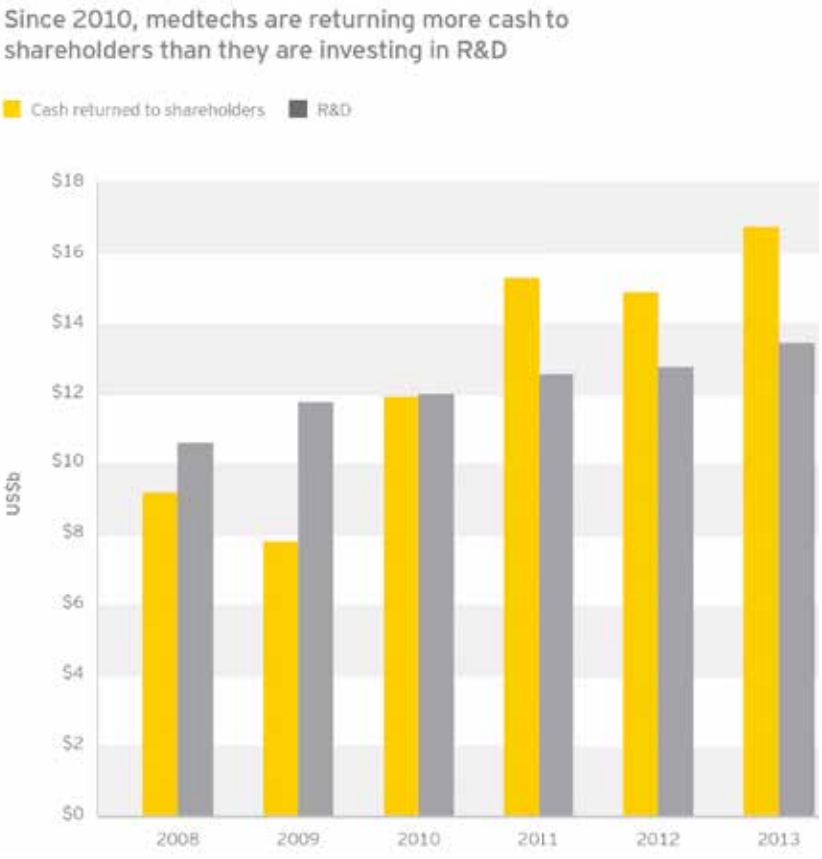
Medical device companies must take advantage of opportunities in eHealth and overcome challenges of exporting.
If the medical devices industry is to keep pace with a technological landscape that is increasingly putting power in the hands of customers, big businesses must embrace the benefits of electronic health and innovate in the same way as technology competitors. Small players will see challenges in exporting, as regulators in attractive export destinations such as Europe and the US demand higher quality of medical devices entering the market.

Early-stage biotechnology companies will see benefits in venture capital but must first focus on due diligence.
Before seeking growth capital, biotechnology companies must first ensure that their ideas are protected and that they are able to conform to an increasingly complex regulatory environment. Companies seeking to generate and protect intellectual property (IP) will see benefits in venture capital funding over public sources that can limit a company's usage and ownership rights, and venture capital advisers will continue to provide invaluable guidance at both the product development and exit stage.

Digital health will present opportunities for start-ups, but big data and closer relationships with customers will lead to compliance issues.
Small to medium-sized enterprises (SMEs) will have an edge over big companies in the development of mobile and digital health products, as they continue to be more agile in the innovation process and remain unhindered by stringent governance processes. However, these companies have the potential to grow rapidly, and need to be aware of the compliance issues that surround closer customer interaction and the use of big data.

Pharmaceutical companies see challenges in R&D funding, emerging markets and industry collaboration.
Demanding investors and enhanced efficiency in spending will make the research and development (R&D) process more challenging for pharmaceutical companies in the next 12 months. Meanwhile, rapid expansion into emerging markets will be fraught with legal hurdles. Pharmaceutical companies will be challenged to expand into regions without proper market access or experience and are likely to experience difficulties, particularly around regulation and corruption. Anti-trust will continue to be a key issue for pharmaceuticals, as the supply chain becomes increasingly collaborative.

Global industry performance (2013 vs 2012) – How cash is being spent



Source: E&Y, Pulse of the industry report, 2014

Future of the medical devices industry

Technology start-ups are fast adapting to the world of bio-medicine. The market for medical devices saw a 7% revenue increase between 2008-11, with a hike in growth in 2013 compared to 2012. Cash holdings among medical technology companies are high and increasing and R&D constitutes a steady 7.5% of revenue for the average medical devices company.

