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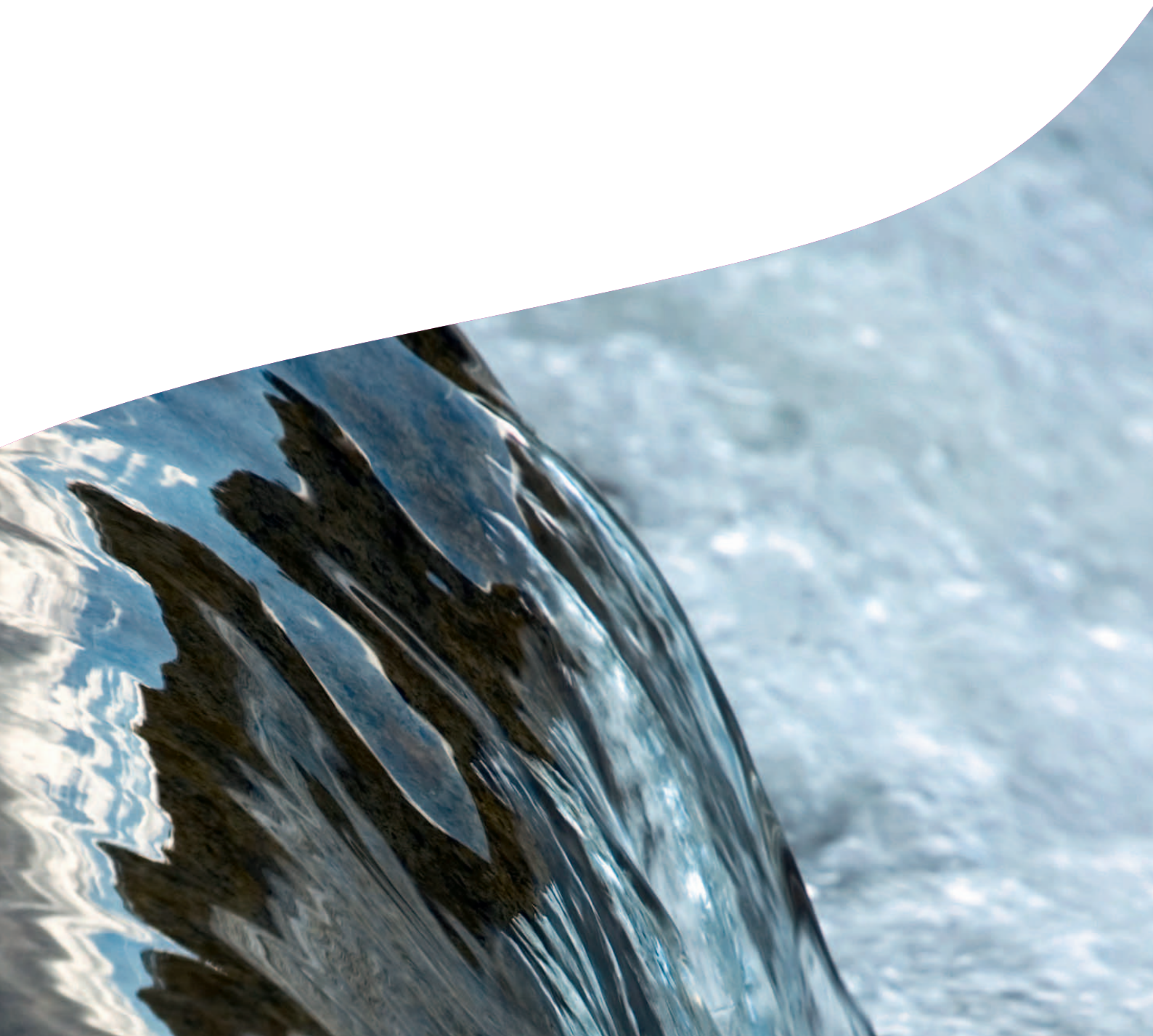
Life Sciences: Performing in the Downturn and Beyond

Vision & Reality, 8th Edition – Global Research Report by Capgemini Consulting



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Executive Summary

In some respects, the current economic climate has brought unexpected respite to the life sciences sector. After five years of trailing behind the Dow Jones Global Large Cap Index, the pharmaceutical index is now tracking it; certain pharmaceutical companies are once again on the M&A trail; rising demand for food and continued spending on core products mean continued growth for the agribusiness sector. Despite these signs of buoyancy, the crisis is also bringing new pressures: for example, pharmaceutical and agribusiness customers are less able to pay, while biotech companies are finding it difficult to obtain the funding for continued investment in R&D. These pressures mean that most life sciences companies are on the lookout for cost reduction opportunities.

However, the need to control cost is not new. The recession is just the latest of a series of influences necessitating better ongoing cost control. Life sciences will be fraught with profitability challenges for the foreseeable future because of deeper changes to the business environment: pharmaceutical companies, in particular, face patent expiries, limited late-stage pipelines, pricing pressures, tightening regulations and changing demand. Not all companies are identically situated in this regard: the agribusiness sector is still growing significantly, whereas the medical devices sector was hit harder and earlier than any other sector by cost pressures. Ultimately, however, all companies will face similar pressures.

