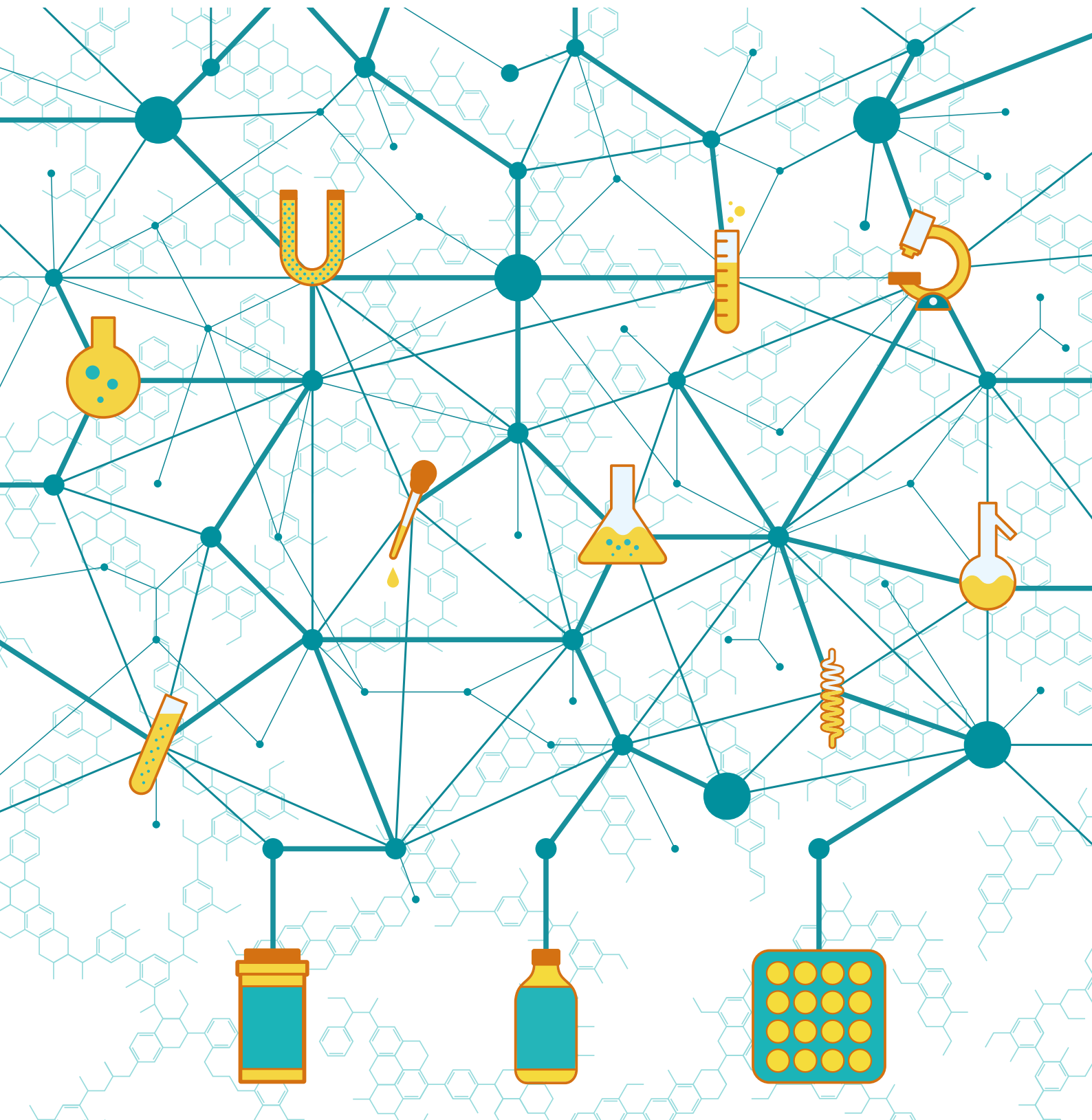


DEAL DIMENSIONS

Life lines:

Life sciences M&A and the rise of personalised medicine



Foreword

As megadeals continue to dominate headlines in 2015, there appears to be no end in sight for life sciences companies' appetite for acquisitions. Almost all respondents in this survey, a remarkable 94%, are planning to make an acquisition over the next year. This should come as no surprise as the future success of many companies in the sector hinges on the ability to stay competitive and innovate by building new product pipelines that safeguard cash flows and avoid the risks of ground up development.

The complex anatomy of cross-border regulations involved in expanding the geographical reach of a product can be very demanding. Nevertheless, strategies that take into account technological breakthroughs can be even more difficult to identify and execute.

The influence of advances in genomics, for example, has yet to be fully explored, both in terms of opportunity and impact on an evolving regulatory landscape. Nevertheless, 70% of respondents in this survey show a strong interest in the personalised medicine segment of the life sciences sector.

Against this backdrop, Reed Smith surveyed the attitudes of leading life sciences businesses around the world about the realities of today's marketplace.

This report explores the main drivers behind the avid pursuit for cross-border life sciences deals, the challenges faced in executing those deals, and how advances in personalised medicine may change the face of the industry.



Diane Frenier
Reed Smith
corporate
partner,
Princeton

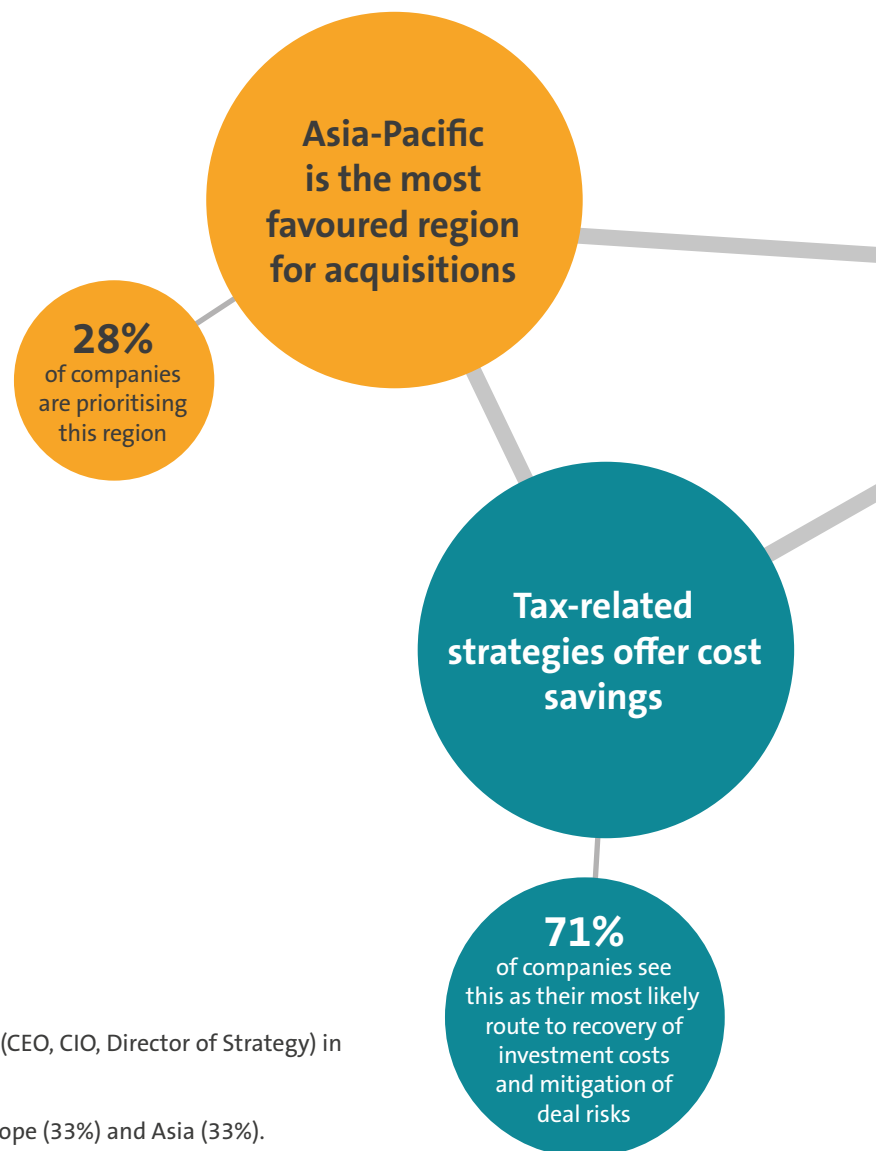


Perry Yam
Reed Smith head
of Private Equity
for Europe &
the Middle East,
London

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Key findings



Methodology

In Q2 2015, Mergermarket surveyed 100 senior executives (CEO, CIO, Director of Strategy) in biotechnology and pharmaceuticals companies.

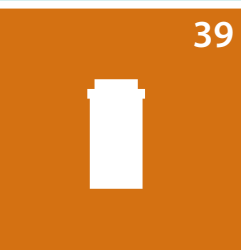
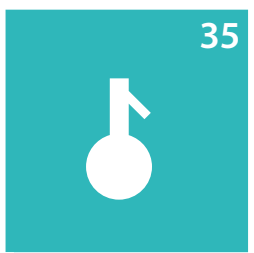
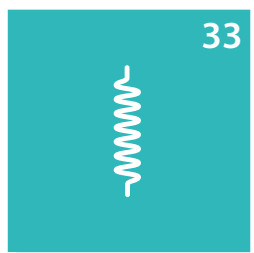
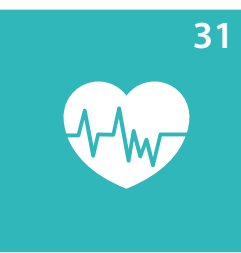
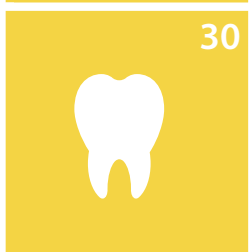
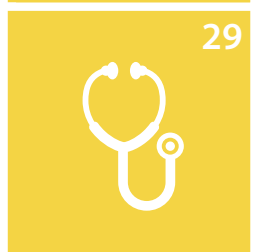
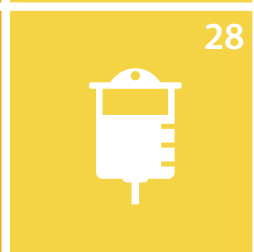
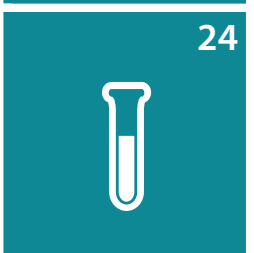
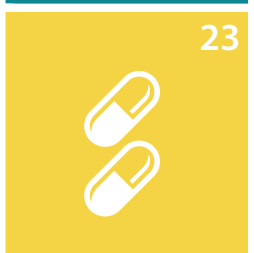
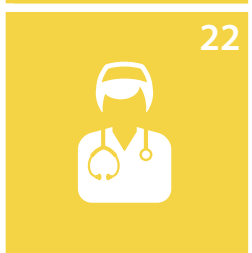
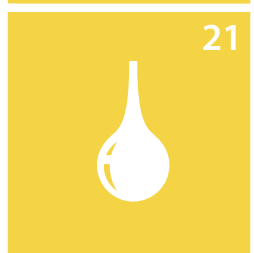
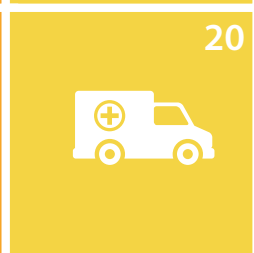
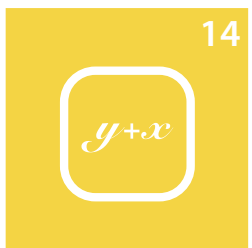
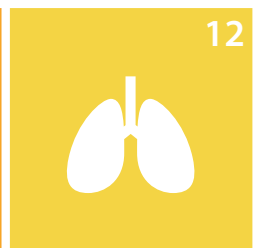
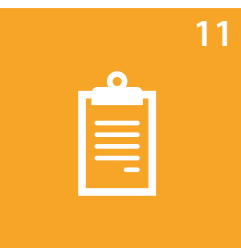
The respondents were evenly split across the US (34%), Europe (33%) and Asia (33%).