Despite this positive performance throughout the global downturn, there is significant change occurring in the medical devices industry as pressure on prices and margins increases, regulatory processes come under increasing scrutiny and concerns mount around increasing cash return to shareholders.

Opportunity in eHealth

One trend driving this change in the medical devices sector is eHealth. Start-up companies and technology companies have taken the spotlight in the development of new medical technology in recent years, and industry-wide speculation around buyouts from bigger players continues.

However, traditional medical technology companies are not sufficiently focused on the benefits available from improved electronic and communicative development. Outdated technologies are apparent throughout the industry, and medical education is not encouraging the development of new systems.

Pierre Slegers, Partner at CMS Brussels, said: 'We anticipate a shortage of skills in the medical technology space to be one of the key issues facing health services in the coming years. Universities are training medical staff in traditional practices, without developing the skills necessary to keep pace with technological advancements.'

Global opportunities for local players

Medical technology companies are increasingly seeking to export, as local competition threatens profit margins in domestic markets. While developing economies present an attractive opportunity for many players, the stability of mature markets such as the US is rendering them the most attractive export destination for medical technology businesses.

Businesses seeking to export to Europe are faced with the challenge of centralised, country-specific regulation aimed at controlling the distribution of medical devices by limiting reimbursement and restricting the free movement of goods between certain countries. In the coming years, national regulators will seek to import better quality products with heightened safety control, which is likely to have a negative impact on smaller exporters in particular.

Despite this, regulators continue to use traditional procedures in their evaluation of medical devices, without considering proposals for improvement. Business leaders in medical technology are concerned about a lack of general and pre-market control, where better regulation might foresee limited access to distribution channels earlier in the production phase.

> For companies seeking to attract early-stage investment from the right sources, due diligence procedures are an essential base layer in ensuring rights over products and procedures.

Venture capital in biotechnology – Funding the future

Attracting investment

Today, biotechnology companies face three key challenges when seeking access to market:

- Increasing cost and time of the drug discovery process.
- Increasing pressure on national health systems to be cost and time efficient.
- Systemic bias towards pharmaceutical companies in gaining access to the market.

For companies seeking to attract early-stage investment from the right sources, due diligence procedures are an essential base layer in ensuring rights over products and procedures. Without these measures in place, overcoming barriers to market entry is impossible. Assurance of regulatory conformity must also be a priority if companies wish to present an attractive case to investors.

Collaboration will also be an essential tool in enhancing the future funding environment for biotechnology companies across the world. Companies are working more closely with universities, customer access groups, regulators and scientists, as they progress towards a system of improved efficiency, quicker R&D processes and better IP development. Companies must be aware of the partnerships necessary to maximise their value.

Fertile ground

Venture capital continues to be a favoured source of finance for early-stage biotechnology companies seeking to overcome the challenges of commercial competition.

For growing companies seeking access to new markets, venture capital provides not only a financial leg up, but also guidance on how to gain proof of commercial relevance, strategic input on assets, positioning and marketing advice as well as product development strategy.

Firms continue to see issues with public funding, and particularly with regard to IP generation, as in a publically-funded entity, a biotechnology company might own intellectual property but is subject to certain access rights that may prohibit its usage. Similarly foreground IP is owned by the company that develops it, but is subject to access rights from third parties for research use.

Companies therefore require 'proof of concept' for new products. The biotechnology industry is driven by specialists who have ground breaking ideas, but who often lack the commercial acumen to know when to apply for consecutive funding, or to obtain patents for market-leading products. Clinical trials must be performed to very specific criteria in order to satisfy regulators, while data sensitivity has increased and testing periods are longer than they were even five years ago.