Already, many companies are taking action to reduce and control costs across the three main Profit & Loss areas (Selling, General & Administrative; Cost Of Goods Sold; Research & Development). To date, however, most of their activities have been reactionary and transactional. To survive in the future environment, companies need to adopt more radical cost reduction strategies, and to transform themselves in ways that go well beyond cost considerations.

Some of the ingredients of this transformation vary by sub-sector, but there are common components. For example, many life sciences companies will need to adapt their internal organization, implementing new operating models that make it easier to deliver integrated product (and sometimes service) offerings to the customer. They must build the end-to-end capabilities required to deliver these integrated solutions, and develop deeper relationships with all stakeholders and industry partners. Finally, they must proactively set up risk management capabilities across the portfolio in order to manage major risks such as cash flow, supplier risk, customer risk and, in the case of pharmaceutical companies, drug approval and monitoring.

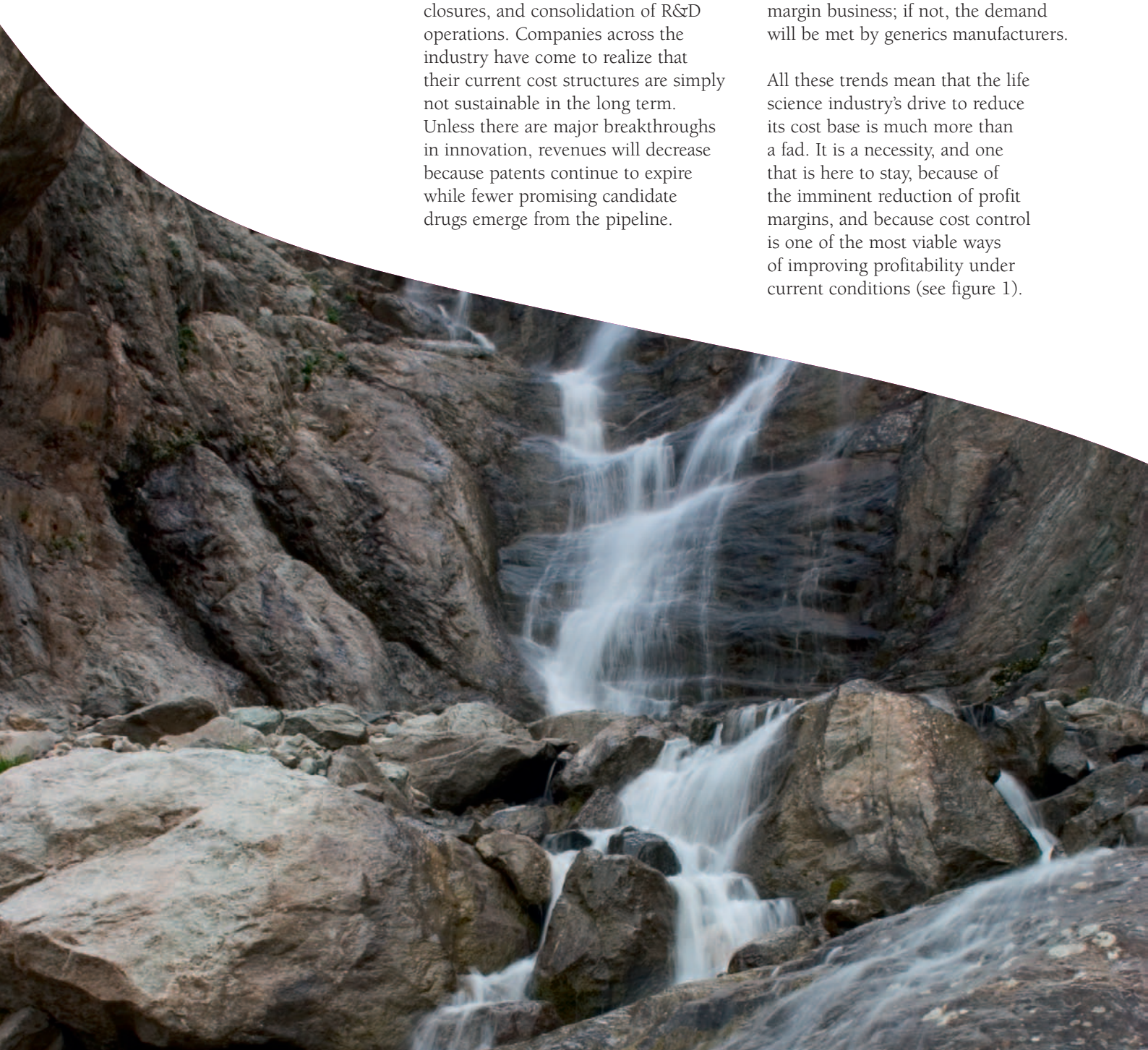
Our belief is that many of today's cost pressures are here to stay. The industry therefore needs to implement lasting changes, both to control costs and to adapt to wider changes in the business environment. This transformation will not be easy, and there is no one model that will work for everyone. The companies that succeed will be those that identify the transformational journey early and then ruthlessly drive its implementation. For the pharmaceutical industry in particular, failure to do so may mean that when the markets recover, the pharmaceutical index reverts to underperforming the global index because other boats can rise faster with the incoming tide.