The representation by company size is \$100m-1bn (34%), \$1bn-5bn (33%) and \$5bn+ (33%).

The survey consisted of a combination of qualitative and quantitative questions and all interviews were conducted over the phone by appointment. Results were analysed and collated by Mergermarket and all responses are anonymised and presented in aggregate. The research is complemented by interviews with Reed Smith's senior practitioners conducted by Mergermarket.

Life lines: Life sciences M&A and the rise of personalised medicine







M&A temperature rising

M&A in the life sciences sector is booming as companies look to fill product lines, build core competencies and find the next super drug. However, challenges to growth and funding need to be overcome

The life sciences (pharmaceuticals, biotechnology and medical sectors) industry is experiencing its busiest periods of M&A activity since the financial crisis, as life sciences companies seek out cross-border deals that will give them multinational reach and access to new product pipelines. The first six months of 2015 saw \$164.3bn worth of deals – an increase of almost 53% on \$107.5bn in the same period of 2014 – while the second half of 2015 began with a burst of new transaction announcements.

These included the Israeli company Teva Pharmaceutical's \$40.5bn purchase of the generics division of Allergan, a US-based pharma company. This is the largest deal announced so far in 2015. That deal, unveiled in July, was just one of four transactions worth more

than \$1bn announced in July. The next largest transaction, Celgene's purchase of Receptos, was valued at almost \$6.7bn.

M&A began gathering pace in 2014 (see figure 1), and was fueled by several drivers. For many life sciences companies, acquisitions are now the preferred way to deliver the growth rates their investors have become accustomed to, with the costs and risks of developing new products in-house invariably far higher than buying a business that already is far along in the development of a breakthrough drug. As one CEO of a European pharma company observes: "It makes sense to acquire companies involved in late-stage R&D as the failure rate of early-stage R&D is so high and the mistakes are only realised when resources and time have already been utilised."

Figure 1: Life Sciences M&A, 2010-2015

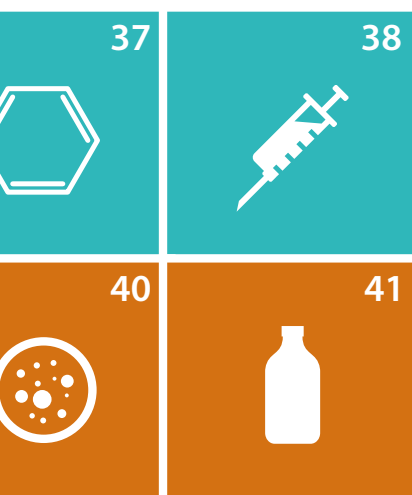
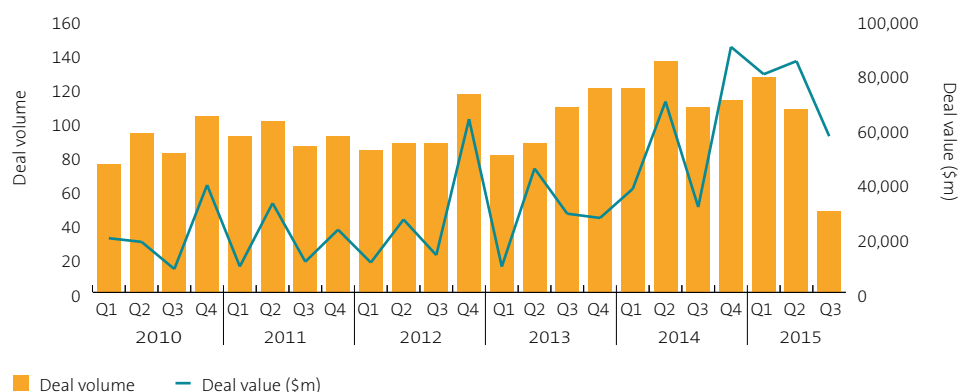


Figure 2: Which of the following are you considering to initiate in the next 12 months? (Please select all that apply)



At the same time, relaxed monetary policy in Western markets means capital is less costly than ever before. The US Federal Reserve has now held the federal funds rate at close to zero for more than six years – and speculation that the Fed will soon begin to raise interest rates is putting pressure on life sciences companies to cash in on this window of opportunity.

As companies reassess their plans against this deal-friendly background, they plan further spin-offs, divestitures and new combinations.

This dealmaking environment is transforming the nature of certain life sciences companies. Mylan, for example, whose \$35bn bid for Ireland's Perrigo would result in a company which is currently a manufacturer of generic drugs becoming a diversified healthcare business. The deal follows Mylan's purchase earlier this year of a portion of Abbot Laboratories, which saw Mylan transform into a Dutch concern.

There is every reason to expect life sciences companies to continue to try to reinvent themselves in this fashion. As figure 2 reveals, more than nine in 10 life sciences businesses (94%) currently expect to explore the possibility of an acquisition over the next 12 months – this rises to a full 100% for companies whose annual revenue is more than \$5bn.

A significant number of companies are also planning other initiatives that could help them secure new products – tie-ups with contract research organisations, for example. But with so many life sciences companies now in acquisition mode, a further spike in M&A activity looks likely. All the more so, since more than a third of companies (39%) are planning divestments. As Reed Smith corporate partner James Wilkinson in London notes: "As more companies engage in M&A transactions, some will inevitably be left with non-core businesses that they will want to dispose of to buyers for whom these units are a better fit."

New horizons

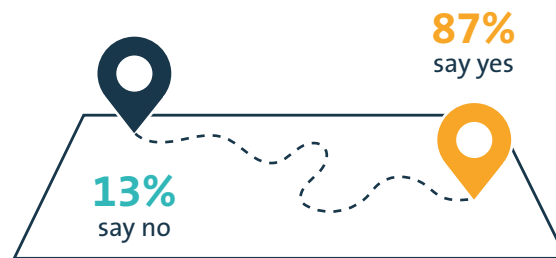
The majority of life sciences businesses expect their acquisitions to be cross-border transactions (see figure 3), as they seek to capture the opportunities offered by growing markets overseas – particularly where growth in their existing markets may be slowing. For example, the director of M&A at one European pharma company focused on oncology drugs says: "We have been considering cross-border deals because our markets are stagnant and offer limited opportunities for growth based on the current volatile market conditions."

In some cases, these deals are likely to see life sciences companies taking their existing products to new markets. The chief executive officer (CEO) of an Asian-Pacific (APAC) business explains: "Products that were bestsellers are being pushed to the exit as other businesses are able to fill their pipeline faster – we now see potential in international markets where we can possibly lower the risk of losing out to the competition."

For other companies, by contrast, the motivation for an international transaction is the desire to find new products to refresh their existing portfolio. "Patent expirations have reduced our capability to gather the same revenues as in the past," says the director of M&A at a US-based life sciences business active in the neurology sector. "We are investing in research and development (R&D) and an offshore acquisition of a like-minded business can help us in a significant way."

In terms of regions, the most popular area with acquisitive life sciences companies is APAC. Indeed, 28% of respondents report they are targeting their search on the APAC region (see figure 4). Part of the draw is the region's large population base combined with developing markets, where demographic changes and increasing personal incomes are combining to create ever larger potential customer bases for pharmaceutical businesses. The

Figure 3: Is your next acquisition likely to be a cross-border deal (outside of your home market)?



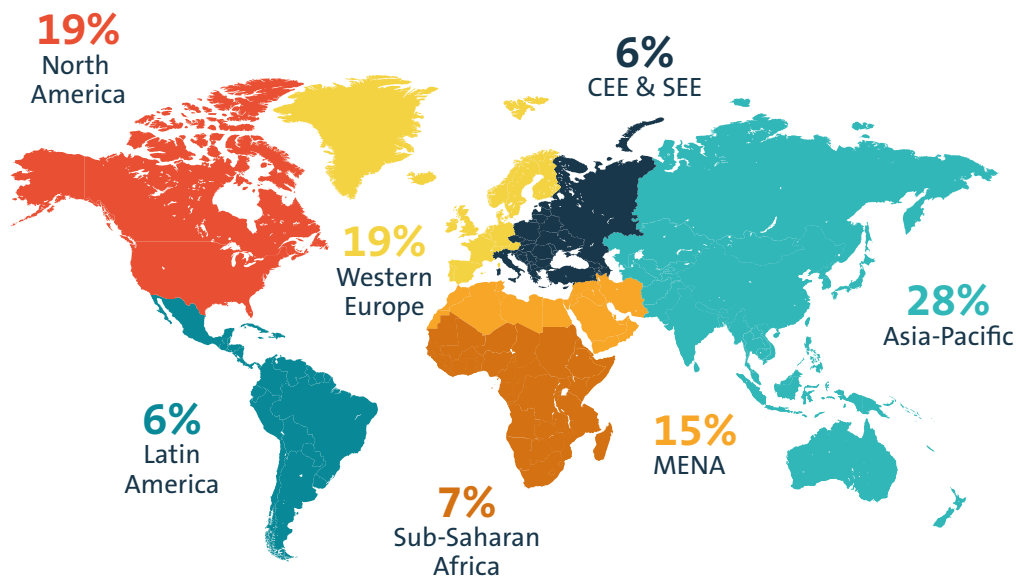
Indian market alone, for example, is expected to see pharma sales grow at 15% per year in the years ahead.¹

¹JLL 2015 Life Sciences Outlook Report (www.us.jll.com)

Just as important, however, is the increasing willingness of many APAC countries to welcome international companies. China, for example, has announced that it is considering relaxing restrictions on international entrants in order to encourage foreign investment.