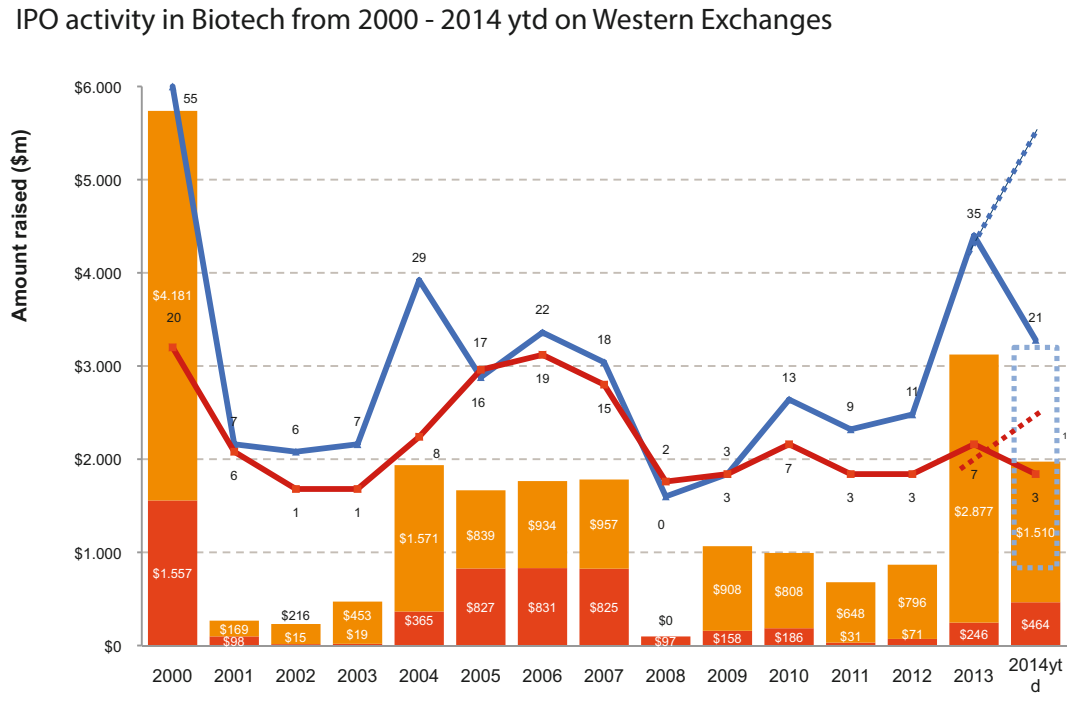
Funding aside, venture capital teams have the industry knowledge and experience to navigate the commercial and scientific issues in this vital stage of development, and are expected to be the driving force of early-stage development for biotechnology companies in the near future.

Maximising valuation at the exit stage

The market for exit in the biotechnology sector has the potential to be at a 14-year high by the end of 2014. Venture capital can have an equally important role in assurance at the exit stage for biotechnology companies, as owners are reassured that long-term management issues are in order and that products are sufficiently marketed to key audiences.

One example of management issues is the staying power of key executives. A recent report by PwC found that the average tenure for biotechnology CEOs is 4.8 years, while heads of research and development stay for an average of just 3.6 years. With the drug development process often outlasting these heads of business, convincing investors of the company's staying power is a challenge, and there have been examples of public companies in Europe where share price slumps have led to liquidation before drugs get past the trial stage.

Top down: the market for exits is wide open – Overview of IPO class of 2013 and Q1 2014



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014ytd
US: $m raised in IPO	$4.181	$169	$216	$453	$1.571	$839	$934	$957	$0	$908	$808	$648	$796	$2.877	$1.510
EU: $m raised in IPO	$1.557	$98	$15	$19	$365	$827	$831	$825	$97	$158	$186	$31	$71	$246	$464
US # of financings	55	7	6	7	29	16	22	18	0	3	13	9	11	35	21
EU # of financings	20	6	1	1	8	17	19	15	2	3	7	3	3	7	3

[1] Q1'14 numbers extrapolated on assumption of two relatively identical IPO windows in Q1 and Q3
[2] Sample set of generalist investors incl: Vanguard, Fidelity, T. Rowe, Capital World, Cap Research Global, Wellington, TIAA-CREF, JP Morgan, BlackRock, PRIMECAP.

Gary Green, Partner and Head of Equity Capital Markets for CMS London, said: 'Venture capital allows a management team sufficient time to grow the business and to develop its strategy before an exit is considered, without the burden of a fluctuating share price. Biotechnology companies face high costs and have limited resources, so require a management team of specialists to ensure product evaluation and due diligence are foolproof before taking a product to market.'

> The lifesciences industry is now facing what the technology sector has undergone for the last 30 years.
>
> *Carina Healy, IP Partner in the Commercial team at CMS Glasgow*

Digital health – Putting the customer first

As the global population gets older and unhealthier, and instances of chronic disease continue to rise, national health services are under increasing pressure to deliver reliable services to more customers. Healthcare tends to be a high quantity but low quality product. Fragmented services and payment methods have led to cost increases and doubt among investors.