1. Background to the Study

The downturn may have focused life sciences companies' attention on cost reduction, but it is certainly not a new topic for the industry. For years the industry has been discussing sales force reductions, manufacturing site closures, and consolidation of R&D operations. Companies across the industry have come to realize that their current cost structures are simply not sustainable in the long term. Unless there are major breakthroughs in innovation, revenues will decrease because patents continue to expire while fewer promising candidate drugs emerge from the pipeline.

Meanwhile, increasing pressure from government and third-party payers has increased demand for more affordable drugs. Manufacturers of branded drugs must decide whether they want to compete in this lower margin business; if not, the demand will be met by generics manufacturers.

All these trends mean that the life science industry's drive to reduce its cost base is much more than a fad. It is a necessity, and one that is here to stay, because of the imminent reduction of profit margins, and because cost control is one of the most viable ways of improving profitability under current conditions (see figure 1).

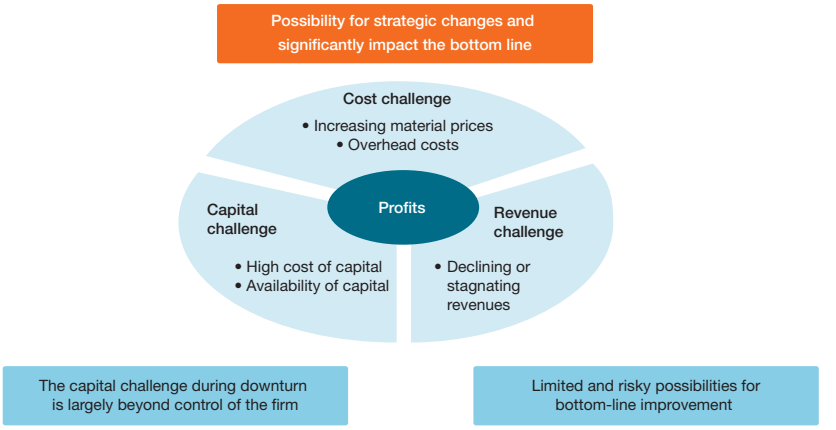


In these circumstances, lowering the cost base and transforming operations to improve performance become highly topical issues, and we have therefore chosen them as the subject for this year's edition of Vision & Reality. This report is the latest of a series of global studies, conducted and published annually by the Capgemini Life Sciences practice since 2001, to examine the issues most likely to impact our industry in the near future.

To achieve a rounded and detailed perspective on all types of cost initiatives, Capgemini has drawn on its global network of life sciences experts and their contacts. In-depth interviews have been conducted with industry executives representing pharmaceutical, biotech, medical device, and agribusiness companies in Europe and North America. To ensure insight into local nuances, these interviews took place in France, Sweden, Denmark, Germany, the United Kingdom, Switzerland, Poland, and the United States of America. In addition to the executive interviews, we incorporated our knowledge of the market, together with secondary research findings where appropriate.

Capgemini would like to thank all those who agreed to be interviewed for their generous participation.

Figure 1: Cost control is often the most feasible way to improve profitability



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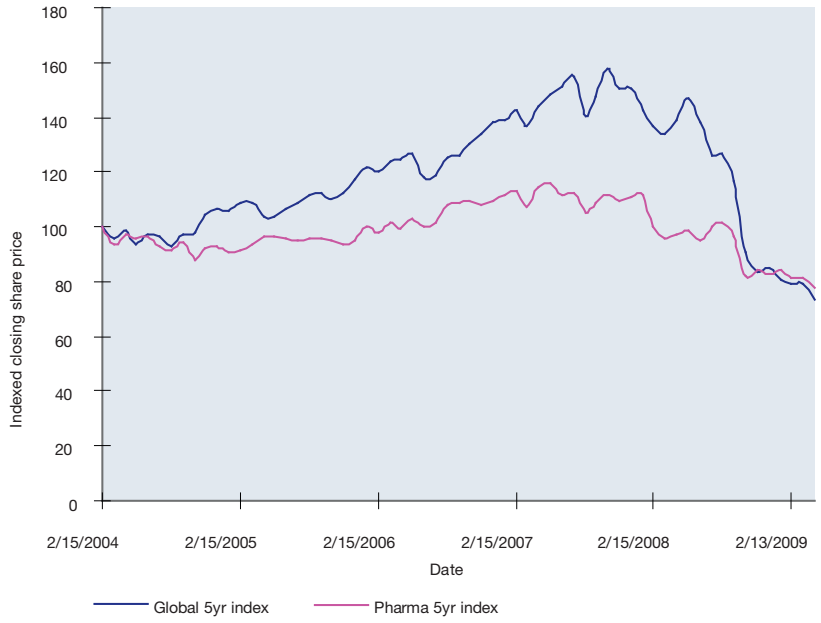
2. The Impact of the Recession – Good News and Bad

Our interviewees expressed mixed opinions as to whether or not life sciences companies are feeling the economic pinch so far. This section discusses how the recession has brought some respite to the industry, but at the same time is forcing many companies to look for greater cost savings and better return on their investment.