"The populations of these countries are large and their governments are pushing for

Figure 4: In which region is your next acquisition most likely to be targeted?



Reed Smith on cross-border transactions

Most of what we see has a cross-border nature to it: companies striving for growth in a saturated marketplace are looking to develop their portfolios, diversify their products, move into new markets and restructure their businesses through divestments.

James Wilkinson
Reed Smith corporate partner, London



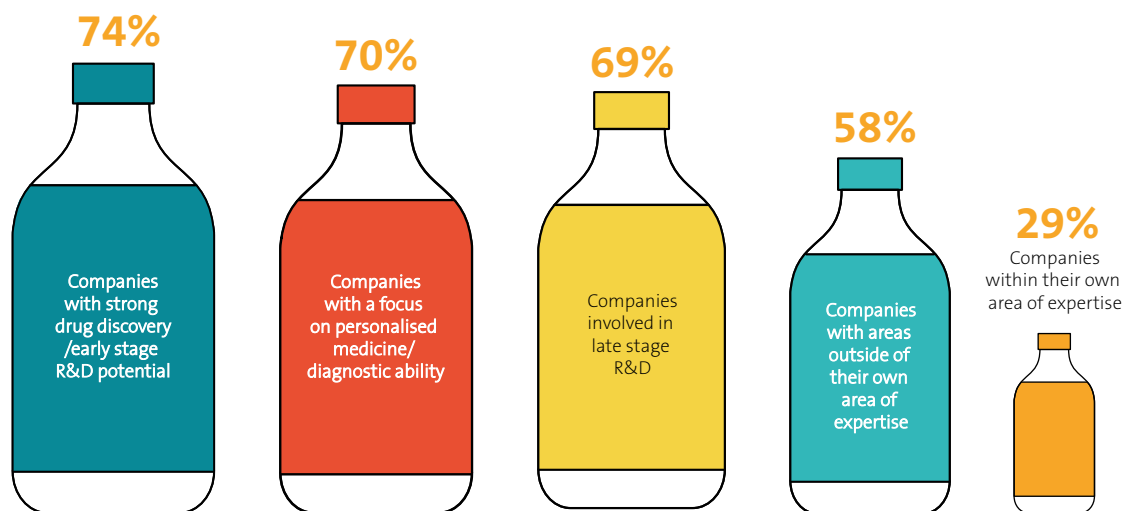
Reed Smith on M&A in China

Despite the slowdown, life sciences companies are still actively exploring opportunities in China. Corporates are doing deals to access new markets, expand their distribution as well as targeting local R&D capabilities. Corporates need to be aware of challenges such as limited assets with the right synergies and the Chinese government's support for local businesses.

Mao Rong,
Reed Smith counsel, Beijing



Figure 5: In which areas do you think major pharmaceutical producers will increasingly look to make acquisitions? (Please select all that apply)



Reed Smith on de-risking strategies

We continue to see the outsourcing of R&D in order to de-risk drug development – the acquisition of an earlier stage single or two-product company with a product close to stage three trials, say, gives a pharma company better visibility than with in-house development, and they're still getting in before a premium for approval is payable.

Brian Miner,
Reed Smith corporate partner in Philadelphia and leader of the firm's US Mergers & Acquisitions Practice



reform in the healthcare sector," says the director of M&A at one APAC life sciences business. "Regulators are expected to offer an adequate amount of support and this would be a driver for success in an acquisition, enabling easy market entry and growth of market share in a new region."

Similarly, the CEO of a US life sciences company says: "Many APAC governments are seeking greater access to generic pharmaceutical products and this will not be achievable by local businesses; the market is currently untapped as many international businesses gave up in the face of regulation, but we now see an opportunity for unprecedented growth through an acquisition in the region."

APAC is certainly not the only region of interest to cross-border buyers. In Europe, buyers are attracted to the high spending of governments on healthcare and point to the relatively low valuation on which many

countries in the region now trade, particularly given the strength of the dollar against the euro. In May, 2015, Baxter International of the US paid \$900m for the acquisition of Sigma-Tau Finanziaria of Italy, for example.

In North America, potential targets are prized for their technology and R&D prowess, while the stable regulatory regime is also an attraction. Eight of the 10 largest deals so far this year have involved the purchase of US companies, ranging from Teva's acquisition of Allergan to Shire's deal to buy NPS Pharmaceuticals.

Other markets are also attracting interest. One director of M&A at an APAC life sciences company says: "We plan to open a manufacturing plant in Bahrain, where the purchasing power of patients means we can earn a decent return, costs are low and the ease of doing business is good." In sub-Saharan Africa, meanwhile, the CEO of a US life sciences firm says: "The improving economic

activity and the development of the middle class in the region will transform healthcare development in Africa.” The executive predicts a significant increase in dealmaking in the area.

It would seem from these findings that life sciences companies currently favour deals over organic growth. Brian Miner, Reed Smith corporate partner in Philadelphia and leader of firm’s US Mergers & Acquisitions Practice, agrees, saying the former is less risky. “A transaction reduces the risk of access to developing markets because you’re buying a company already proven in that territory, rather than having to start from the ground up,” he says.

New visions

As well as deciding which geographical regions to prioritise for M&A activity, businesses must also decide what type of company to target. Figure 5 underlines the extent to

which life sciences companies see acquisitions as a crucial source of new products as their existing portfolios struggle to deliver sustainable revenue growth. Almost three-quarters (74%) of companies hope to buy companies with products that have early-stage R&D potential, while almost as many (69%) are targeting companies active in late-stage R&D. Respondents’ interest in making acquisitions in personalised medicine (70%) is explored in more detail in chapter two of this report.

The data also suggests that many pharmaceutical companies are keen to diversify by moving into new areas of business. More than half the companies in this research (58%) are looking to make acquisitions in areas where they do not currently have expertise. Meanwhile, less than a third (29%) are focusing on companies within their own area of expertise. “It is quicker,

potentially less expensive and certainly less risky to buy in this expertise than to develop it from scratch in-house,” says Reed Smith’s Brian Miner.

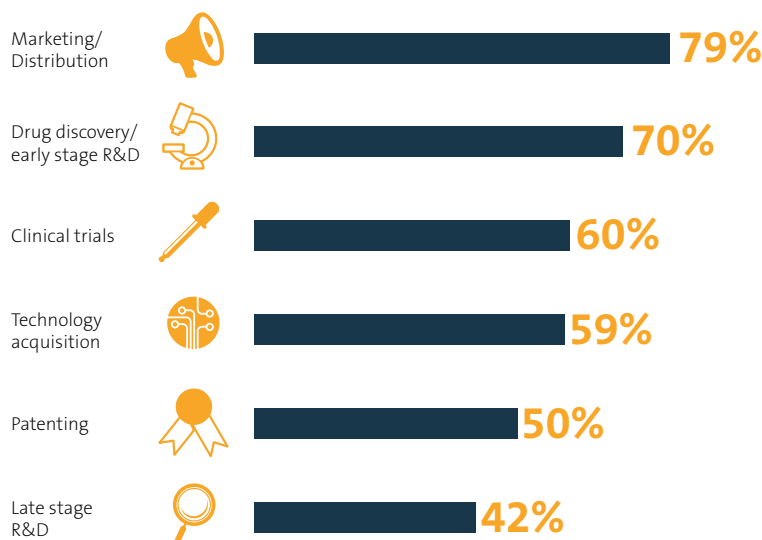
Machines and marketing

Meanwhile, while businesses are prioritising these M&A targets, they must manage other demands on their resources. These will include different types of acquisitions – as figure 6 shows, some 59% of life sciences companies see a technology deal as a priority for investment over the next 12 months. For example, the vice president of M&A at one APAC life sciences company says: “Technology is our main area of investment focus as we see changes taking place in treatments and effectiveness increasing based on the right use of tools and technology; the possibility of printing tissues and muscles with 3D printers has inspired us.”

This area has already seen some unusual partnerships. For instance, Novartis has been working with Google to develop contact lenses that can measure people’s blood sugar levels in real time.

Alongside M&A, many companies are now focusing on how they get their products to market, with more than three-quarters (79%) citing marketing and distribution as an investment priority. In Europe, the director of M&A at a leading pharmaceutical company says a more benign regulatory climate is encouraging. “We plan to increase investments in marketing our branded products mainly because of less regulatory intervention and attractive margins,” the executive says. “Our focus is on leveraging synergies for positioning of our products in international markets.”

Figure 6: In which areas are you planning to increase investments over the next 12 months? (Please select all that apply)



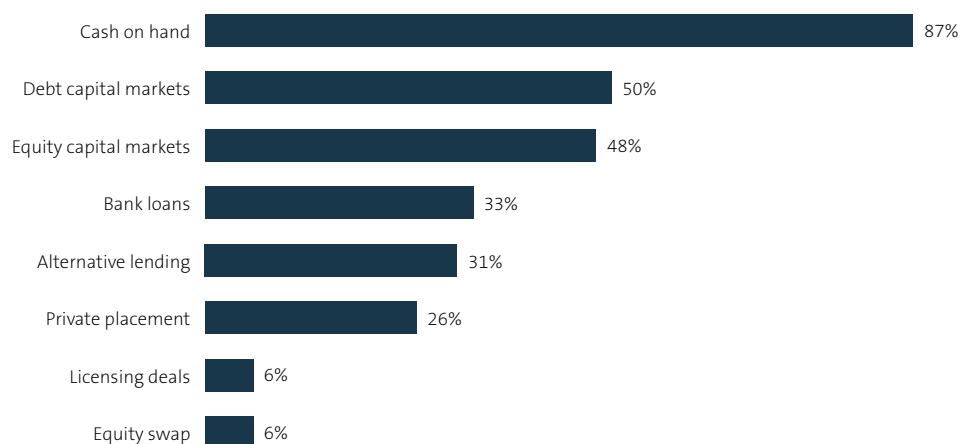
The power of private equity

There was a time when private equity firms were active buyers at every level of the life sciences sector. Today, these investors are far less likely to be found backing early-stage biotech companies, but are increasingly competing for the best deals among more established pharma businesses, where they are attracted to the growth potential of several sectors.

“Private equity funds are active buyers in the life sciences sector, particularly of contract research organisations and generics manufacturers,” says Perry Yam, head of Private Equity for Europe & the Middle East at Reed Smith. “But there aren’t enough interesting opportunities on the market and valuations are high – firms must be clever, seeking out spin-outs and divestments, for example.”

Notable deals this year include CVC Capital Partners’ \$2.03bn purchase of Iceland and US-based Alvogen and Capital International’s \$200m purchase of an 11% stake in India’s Mankind Pharma.

Figure 7: How are you planning to finance your next deal? (Please select all that apply)



While selling more of their existing products, life sciences companies must also prioritise the development of new treatments. More than two-thirds (70%) plan to increase investment in drug discovery and early-stage R&D over the next 12 months, while more than half (60%) will spend more on clinical trials.