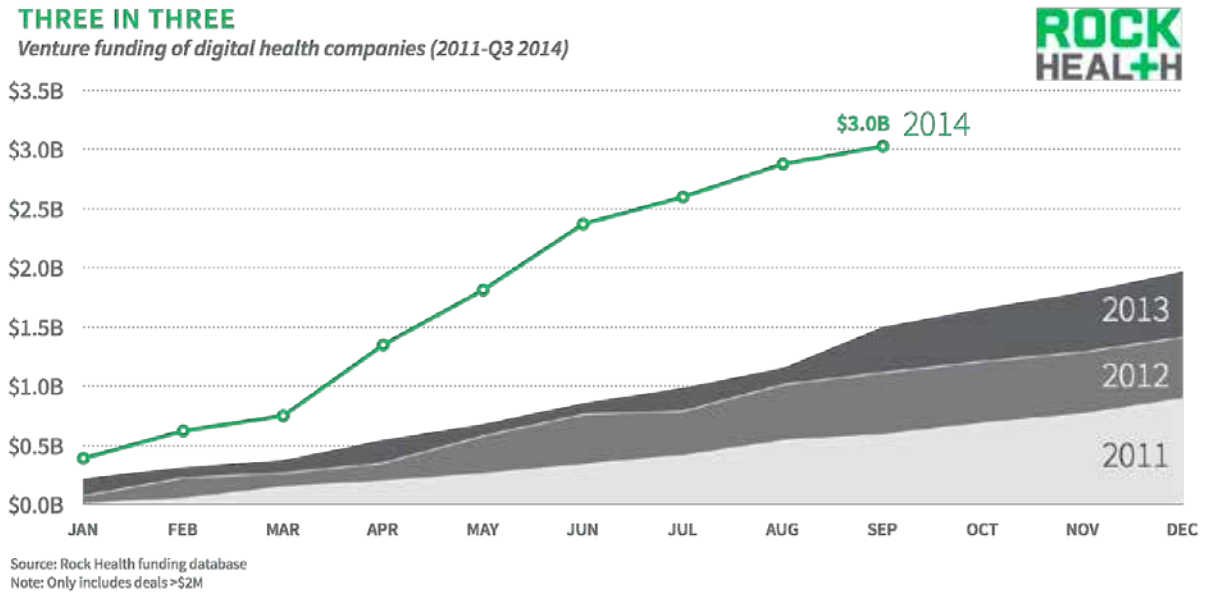
Customers seek empowerment and technology companies have latched onto a demand for healthcare products that perform simple medical procedures at low cost. Mobile and eHealth companies are growing in number and providing more services, and there is no shortage of funding available as technology investors anticipate a new age of healthcare.

Big companies less agile than start ups

Despite the positive funding environment, big businesses are lagging behind in the development of consumer-focused apps and devices that could complement existing products, particularly in the pharmaceutical industry.

The main reason for this is governance. While SMEs have little experience of past issues, big businesses are wary of developing consumer-focused products with potential legal hazards, and are under a more watchful eye from regulatory authorities.

Carina Healy, an IP Partner in the Commercial team at CMS Glasgow, said: 'The lifesciences industry is now facing what the technology sector has undergone for the last 30 years. Big pharmaceutical companies are less agile than new companies in the development of consumer technologies. Innovators are always ahead of the regulation curve, whereas larger companies are typically experienced in liability issues and are therefore more rigorous in their compliance processes. New entrants tend not to be hung up on the legal issues, and it is often not until these companies start to have significant market influence that the authorities and regulators sit up and start to take notice.'



Big data

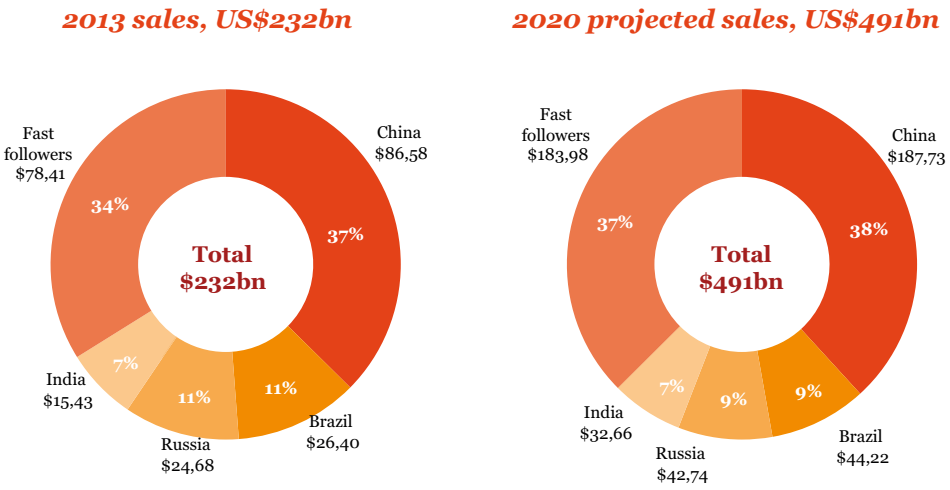
One of the concepts that underpins new user technologies in healthcare is big data, which presents a potential stumbling block for companies which are often unaware of the compliance issues around data protection. SMEs tend to be preoccupied with fundraising and product launches, with little consideration given to the legal minefield of using consumer data. It is often not until these companies are well-established that issues come to light.