Figure 2: Global Large Cap Index, closing price (June 2004 - June 2009)



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2.1 The industry is weathering the downturn well so far…

To some extent, the life sciences industry has been faring reasonably well during the recession. In the five years to September 2008 the Dow Jones Pharmaceuticals index was significantly underperforming the Dow Jones Global index. Since September 2008 the gap has narrowed and the pharmaceutical index is now tracking the global index (see figure 2). (One could argue, however, that this convergence is more indicative of the fact that investors see the sector as a relatively safe place to invest during a downturn than of improved performance by pharmaceutical companies.)

We have also seen an increase in merger and acquisition (M&A) activity, and while this is more a response to the patent cliff than a direct implication of the financial crisis, it offers opportunities to those companies with cash to spare. Early in 2009, Pfizer made known its intentions to acquire Wyeth for $68 billion, and Merck announced soon afterwards that it would acquire Schering Plough for $41 billion. Roche also formally agreed to acquire Genentech for $95 per share at a total price of $46.8 billion in March. This was followed by acquisition of a number of small companies including Antisoma, BiPar Sciences, and Laboratorios Kendrick. Others on the M&A trail include sanofi-aventis and GSK.

2.2 …but the industry is not immune from economic stringencies

This relatively buoyant performance does not mean that the life sciences industry is not feeling any pressure as a result of the recession. Right across the industry, although interviewees disagreed about whether or not they were suffering just at present, the vast majority expected to be affected in the near future.

Perhaps the most daunting and imminent danger that emerged from the responses is a reduced ability to pay for the products of life sciences companies. As governments collect less tax revenue, and use increasingly large sums to prop up the financial services sector, they will have less money to spend on healthcare. Meanwhile, health insurance companies too are facing reduced revenues. In this way, even pharma – long considered recession-proof – is being affected by the downturn. With diminished cash streams, both public and private payers will be forced to tighten their budgets, and there are already signs that governments are doing so: several of our interviewees from pharmaceutical companies, especially those with significant business in developing countries, have been seeing slower cash collections. Lack of cash, combined with growth in demand, means that the switch to generics is likely to accelerate wherever there is an alternative to the branded product.

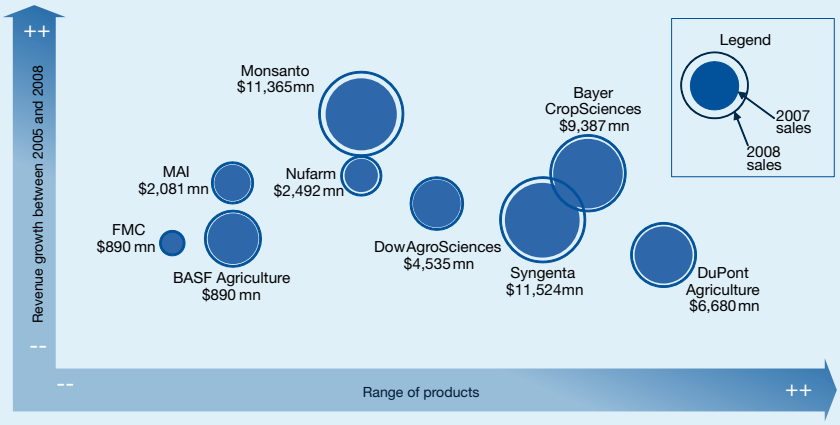
Several interviewees agreed with media predictions that branded OTC drugs will suffer the effects of the economic crisis long before other pharma products do. Patients are increasingly experiencing difficulty

The agribusiness experience

Within the life sciences industry, some sectors are proving more immune to the effects of the recession than others. The agrichemical industry, in particular, continues to grow. On the demand side this growth has been driven in part by the increase in global population combined with the shift towards protein-rich diets in emerging countries. Growing demand for alternative energy sources, combined with limited availability of arable land and water, can be expected to drive increased farm productivity, implying increased usage of agrichemicals and GM seeds.

The strong demand for their products has also been helped by the record levels for world commodity reference prices, with a dramatic increase since 2005 - 2006 which is partly the result of adverse weather conditions in major grain-producing regions. The higher the commodity prices go, the lower the relative value of the subsidies the farmers receive for not growing. Hence crop growing becomes more attractive to farmers and their demand for agrichemical products increases. Almost all agrichemical companies have seen a period of significant growth from 2005 to 2008. Figure 3 shows the top agrichemical companies and their sales growth in this period between 2005 and 2008.