In the US, the director of strategy at one pharmaceutical company stresses the need for a virtuous circle – better distribution boosts sales and facilitates a larger M&A budget. “By investing in marketing, we aim to maximise revenues, enabling us to focus more on creating similar therapies for other medical conditions,” the director says. “That can help us retain market position in the long run.”

Money talks

In fact, many pharmaceutical companies are already sitting on large cash piles. In the US alone, one analysis published by Moody’s earlier this year suggested that businesses in the pharmaceutical sector had combined cash reserves of \$136bn.

This is a further driver for dealmaking in the sector, as companies come under pressure from shareholders to put that money to good use, or to return it to investors. It also explains why 87% of companies expect to be able to finance their next deal from cash on hand (see figure 7), including many businesses in Europe and APAC. The vice president of M&A at one European life sciences company says: “We find it rational to use funds when available instead of taking up loans which demand commitment and adherence.”

Still, the supportive conditions for creditworthy companies in the debt market are encouraging some businesses to seek this type of finance, particularly as there are other advantages to raising money this way. “We will focus on debt capital markets as they represent an integrated global platform, which can help with funding, and also enable us to get to know investors in the region, which can help in future,” says the CEO of a European life sciences company.

Not that raising funds is guaranteed to be straightforward, warns Reed Smith's James Wilkinson. "Established businesses with strong products that have been producing revenues for some time have less difficulty tapping into external capital," he says. "But it has been hard for earlier stage businesses, particularly outside of North America, where the appetite for and understanding of this sector is very different."

As figure 8 shows, large numbers of life sciences companies point to a range of barriers that potentially hamper their efforts. One major issue is clearly the highly competitive nature of the sector (highlighted by 74% of respondents). In the US, the director of M&A at one mid-sized life sciences company complains: "Patients are looking for effective treatments and businesses are making this possible through investments in technology that at times seem to be way beyond their budget." In Europe, meanwhile, the CEO of a European pharmaceuticals business says: "Fundraising is difficult mainly because competitors create new products and commercialise products to eliminate their opponents."

Perry Yam, Reed Smith partner in London and head of Private Equity for Europe & the Middle East, warns that periods of stability in the sector can be interrupted unexpectedly. "The sector is relatively robust and continues to attract investment, but it can be disproportionately affected by global factors," Yam says. "For example, during the Ebola crisis, we suddenly saw massive demand for businesses in the vaccine sector."

The uncertain outlook is another challenge, as businesses wonder

whether the economic recovery in the West is sustainable and whether China's problems will lead to a global slowdown. "The uneven economic environment only adds to the pressure," says the CEO of a European specialist in immunotherapy drugs. "Businesses cannot be sure about the response of populations towards products as competition is high and regulatory bars are rising – that makes fundraising a challenge."

Meanwhile, a minority of investors are simply turned off by the life sciences industry – 43% of respondents said that the greatest challenge to raising funds was a lack of interest from investors. As the CEO of a US business warns: "The majority of investors are following a diversified investment approach to avoid risk," the executive says. "The pharmaceutical sector is exposed to risks of regulation, quality, compliance and competition which investors would prefer to avoid."

Reed Smith's Perry Yam agrees. "We live in an environment where consumers are better informed than ever before and regulators are more stringent than ever," he says. "That impacts on the attractiveness of these companies to investors." These issues can be overcome, Yam says, but investors are choosy about where and how they invest. "Potential purchases must be able to demonstrate the highest standards of due diligence."

Fighting fires

While pondering these fundraising challenges, life sciences businesses must also confront other difficulties that threaten their growth strategies. As figure 9 reveals, companies in the sector see a very broad range of barriers standing in their way, while figure

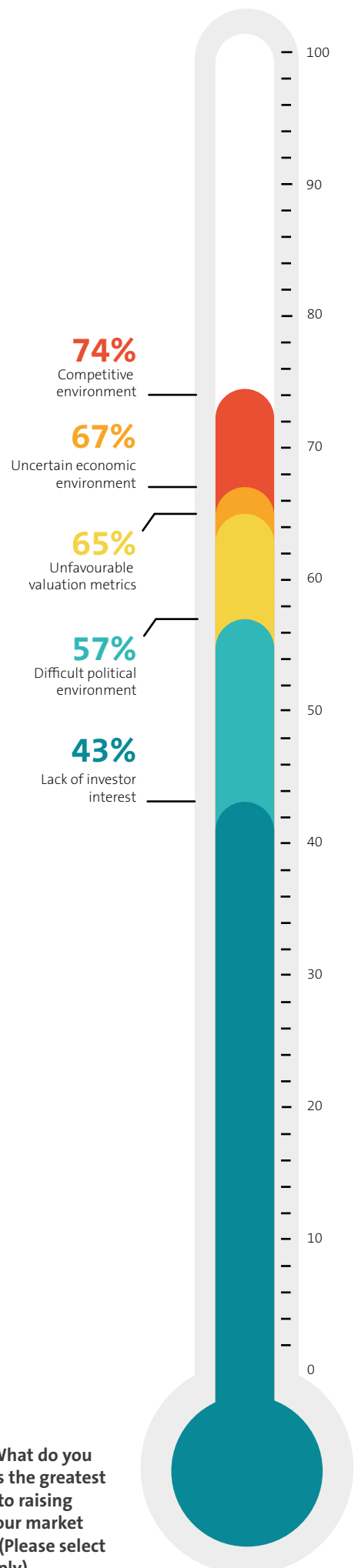
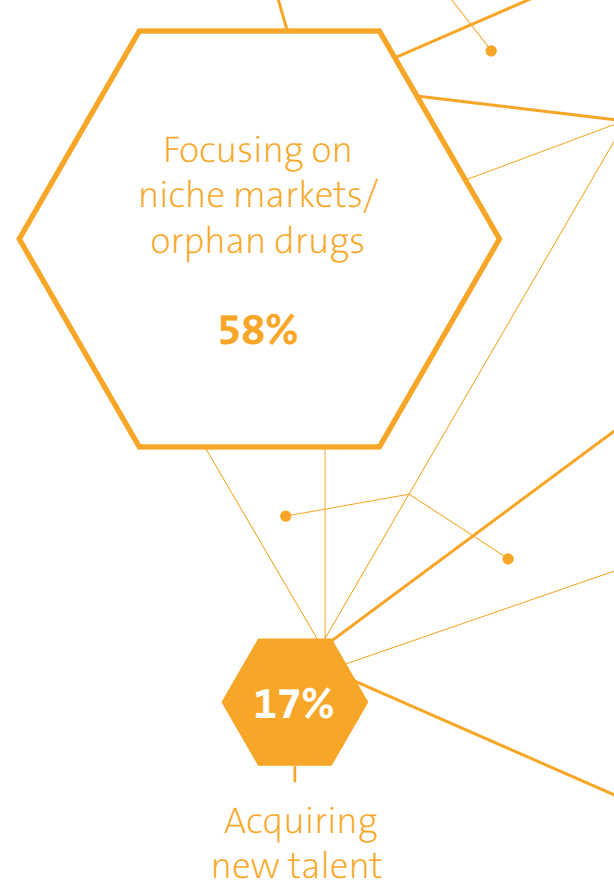


Figure 8: What do you perceive as the greatest challenge to raising funds in your market segment? (Please select all that apply)

Figure 10: Which strategy do you think will most benefit your product development? (Please select all that apply)



10 suggests they will draw on a wide range of strategies as they seek to develop new products.

The need for diversification is one pressing issue says the director of strategy at a US life sciences company. “As competition in the industry is high, companies will focus on broadening drug portfolios as demand tends to reach uncertain levels at some point in time,” the executive says. “In some areas over-the-counter drugs are selling well, while in others personalised medicines are strong, so having a good mix of therapies will help counter the competition.”

Companies will need to be imaginative in order to prosper, adds the CEO of a leading European specialist in diagnostics. “We will see more companies entering new geographies through partnerships to create new revenue streams, while having a broad range of products could prove highly productive.”

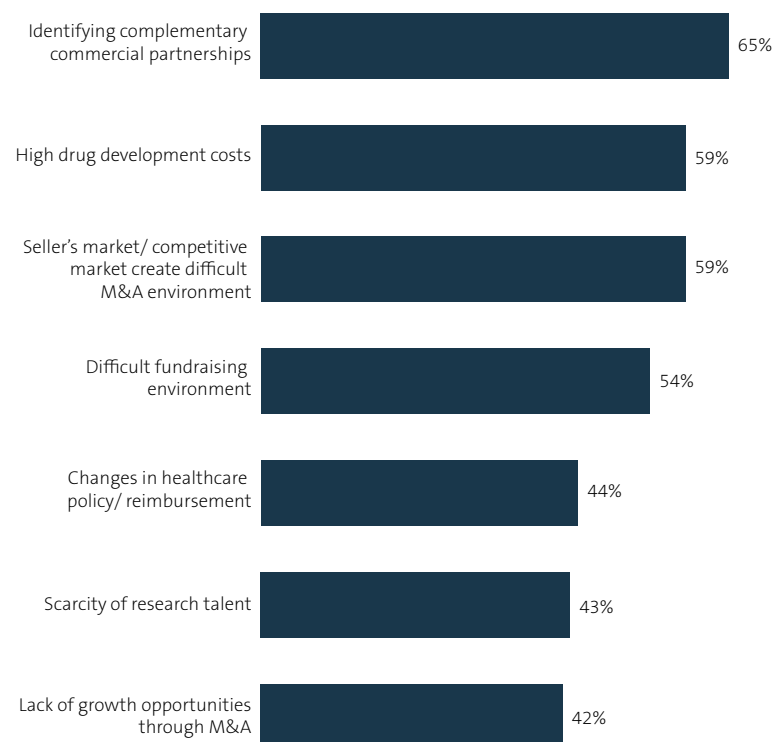
Finding those partnerships may be difficult, however. Competition for the right alliances will be intense, with three-quarters of companies seeing partnerships with new entrants and biotech businesses as likely to be of most benefit to their product development. Already, almost two-thirds of companies (65%) see identifying complementary commercial partnerships as their greatest growth challenge.