Carina Healy, Partner at CMS Glasgow, said:
'New entrants using big data in the development of technologies tend not to focus on compliance, and can also be blinded by the notion that they're 'doing good'. It is often not until these companies have significant market influence that authorities take notice and regulators wade in.'

Customer relationships

Big companies must be wary of customer relationships that may develop with the use of mobile and eHealth devices, and again this varies with company size. Traditional pharmaceutical companies are kept furthest from the end user by regulators to prevent upselling, so must be extremely cautious when communicating with the public through apps or web-based platforms. Small companies, particularly those devoted purely to technology, have no such obligation.

Rising demand for medicines in the growth markets



17 markets, >$491 billion a year by 2020 – up from $232 billion in 2013

Source: Business Monitor International
Notes: (1) All sales are expressed in US dollars at constant exchange rates; (2) The fast followers include Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, Turkey, Ukraine, Venezuela and Vietnam.

Pharmaceuticals – A global view

Challenges in the R&D process

R&D remains at the top of the pharmaceutical agenda and the last 12 months has seen a decrease in company spending for the first time due to constrained budgets and an increase in generic sales. Companies are questioning whether this will stimulate the reduction of R&D expenses, and there is widespread concern around who is going to finance the innovative products of the future.

Meanwhile, as CFOs tighten belts and more focus is put on bottom line profits, companies want to see more bang for their buck in terms of return on investment.

Jo Pisani, Partner in Pharmaceuticals Strategy at PricewaterhouseCoopers (PwC), said: 'Up until a few years ago the last thing Pharmaceuticals CEOs wanted to do was reduce R&D spend, but new models are being developed in a move to stimulate efficiency in the R&D spending process, whilst not reducing the quality of products. While there are new financing mechanisms available, most big pharmaceutical companies are still cash rich, so are focusing more on driving efficiency in their R&D processes.'

Stumbling blocks in emerging markets

Health services in the developing world are coming under substantial pressure as people get richer and awareness of life-saving treatment increases. The emerging economies will experience the most rapid growth in demand for medicines over the next 11 years according to a report by PwC*, but funding this demand will present challenges.

*http://www.pwc.com/en_GX/gx/pharma-life-sciences/pdf/challenge.pdf

> In the developed world, where pharmaceutical companies are focusing on closer interaction with customers, IT and web-based services will play an increasingly important role in communication, marketing and distribution, presenting further opportunity for collaboration.

A fundamental issue for multi-national corporations (MNCs) in emerging economies is market access. Many countries are not covered by WTO agreements and, while opening representative offices may be relatively straightforward, profit making activity is often prohibited. Importing, selling and distribution is therefore difficult and local third party distributors must be used (often at great cost) in order to get products to market.

Legal issues are rife in developing markets. In formerly centrally planned economies, regulation is sparse and a lack of case law underpins uncertainty around the legality of marketing and business development. Corruption is often deeply rooted in the business and government culture of some of these countries. For Pharmaceuticals – which has been widely criticised for corrupt practices – business leaders must be mindful of the risks associated, even behind their own doors.

Due to the absence of case law and regulatory control in some emerging markets, many pharmaceutical companies will have a lack of past precedents by which to benchmark business development strategies in coming years. Rather than undertaking sufficient care in the slow expansion process necessary to navigate legal grey areas, many will take a giant leap, putting them at serious risk of a breach.

Anti-trust in an industry of collaboration

The future of pharmaceutical trade will be driven by greater collaboration across almost every aspect of the supply chain, as companies continue to eliminate the cost of under-utilising assets and third parties involved in healthcare provision seek to benefit from economies of scale.

In the developed world, where pharmaceutical companies are focusing on closer interaction with customers, IT and web-based services will play an increasingly important role in communication, marketing and distribution, presenting further opportunity for collaboration.

With this development comes the issue of anti-trust – an issue with which large pharmaceutical companies are all too familiar. It also presents a challenge for IP lawyers, in determining ownership and causality in a more digital environment.

Furthermore, there is fear that increased collaboration, particularly between academic institutions and big businesses, has potential to influence the direction of drug research. The anti-competition and compliance issues surrounding such collaboration are significant.

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