Figure 3: Growth and portfolio profiles of the major players in the seed and crop protection industry



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Note that all players in this industry are growing. Both Monsanto and Bayer are outpacing the growth of several of the other players, with a decreasing gap between Monsanto and Syngenta who compete for market leader position.

The OECD suggests that commodity prices – in nominal terms – over the medium term will average substantially above the levels that prevailed in the past 10 years, and therefore we should expect agrichemical revenues to continue to rise.

in paying out-of-pocket which is the case for both co-payment and for branded OTC drugs; as a result, many have begun reducing or dropping their diabetes or cholesterol treatments. Branded drugs such as Prilosec[1] are being passed over in favor of less expensive store-brand competition.

From an agribusiness perspective, too, there is concern that customers (often farmers who have already received the products) will not be able to pay. This concern is leading some companies to adopt enhanced risk management strategies, such as receiving payment based on a percentage of crop sales, or even accepting payment in kind (that is, the farmers are allowed to hand over a portion of the crops they have grown in lieu of cash).

Biotechs, too, have been among the first to suffer from the recession. Decreased availability of venture capital funding has already hampered companies' ability to pursue new projects and products. In November 2008, the Biotechnology Industry Association disclosed that in the U.S., where the bulk of these companies reside, 91 biotechs were operating with less than six months' worth of cash on hand. Out of the 370 public biotechs in existence at the time, 140 had less than one year's cash[2]. Many are likely to fail unless they are able to come up with additional sources of funding to run their businesses.

As well as experiencing difficulties themselves, life sciences companies may also be indirectly affected by the difficulties faced by their suppliers and distributors. Several companies cite distributors such as German wholesaler Phoenix Pharmahandel as partners that have become casualties of the world economy. These events make pharma companies more cautious about how much money they have outstanding with partners like these.

In the agribusiness sector, too, certain beleaguered chemical suppliers may need financial assistance if they are to ensure consistent supply: according to several interviewees, currency devaluation has driven more than one distributor to request that customers agree new contract terms under which they will share in the risk of currency swings. The situation is comparable for the other players in life sciences: "sole sourcing is becoming particularly risky," as a head of supply chain at a U.S. biotech points out.

Renegotiations between customer and supplier are taking place to reduce costs and manage increased market risks. In addition, to ensure continuity of supply, it is important for customers of these companies to be aware that they might have to take action to protect critical suppliers from going out of business.

2.3 Companies' response to the recession

How companies respond to the recession depends to a great extent on how long they think it is likely to last. Most interviewees acknowledge that it will take some time for the economy to recover, but do not believe that the downturn is anywhere near permanent. All but a handful of responses point to recovery within the 12-24 month time range (figure 4).

When asked if the economic situation is causing their company to do anything differently, a slim majority, 57%, says "no". Those that answer in the negative usually add that they already have cost-cutting initiatives as part of previously defined strategic plans. Interestingly, though, many qualify their "no" response, saying that, while they are not doing anything differently, they are increasing the scope or speed of initiatives that were already in place before the downturn.

Not surprisingly, respondents who say "no" (that is, who say they are not doing anything differently because of the economic situation) are largely representatives of large to mid-size pharmaceutical companies. Companies that have more cash on hand also have more flexibility to stick to their pre-defined strategic ambitions despite troubled markets.

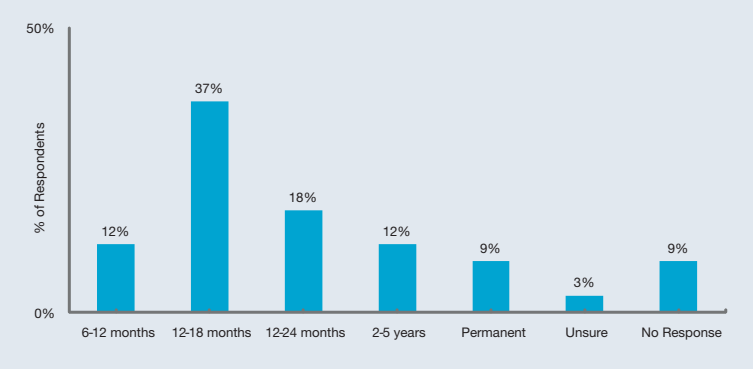
By contrast, the other 43% of interviewees who say "yes" (that is, they are doing something different to cope with the economic situation), predominately came from mid to smaller-size players (pharmaceutical,

1 "AstraZeneca Stumbles", Forbes.com – 1/29/2009
2 "Biotech funding down to last drops Investments for medical breakthroughs in jeopardy", Bruce Japsen, Blue Cross Blue Shield Web Site, 11/23/2008, accessed 3/19/2009

biotech, and medical device). The actions they are taking are mostly transactional rather than strategic. Cuts are being made to personnel through hiring freezes, limits to the use of temporary staff, and more layoffs. Administrative and general expenses are being more closely watched, with special attention paid to travel as an area for quick-hit savings. International trips are being reduced, more managers are being pushed back to economy class, and fewer are allowed to hire private drivers to and from the airport.