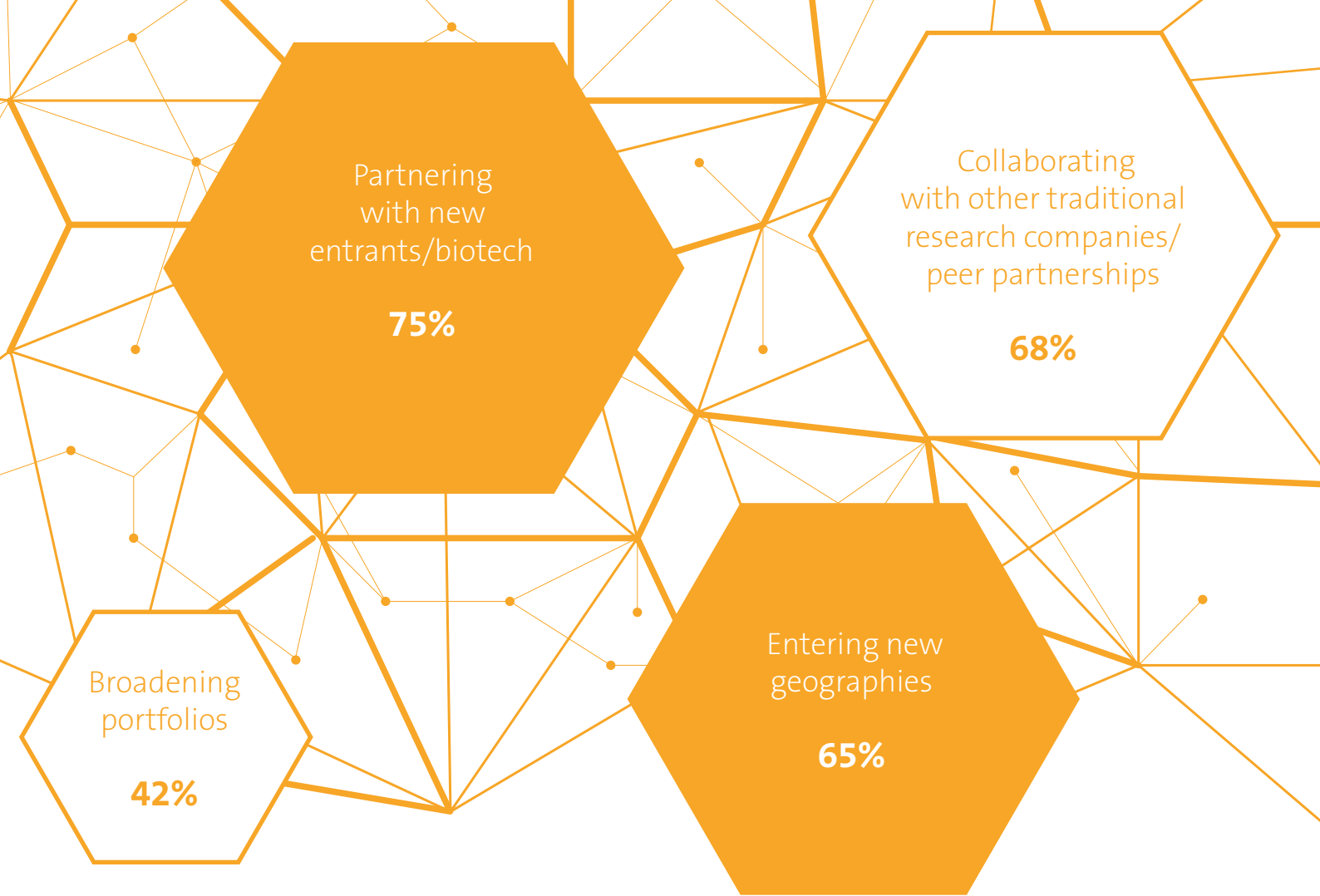
That challenge must be confronted, says Carol Loepere, Reed Smith partner in Washington D.C. and chair of Reed Smith’s Life Sciences Health Industry Group. “The trend that we’re seeing is for collaborations where there may be a long-term licensing or a co-promote arrangement

which may in the future result in or lead to an acquisition,” she says. “The collaboration model is a very promising one – for cross-border arrangements and for developing in a particular market.” That certainly worked for Skyepharma and Mundipharma, two UK life sciences firms, which together developed the Flutiform respiratory drug now sold in 18 European countries as well as global markets such as Australia and Israel.

One important strategy as pharmaceutical businesses seek to free up funds for further investment in growth strategies will be to identify potential cost savings. Companies are already targeting a broad range of areas

Figure 9: Where do you see the greatest challenges to growing your business? (Please select all that apply)





for such savings. As shown in figure 11, tax-related strategies are a priority for almost three-quarters of companies (71%) while new delivery systems are front-of-mind for close to two-thirds (64%).

Reed Smith’s James Wilkinson points out that the spate of inversion deals seen in the US last year, with US businesses using acquisitions to shift their headquarters to overseas markets for tax savings, has now ended, following a tightening of the rules. In the best-known example, Mylan’s purchase of Abbott Laboratories saw it become a specialty and branded generic pharmaceuticals business based in the Netherlands that was expected to drop its US tax rate from 25% to 21% in its first year.

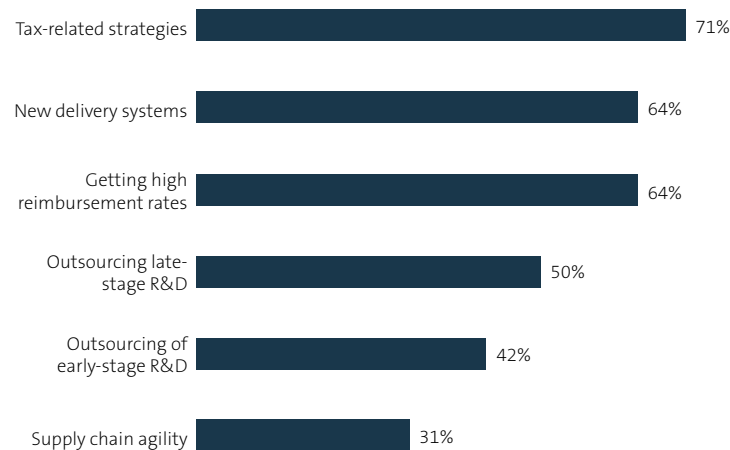
Nevertheless, Wilkinson believes tax will remain an important element of dealmaking. “While inversion deals are likely to be less common following the IRS’s intervention, tax is a crucial feature of any deal and it’s vital to structure transactions in the right way,” he says. “One of the first things we do when advising on

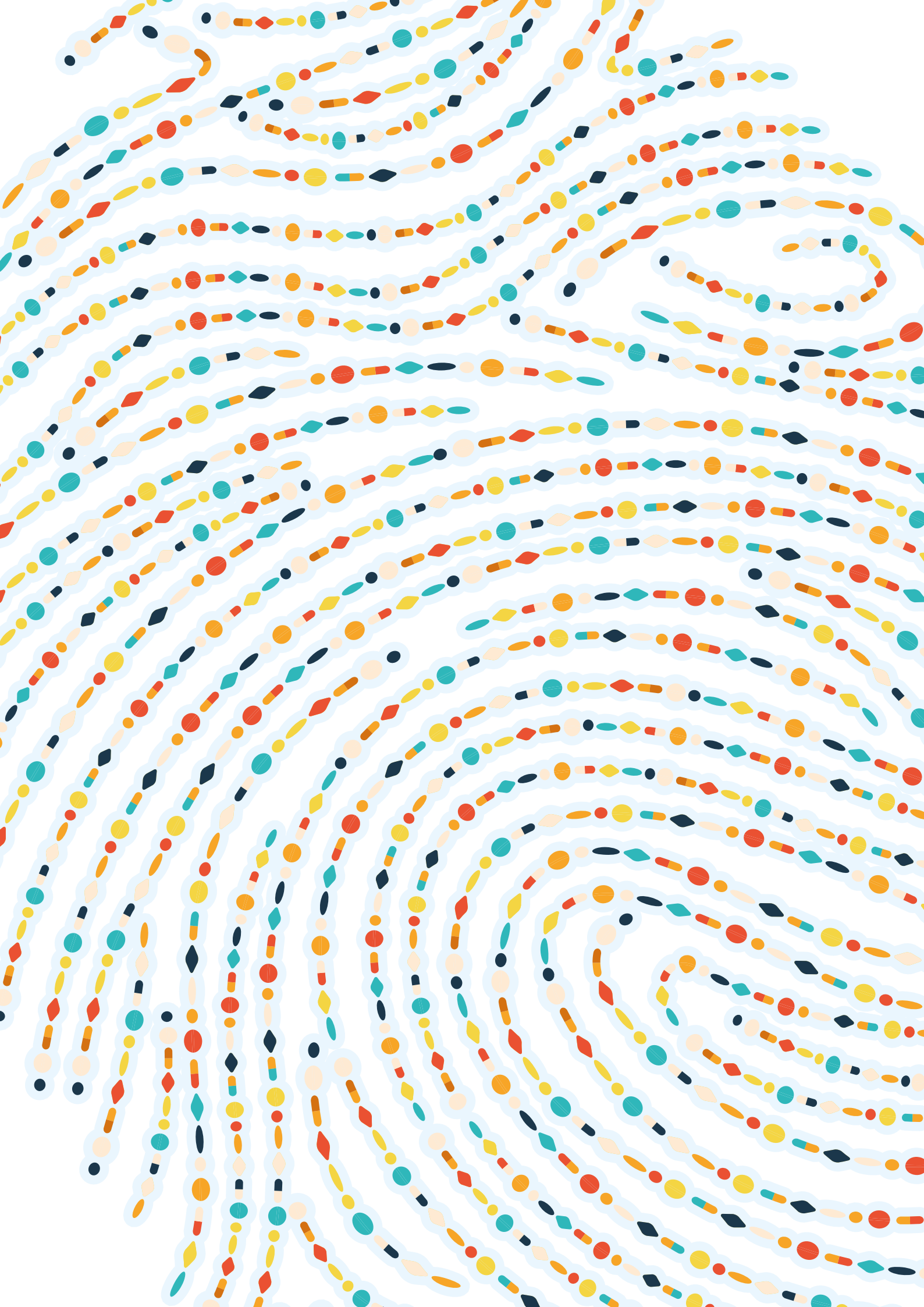
any transaction in this sector is to consult our tax experts in order to ensure we’re planning strategically for these issues.”

Many companies are exploring other options – for example, they see a focus on reimbursement rates as potentially lucrative – this is likely to prove to be a well-used approach in developed markets. “We are aiming at recovery of funds through a high drug price tag,” says the director of M&A at a European

life sciences company. “We don’t feel this will be an issue as the patient that has the funds and the urgency to recover will certainly avail of our personalised medicine considering its rate of efficacy.”

Figure 11: Which strategy will enable you to the greatest cost-recovery? (Please select all that apply)





The personal touch

Life sciences companies are beginning to reassess their strategies with many looking beyond the well-travelled broad indication drugs and seeing personalised medicine as the future

More than two-thirds of life sciences companies (70%) now cite businesses that have a focus on personalised medicine as an area where they will increasingly look to make acquisitions (see figure 5 on page 10). Indeed, this was the second most popular area in the survey – a strong indication that personalised medicine has a significant part to play in life sciences companies' future strategies.