All of the effects of the recession, positive and negative, put increased pressure on life sciences companies to contain their costs, if only so that they have cash available for necessities such as absorbing bad debts, bailing out suppliers or acquiring competitors. As we shall see in the next section, however, the impact of the recession is just the latest of a series of reasons why life sciences companies need to get costs under control.

Figure 4: Expected duration of impact of recession



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Other responses to the recession

Even where companies have not taken economy-induced actions so far, they may still be building contingency plans in case the recession lasts longer or goes deeper than expected. In the words of one medical device company board member, "Every company should have a plan on its desk ready to implement in case the situation continues to get worse."

What is included in those plans? It is evident from our discussions that companies are making provisions for risk: for example, they will try to understand the future by developing a range of scenarios combining different assumptions about market growth, supplier shortage and customer cash flows – all factors that lie outside their control – and modeling how their market will change under each set of assumptions. This thought is summarized by one director of strategy and business development: "We are adapting to manage the extreme scenario."

"The current level of uncertainty necessitates prudence," as one agrichemical supply chain head put it: therefore, companies are re-evaluating their current corporate objectives – such as growth ambitions and entry into new markets – to make sure they still work in light of economic conditions.

From a structural perspective, many interviewees report a shift toward streamlining decision-making processes. Some companies are conducting full organizational reviews to flatten the reporting structure. There is faster top-down decision making in many companies, with more decisions being made at the global level. At the same time, accountability for results is being placed further down in the organization, where the relevant actions are executed: for example, at sales management level.

3. Industry Drivers for Cost Reduction

As we have seen, the economic crisis has given new impetus to the life science industry's efforts to control costs. However, the need to reduce costs is not new and is certain to outlast the recession, since it arises from profitability challenges that are now endemic to the industry. Here we examine first the factors that have triggered cost-reduction efforts to date, and then some additional drivers that will increase the motivation to cut costs in future.

3.1 Current drivers: Patent expiries and lack of products in late-stage pipelines

In this subsection we look at what our interviewees identified as the top two drivers of their cost reduction efforts to date: firstly patent expiries (with associated pressure from generics), and secondly the lack of significant new products in companies' late-stage pipelines.

It is estimated that approximately $100 billion of pharmaceutical sales could be lost between 2007 and 2011 as a result of patent expiry and competition from generics[3]. Major pharmaceutical companies such as Johnson & Johnson (J&J) will stand to lose up to 55% of revenues to patent expirations over the next five years. In 2012, the year of the "patent cliff," patent losses are expected to hit a record high, with the equivalent of approximately 8% of prior-year sales at risk from generics[4]. Worse, as blockbusters go off patent, payers will require patients to switch to generic products. In 2007, the use of generic prescriptions rose to an unprecedented 61% of total activity in the US, and this trend is expected to continue[5].

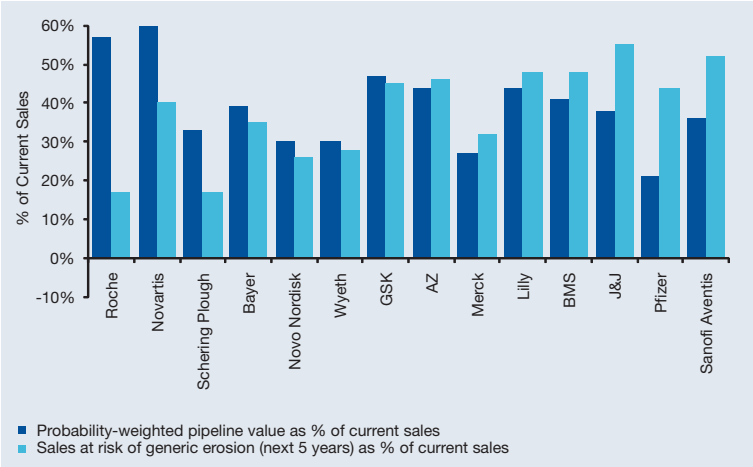
Meanwhile, the seriousness of the pipeline problem can be judged by the number of new molecular entity (NME) approvals made by the FDA, which fell to a 10-year low in 2007 with only 16 approvals made. In 2008 there were 22 approvals, but the overall picture is of significant decline in an industry that once boasted 53 NME approvals in a single year (1996)[6].

The paradox is that pipelines are full of promising candidates, but these are mostly in the earlier stages of development. While the number of candidate products in phase III continues to grow, the number of new launches has decreased by 150 when comparing 2008 to 1998[7]. This pipeline profile means not only that products are not coming on to the market fast enough to replace those whose patents are expiring, but also that companies have issues in funding the development of promising drugs. Considering the tremendous cost of developing a product, companies need to select the compounds to go forward with great care, as we shall discuss in section 4 of this report.

To summarize, patent expiries (with subsequent loss to generics) and the pipeline profile conspire to make the top line hard to grow. For companies such as sanofi-aventis, J&J, and BMS, the loss to generics is likely to exceed the value of their pipeline over the next few years, as shown in figure 5. The fact that it is so hard to grow the top line under these conditions is a major reason why companies like these are increasingly seeking cost savings.

3 "$100 Billion of U.S. and European Pharmaceutical Company Revenues Threatened by Generic Drugs Forecasts URCH Publishing", BusinessWire, 2/20/2007, accessed 2/23/2009
4 "European Pharmaceuticals – Where to Hide", Karl Heinz Koch and Odile Rundquist, Helvea SA, October 2008
5 "Verispan Year in Review – 2007", Tara Hamm, Presentation to Association of Medial Media, 6/12/2008
6 "NME Approvals up a Tic in 2008", Matthew Arnold, Medical Marketing & Media, 12/30/2008
7 "Bio/Pharmaceutical R&D Statistical Source Book: 2008/2009", Parexal, June 2008

Figure 5: Pipeline potential versus generic risk exposure among major pharma companies in the U.S. and EU



Source: "European Pharmaceuticals – Where to hide?", Helvea, October 2008 (Note: data is for 2008-2013 and predates Pfizer and Merck merger announcements)

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3.2 Future drivers: Changing demand, pricing pressures and regulatory environment

As shown in figure 6, interviewees indicate that future cost-cutting initiatives will be driven by three additional factors alongside the lack of products described above: these are changing market demand, pricing pressures and tougher regulatory environments.

Changing market demand

Generics represent a major segment of the market (60% of volume in the U.S.) and will be even more important in the future. At the same time, the aging population and the spread of a western lifestyle (together with its associated ailments) to other parts of the world are fundamentally altering the market, as is the growing focus on wellness and prevention. As a consequence, the first major driver of future cost reduction uncovered by our study was the fact that changing market demand is causing industry decision makers to restructure their cost bases in preparation for the new therapies and customers of the future.

Many interviewees pointed out that personalized medicine, once a far-off utopian prospect, looks likely to become a reality within the next decade. In the words of one executive at a mid-size pharma, "Today, despite some progress with targeted therapies, we are still working in the traditional 'one size fits all' model: one capsule, one tablet for all patients. Personalized medicine will not only impact R&D but will also have a huge impact on the supply chain."

The first step on the road to a more targeted therapeutic approach will be to develop new diagnostics: some to identify the individuals who will benefit from a drug, others to analyze whether or not a drug is working. As we shall discuss in section 4, companies will also need to decide if they want to cover the new holistic perspectives of diagnostics, prevention and cure in addition to treatment as we know it today. For those who decide to go down this route, significant capital will need to be redirected towards re-designing

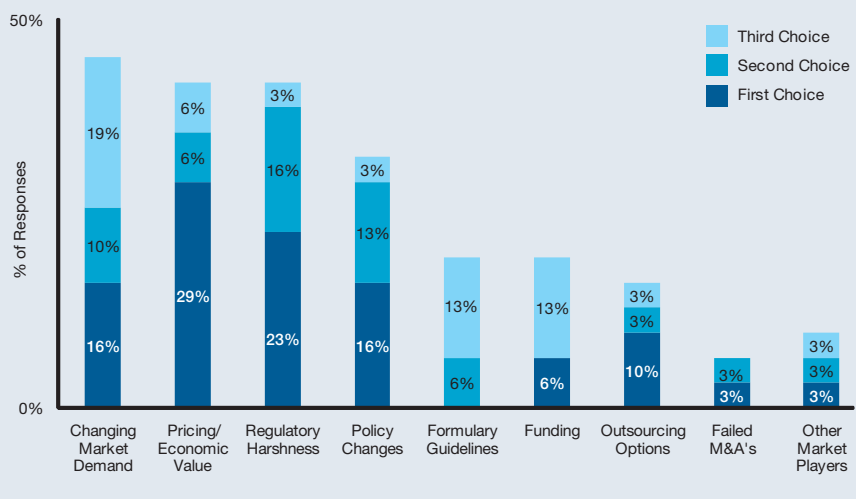
R&D to move away from the "one bug, one drug" model; the money will probably have to come from lower-priority projects and from cost reductions elsewhere.

Price squeeze

Growing price pressures will become a key driver for cost reduction. Many interviewees mentioned the rise of an outcomes-based approach to reimbursement on the part of both public and private payers, with wider adoption of strategies already seen in many European countries. Payers are already pressing manufacturers to lower prices on standard products, and are willing to pay premium prices only for therapies that deliver a significant medical benefit when compared to alternatives. In the U.S., for example, insurance companies are increasingly giving reimbursement funding only to truly innovative products. In countries where most healthcare is provided by the state, governments are faced with escalating demand for healthcare plus constrained budgets.