In an era where medical practitioners are increasingly focusing on the idea of “the right drug for the right patient at the right time”, the potential prize for the producers of those drugs is a valuable one. The “one-size-fits-all” approach to drug prescription feels increasingly out-of-date now that it is often possible to identify the right therapy for a patient depending on their genetic make-up and other predictive factors. “We are moving to a world where the emphasis is on gathering evidence to identify interventions that are most effective at improving health outcomes and technology is making this possible,” says the CEO of one large US pharma company.

For the time being, broad indication drugs remain the mainstay of the portfolios of the majority of pharmaceutical companies. “The generics sector will continue to consolidate,”

says Reed Smith's Brian Miner. “We are now seeing some very large companies with extensive portfolios of these products.” The CEO of one US company says: “The predictable regulatory path makes development of broad indication drugs more reliable and effective and gives us a clear path to follow.”

However, in a highly competitive marketplace, where the struggle for differentiation has never been tougher, this will change, particularly given developments such as sophisticated new data analytics tools. Reed Smith corporate partner Diane Frenier in Princeton is convinced of the attractions of personalised medicine to many companies in

Figure 12: Do you think technological breakthroughs will drive the sector towards personalised medicine?

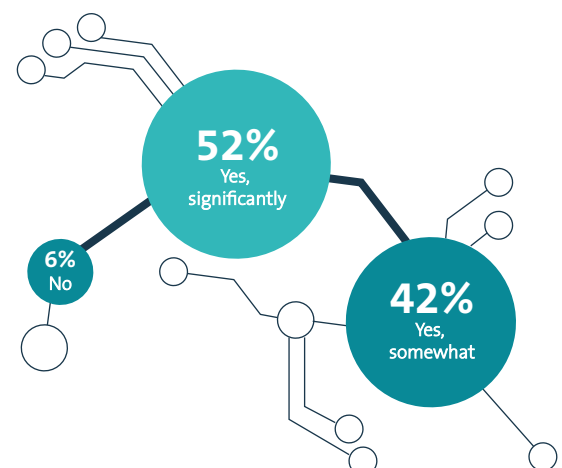
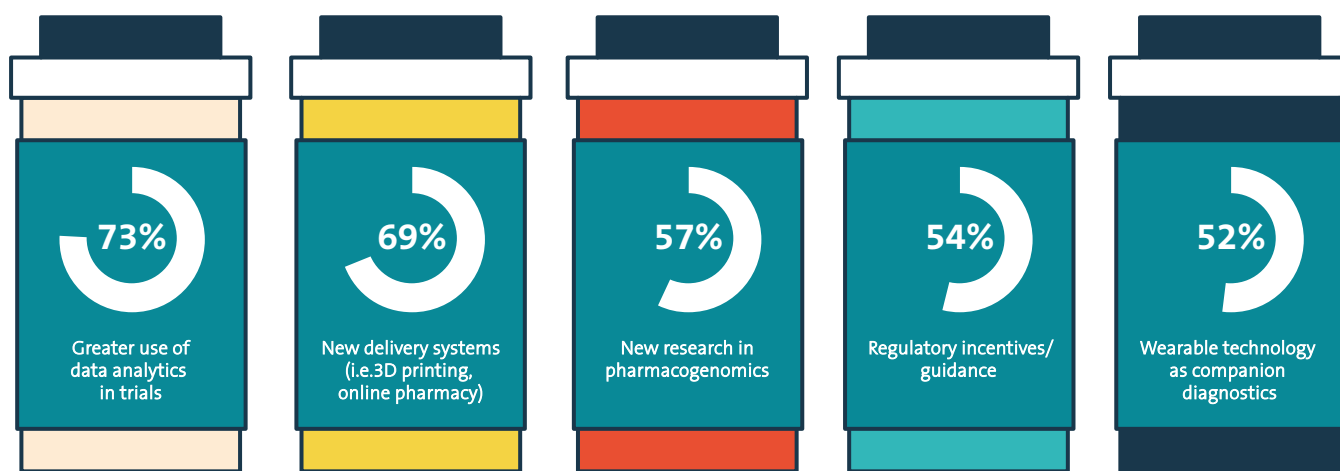


Figure 13: Which developments do you think will be the strongest drivers for personalised medicine over the next two years? (Please select all that apply)



Reed Smith on personalised medicine

The future of medicine is to have the right medicine for the right patient and the right dose at the right time; there are already over 100 different drugs that are recognised by the FDA as having some type of personalised labelling in their usage.

Carol Loepere, Reed Smith partner in Washington D.C. and chair of the Life Sciences Health Industry Group



the sector. “Targeted therapies enable them to differentiate their products with the payers and they’re likely to get better coverage as a result,” she says. “They’re also improving patient compliance – one of the biggest challenges with therapies is that patients don’t take the medication, often because they’re not seeing the benefits, but with targeted therapies, patients are more likely to see a benefit and to comply.”

Despite a continued and current focus on broad indication medicine, personalised medicine offers the promise of higher returns despite smaller potential patient populations given the more targeted nature of drugs. And there are a number of indicators which point to an even brighter future.

Tech in the driving seat

As figure 12 (page 17) reveals, the vast majority of pharmaceutical companies believe technological advances will drive the move towards personalised medicine. More than half (52%) believe

this move will be significant. “Personalised medicine enables businesses in our sector to make changes and to create an impact taking into consideration the choices a patient has made,” says the CEO of an APAC-based specialist in infectious diseases. “The efficiency rate is high which makes it a good catch for many in our industry.”

A broad range of technological drivers are enabling pharmaceutical companies to move towards personalised medicine (see figure 13). The director of M&A at one European life sciences company says: “Identifying effective biological compounds through the use of new technologies is likely to impact the odds of clinical success and this is possible through quality data.”

More sophisticated big data tools enable much more advanced analysis of patient information, while new delivery systems ranging from 3D printing to online pharmacies facilitate a much more

Reed Smith on R&D talent

While there isn't a shortage of R&D talent, there may well be a shortage of talent that can really focus their efforts on potential business as well as scientific research. And that's the challenge for the scientific community – finding someone who not only has the scientific talent but can also see the business case for what they're working on.

Diane Frenier,
Reed Smith
corporate partner,
Princeton



bespoke approach to treatment. In China, for example, e-commerce firm Alibaba now runs a major online pharmacy operation, which is poised to benefit as regulation is eased to allow such operations to sell prescription drugs.

So too do advances in studies of the genetic differences that cause patients to respond differently to the same drugs. Almost as important is the attitude of regulators, with medical authorities increasingly keen to encourage advances in this area.

Enabling a strategic approach in terms of geography also promises further efficiency. The director of strategy at an APAC-based business adds: "Greater use of data and analytics in clinical trials would help in determining the healthcare region on which to focus – this is the crucial element

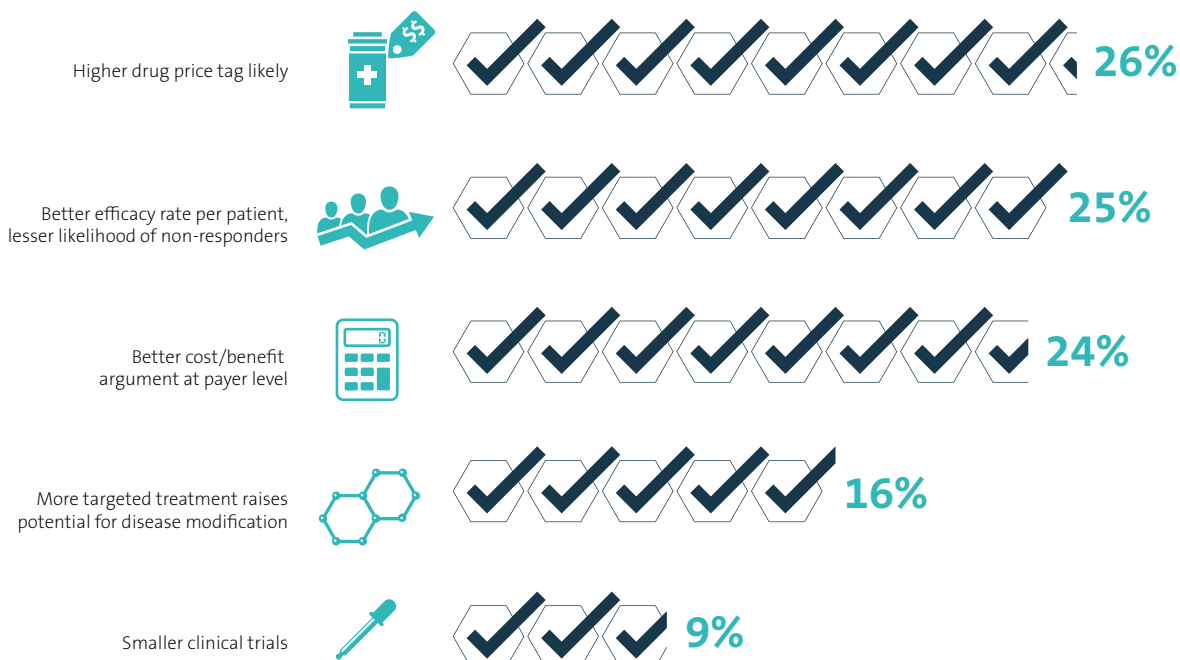
of the initial stage of creating personalised medicine."

Why personalise?

The promise of personalised medicine is a happy combination of improved outcomes for many patients and an enhanced commercial performance. Most obviously, more than a quarter (26%) of life sciences companies see an opportunity to charge higher prices for more targeted drugs (see figure 14). Almost as many (25%) point to the higher efficacy rate per patient of these treatments. That should encourage drug buyers to pay the higher prices quoted, since with fewer non-respondents to a treatment, its cost-benefit case improves – this is a consideration for 24% of life sciences companies.

"Businesses that have the capabilities to create personalised

Figure 14: What are the advantages of developing personalised medicines? (Please select the most important)



Patient-focused personalised medicine

Investors looking to explore personalised medicine may find that one of the key advantages of these particular drugs – because they are specific to a patient or patient population – is that they get investors closer to the patient.

Carol Loepere, Reed Smith partner in Washington D.C. and chair of Reed Smith's Life Sciences Health Industry Group, says: "For many of these drug usages, this could be a lifetime or a long-time usage, and so you have that additional connectivity with your patients."

medicine will be rewarded with higher drug prices as they will provide a higher degree of security on treatment results," argues the director of strategy at a European life sciences company. "This will create a difference in market position and get the business positive attention in the markets."

It is relatively early days in personalised medicine, but advances are being made quickly. The UK research firm Diaceutics says 19% of therapies on the market today are targeted in some way, up from 6% in 2010, with the sector led by Roche, Johnson & Johnson and Novartis.

This differentiation point is crucial, says the CEO of another European pharmaceuticals company: "The main advantage of personalised medicine would be efficacy rates that help businesses distinguish themselves from competitors."

Jumping the hurdles
Regulation is by far the biggest challenge inhibiting further advances in the development of

personalised medicines. More than a third (34%) of life sciences companies complain that a lack of regulatory guidance on how they should proceed is causing them difficulties, almost twice as many as those who worry about the next most significant hurdle (see figure 15).

"Some of the challenges are around reimbursement and payment because if you have a drug and then an accompanying laboratory test to see whether the patient would benefit from it, whether the insurance company or the payer will pay for both the product and the test is an area of regulatory uncertainty," says Reed Smith's Carol Loepere. "There are also issues about post-market surveillance because if you start with a relatively small patient population, it's more likely that other symptoms or negative outcomes will come to light later on."

While there has undoubtedly been some progress in certain countries, the regulatory regimes that govern drug development

Figure 15: What are the hurdles in developing personalised medicines? (Please select the most important)

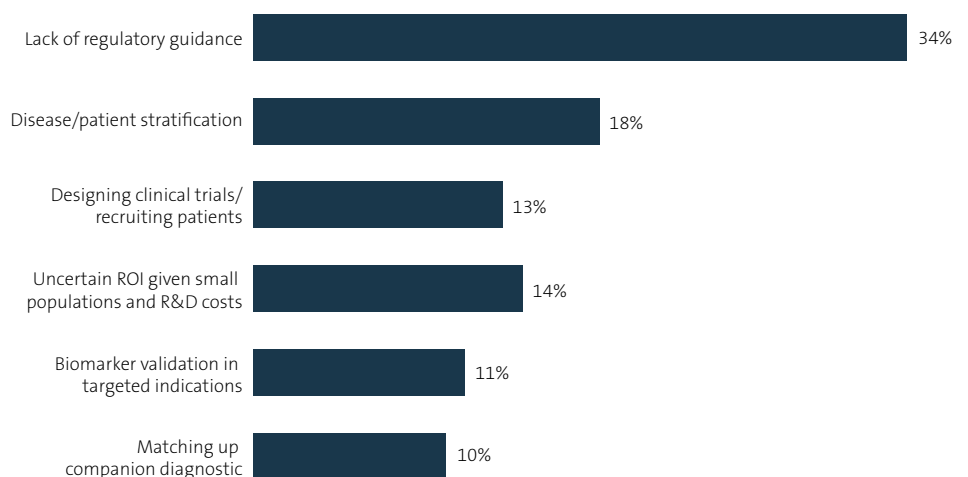
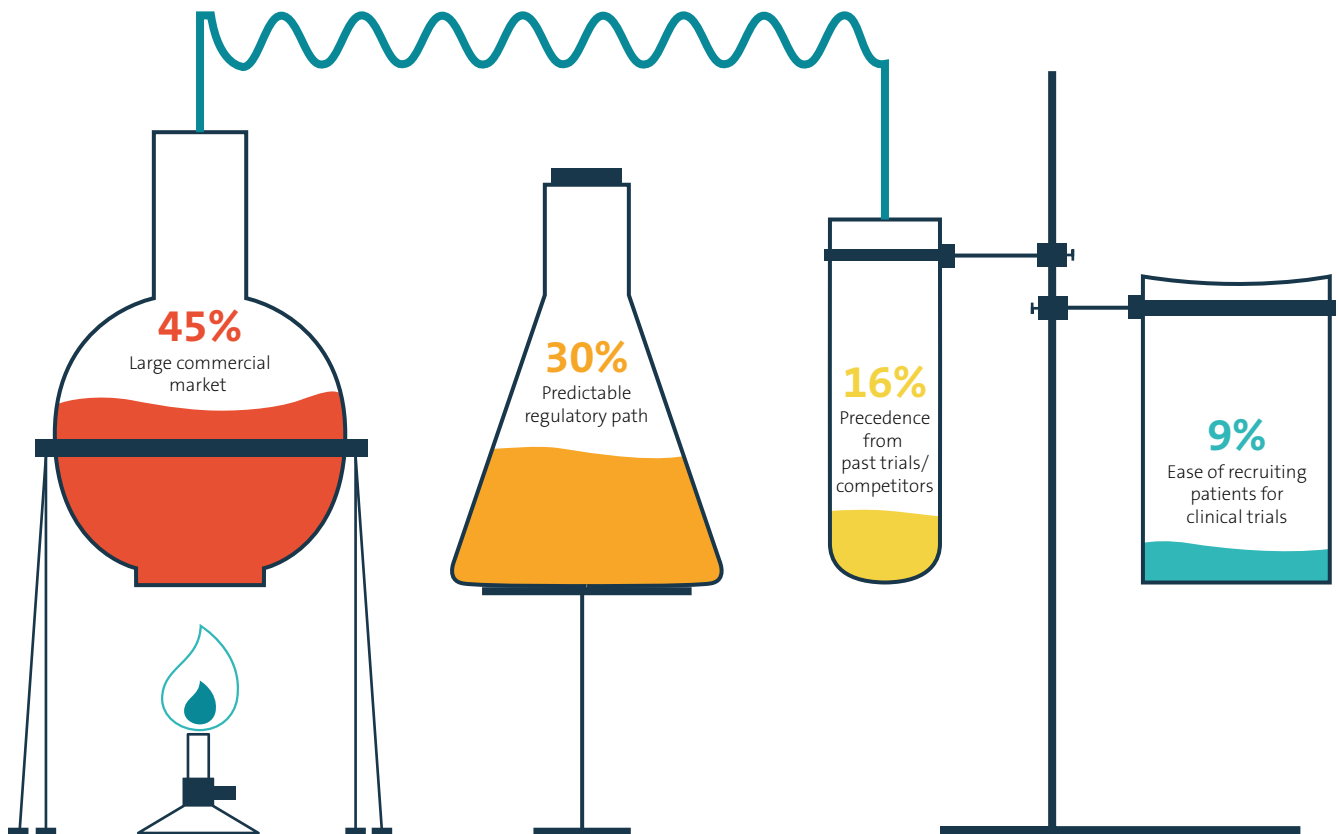


Figure 16: What are the benefits of developing broad indication drugs?
(Please select the most important)



have so far failed to keep pace with the development of personalised medicine. The US is doing best – the number of FDA-approved drugs linked with a particular biomarker has leapt over the past three years, to more than 80 from just over 20 – but in other markets, progress has been slower.

“The lack of regulatory guidance is making it difficult,” complains the CEO of a US specialist in neurology, though the executive also believes this is likely to prove a temporary roadblock. “With appropriate support, new products will reach the market for sure – many governments are now working on this and once they resolve these issues what currently looks like a great challenge will turn out to be a big opportunity.”

Reed Smith’s Diane Frier says life sciences companies are beginning

to work to help the regulatory authorities to move more quickly. “Companies understand that they have to find new ways to present data showing the efficacy of therapies,” she says. “They will have to make this even more of a priority.” One possibility, for example, is to work on a cross-industry basis. In Europe, for example, the European Alliance for Personalised Medicine is doing exactly that.

All on broad

Despite the optimism shown for personalised medicine, the sector is unlikely to turn its back on broad indication drugs for the foreseeable future, as they continue to present significant commercial opportunities. The huge commercial market for these drugs is one attraction – almost half (45%) of life sciences companies see this as a benefit

of developing further treatments (see figure 16).

Moreover, the regulatory process during the development of broad indication drugs is smoother – almost a third of companies (30%) cite this as a benefit. The CEO of a US life sciences company in the haematology sector puts it this way: “The predictable regulatory path makes development of broad indication drugs more reliable and effective – we have a clear path to follow in order to match global health standards.”

Broad-based issues encourage personalised medicine

Nevertheless, the life sciences sector’s frustrations with broad indication drugs are likely to encourage more companies to pursue opportunities in personalised medicine. As figure 17 reveals, almost a third of life

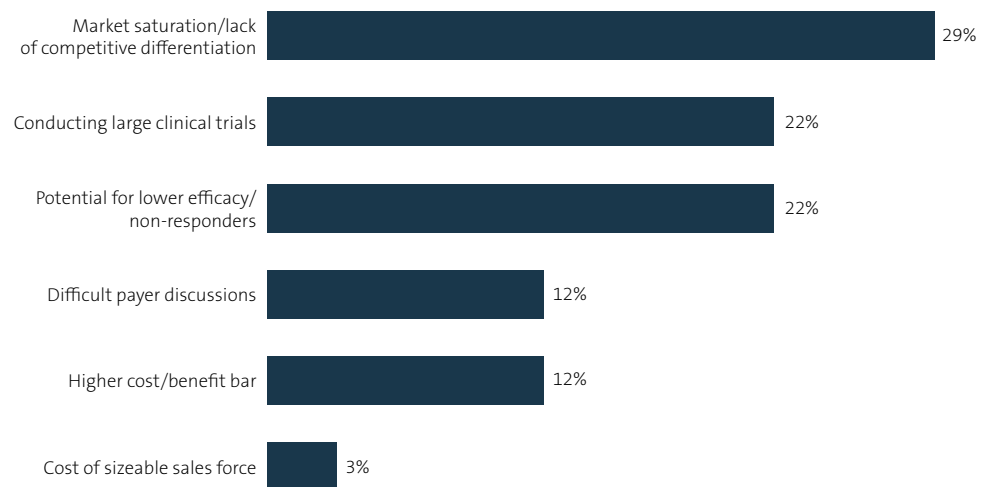
Personalised regulations

Regulation of personalised medicine is evolving, but frustrations remain for many pharmaceuticals companies active in this area. As they work to build the data cases necessary to convince regulators of the efficacy of new targeted therapies, approvals may take longer to gain than hoped for.

Reed Smith's Diane Frenier says the key is for the industry to work with regulators and other stakeholders. "The regulatory approval process will continue to evolve and life sciences companies need to find more ways to work closely with the agencies," she says. "They need to educate them on what technology is coming through and to help them think about how to analyse these technologies during the approvals process."

It may also be necessary to work with broader groups. In Europe, for example, personalised medicine advocates have begun preparing briefing documents for MEPs and other politicians, as they seek to educate a broader audience.

Figure 17: What are the challenges in developing broad indication drugs? (Please select the most important)



sciences companies (29%) are now concerned that the market for these products has become so saturated that it is very difficult to find any points of commercial differentiation. More than a fifth (22%) are worried about the lack of efficacy of broad indication drugs – drugs with high rates of non-responders will suffer diminishing returns. The same number point to the difficulty of conducting the large-scale clinical trials that broad indication drugs require.

These problems seriously worry many life sciences company executives. "Broad indication drugs can have a different impact on different patients which can make it difficult for businesses to achieve the expected output – commercial success is not a guarantee," cautions the director of strategy at a European pharmaceutical company.

"The scope of differentiation is as good as zero as most businesses will take a step back in making further investments in R&D activities," adds the chief strategy

officer at another European business. "Broad indication drugs serve a common purpose and at times can fail to enhance patient health – this exposes them to the risk of low productivity, uncertain revenue and unpredictable demand; development is therefore challenging."

The traditional response to these issues has been to stress the importance of diversity – if one product disappoints or suffers unexpected setbacks, there are other drugs within the portfolio for the company to fall back on. However, diversification has its own difficulties – large numbers of life sciences businesses point to a number of problems with this strategy, as figure 18 shows.

Most significantly, it is expensive and practically challenging to recruit and retain teams of people with sufficiently high-level scientific and R&D expertise to lead credible development in a number of different areas simultaneously. More than two-thirds (69%) of life sciences

businesses see this as a problem, while almost as many (67%) say that the company's areas of strength are likely to be compromised as it tries to stretch itself too thinly.

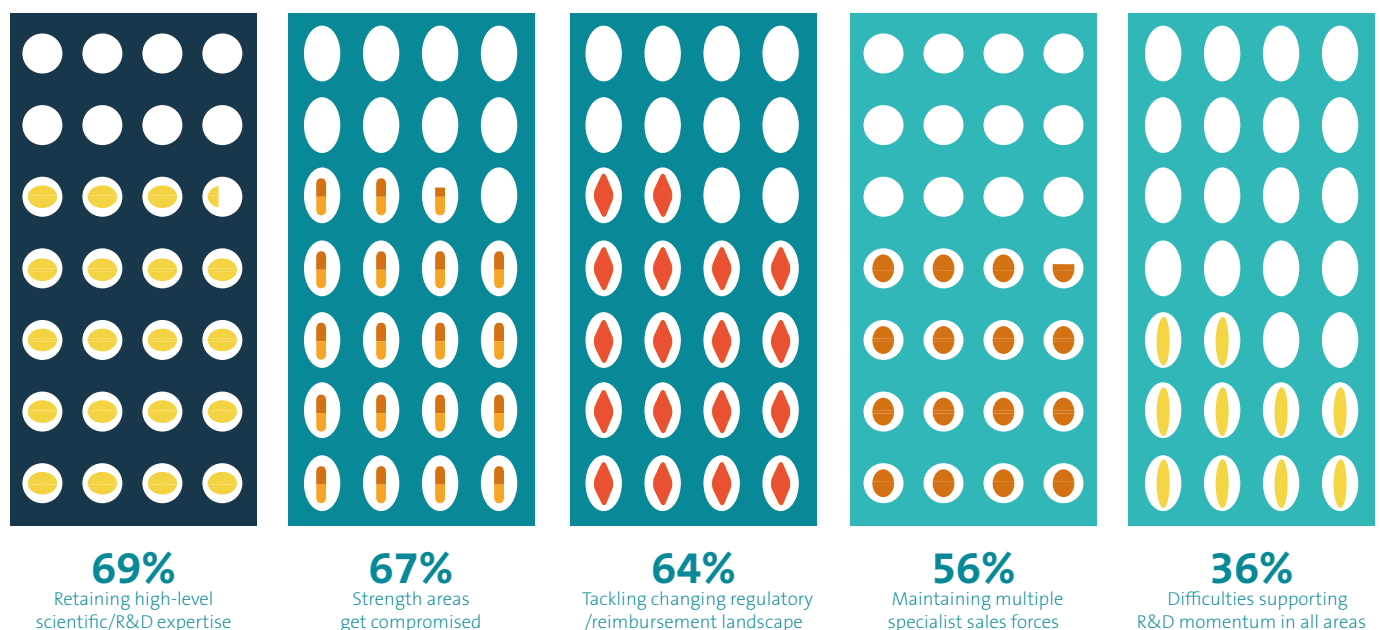
Nor is this only an issue on the scientific side of the business – more than half of the life sciences companies in this research (56%) are worried about the difficulties of maintaining and supporting a number of different specialist sales teams. There is also the issue of regulation – with a landscape that changes in different ways in different areas of the life sciences industry, managing that change across multiple areas of activities is highly challenging.

Given these difficulties, some companies are turning away from diversification, says Reed Smith's Carol Loeper. "In the past, you

may have had companies that had really diverse product offerings along different disease and specialty areas, but today we are seeing more focus on a particular area or disease state," she says.

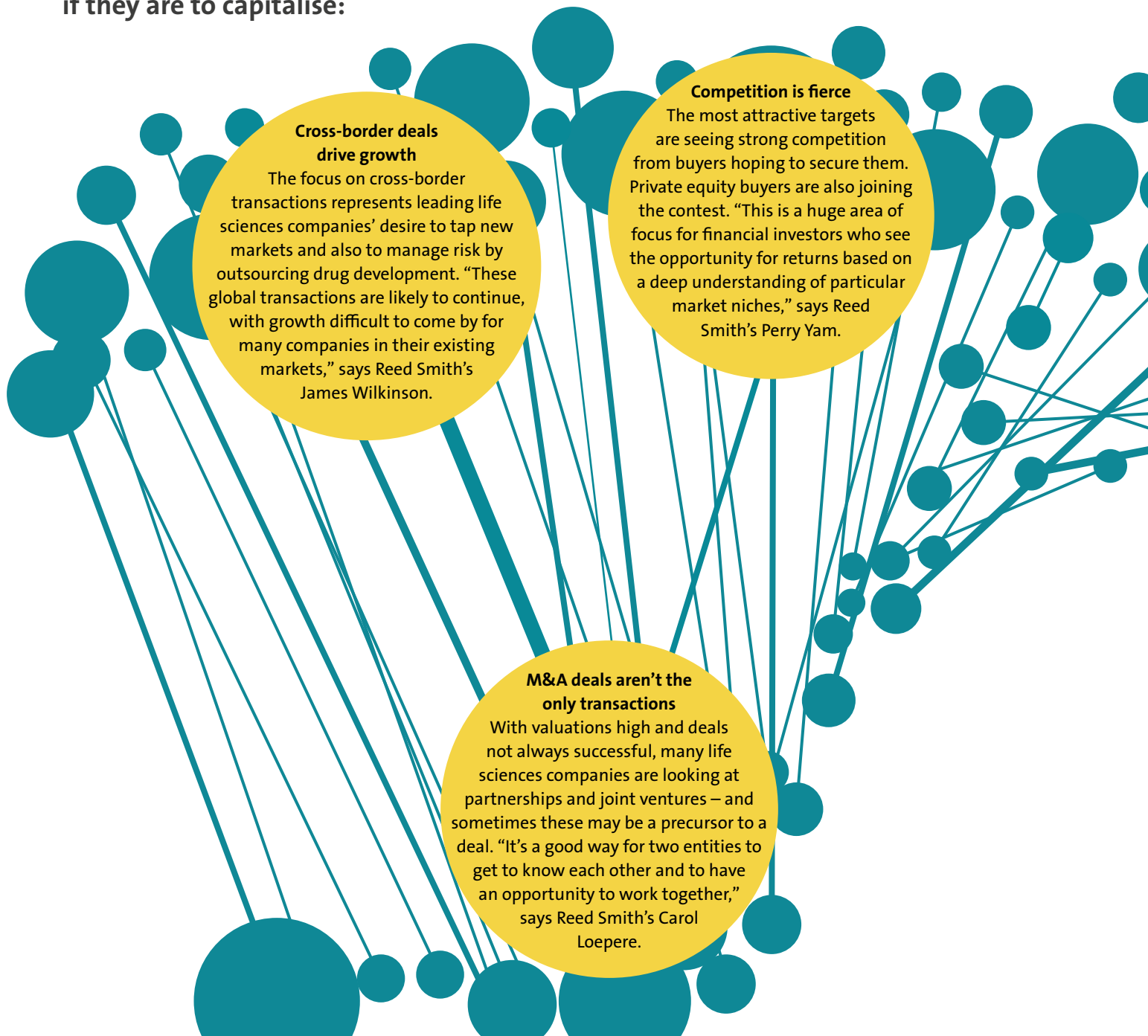
Nevertheless, some diversity will continue – and while personalised medicine is undoubtedly an area where life sciences companies continue to see huge potential, this area of their businesses will continue to operate alongside the traditional broad indication portfolios for the foreseeable future.

Figure 18: What are the major challenges in sustaining a broad drug portfolio? (Please select all that apply)



Conclusion: DNA of deals

The M&A market is booming and the outlook for the life sciences sector is extremely optimistic – particularly the acceptance of those within the industry of the part that personalised medicine will play in the future. However, there are six aspects that firms will need to take into account if they are to capitalise:



Cross-border deals drive growth

The focus on cross-border transactions represents leading life sciences companies' desire to tap new markets and also to manage risk by outsourcing drug development. "These global transactions are likely to continue, with growth difficult to come by for many companies in their existing markets," says Reed Smith's James Wilkinson.

Competition is fierce

The most attractive targets are seeing strong competition from buyers hoping to secure them. Private equity buyers are also joining the contest. "This is a huge area of focus for financial investors who see the opportunity for returns based on a deep understanding of particular market niches," says Reed Smith's Perry Yam.

M&A deals aren't the only transactions

With valuations high and deals not always successful, many life sciences companies are looking at partnerships and joint ventures – and sometimes these may be a precursor to a deal. "It's a good way for two entities to get to know each other and to have an opportunity to work together," says Reed Smith's Carol Loepere.



It's time to get personal

Personalised medicine offers benefits such as higher pricing, greater efficacy and improved compliance. "We certainly expect to see more life sciences companies move towards personalisation," says Reed Smith's Diane Frenier. However, broad indication drugs will continue to be the mainstay of many companies' portfolios for the time being.

Diversity suits some while specialisation appeals to others

Maintaining a broad product portfolio across several sectors is challenging and companies will need to manage M&A activity in this context; but some firms will manage risk in this way. "Businesses will inevitably reshape themselves following major deals, directing their businesses according to their strategic priorities," says Reed Smith's Brian Miner.

Technology can be a differentiator

Advances in areas ranging from big data to 3D printing offer life sciences companies new opportunities to grow. "Businesses are getting more strategic about where they want to focus – they have money on the balance sheet that they want to put to use for shareholders; they're looking for ways to add value," says Reed Smith's Diane Frenier.

Against this backdrop, and with a supportive financial environment and an improving economic climate – at least in some markets – the M&A boom in the life sciences sector looks set to continue. Deal volumes are on track to beat 2014, itself the busiest year for transactions since the financial crisis seven years ago.

However, the frenetic pace of dealmaking might be taken as a sign that the life sciences sector is confident about its future – that it is now investing in its future growth from a position of stability. But while there are undoubtedly huge opportunities for life sciences companies to exploit – and many businesses are excited about those opportunities – the M&A boom is also a story of uncertainty.

The difficulty is that it remains far from clear what the life sciences sector of tomorrow will really look like. Many companies are nervous about economic and political uncertainty. Competition is fierce. The regulatory outlook is muddled, particularly for personalised medicine, where many businesses are still not sure how big a bet to place on emerging technologies.

These uncertainties will take some time to resolve. In the meantime, transactions will continue apace, as life sciences companies work out where the pieces will fall for their strategies – and seek to build organisations that are fit for this purpose.

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