Even the U.S. is likely to be affected by government pressure on prices: President Obama has expressed his determination to make cheaper drug options more easily and widely available on the American market[8]. At the same time, we are increasingly seeing requests for additional comparative effectiveness data. Given the exorbitant cost of new agents, many more U.S. healthcare stakeholders will want to understand the overall benefit and value of a drug or treatment. This is true not just of payers but also of patients; the implications of funding them will be felt by all.

Figure 6: Trends expected to influence future cost-cutting initiatives



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These trends will drive more companies to reassess their product portfolios, applying a more critical attitude to investments, and doing so earlier in the development process. In February 2009 Pfizer announced that it would drop two drugs in late-stage development – one for anxiety and one for fibromyalgia – after trial data showed they would not work much better than existing treatments[9]. A "fail fast and cheap" mindset can save the industry unnecessary investments, refocusing resources on projects with greater potential, as we shall see in section 4.

8 Barack Obama Campaign Website, http://www.barackobama.com/issues/healthcare/, accessed 3/19/2009

9 "Pfizer cancels development of two late-stage drugs", Reuters, 2/24/2009

Not all companies are identically situated in this regard: for reasons discussed in the previous section, the agribusiness sector is still growing significantly (as the pharmaceutical sector was in the 90s), but in future it will surely encounter similar margin pressures to those currently faced by pharmaceutical companies. On the other hand, the medical devices sector was hit harder and earlier than any other sector by cost pressures.

An intensifying regulatory environment

In the near future, life sciences executives expect to face harsher regulatory environments, particularly when it comes to demonstrating efficacy and safety. This prospect is just as worrying to our respondents as pricing pressures.

As already noted, in order for companies to obtain reimbursement, treatments will have to prove superior value, which will necessitate additional clinical outcome trials. There have also been a growing number of instances where products have been withdrawn from the market, or cancelled at a late stage of development, owing to safety concerns. Industry representatives know they will have to satisfy more exacting safety regulations in the future, again necessitating extra trials. These additional regulatory requirements will unavoidably increase development costs, forcing companies to look for savings in other areas.

The FDA Amendment Act of 2007 contributes to this picture of intensifying regulation. It gave the FDA the authority to require manufacturers to complete risk evaluation and mitigation strategies (REMS) for the products they market. From 2008 until May 2009, the FDA required selected manufacturers to complete REMS for 52 products. In the majority of cases these REMS consisted of a medication guide; however in a few cases they also included communication plans, precautions to ensure safe use, and implementation systems. It can be seen that planning and preparing these REMS can become a very significant program, and

one that manufacturers will need to manage better in future.

Along with regulatory changes, voluntary codes of conduct are increasingly impacting manufacturers' behavior in the marketplace. These codes are limiting the information that drug companies can use for promotion, the way they can interact with health care professionals and their ability to run direct-to-consumer (DTC) campaigns, among other commercial activities. In the UK, the ABPI's newly published code of practice[10] requires physicians to declare any collaborations with the industry in topic areas about which they are writing or speaking in public; in fact, the code strongly encourages companies to put the professionals with whom they work under a contractual obligation to make these disclosures.

3.3 Cost reduction pressures are here to stay

As we have seen, although companies may perceive their cost reduction requirements as arising from the recession, in most cases they are rooted in industry trends, and therefore can be expected to remain relevant long after the upturn. In the next section we discuss what constitutes an effective approach to cost reduction and evaluate how well current initiatives measure up.

Medical devices: ahead of the cost reduction game?

Downward pressure on prices is inexorable, but so far some sectors have been affected more than others. The medical device sector has attracted increasing attention from health policy makers in recent years, and although it has experienced steady growth during the last decade, it has recently been hit hard by cost pressures arising from healthcare reforms, especially in larger, more mature markets such as Germany, France and the U.S. These pressures have resulted not only in cost reduction programs but also in consolidation. The remaining players tend to leverage global markets more and to target their innovations at a smaller number of carefully selected therapeutic and treatment areas – those where good levels of reimbursement can still be expected.

Current healthcare reforms tend to focus on containing the cost associated with medical innovation and technology. It is expected that one focus area for healthcare reform in the U.S. will be to reduce the number of tests performed, which will impact the medical device industry negatively since each test often uses medical devices, as well as diagnostic equipment. There is no doubt that the medical device industry in future will be tasked to provide more evidence on health economic benefits; this point was again confirmed by our interviewees.

10 Code of Practice, ABPI, 2008.

4. Cost Reduction Efforts – Past, Present and Future

In this section we discuss what cost initiatives should look like if they are to be effective for the long term; in doing so we also describe some current initiatives. Our discussion is organized around three familiar cost "buckets": COGS (Cost Of Goods Sold), R&D (Research & Development), SG&A (Selling, General & Administrative). We shall look at the SG&A bucket in two parts, the first covering commercial functions and the second shared services and outsourcing. Although many of the examples mentioned in this section are from pharmaceuticals, the same principles often apply to biotech, medical devices and agribusiness.

Under each of these headings we consider three imperatives that we believe life sciences companies must embrace if they are to remain competitive in the future.

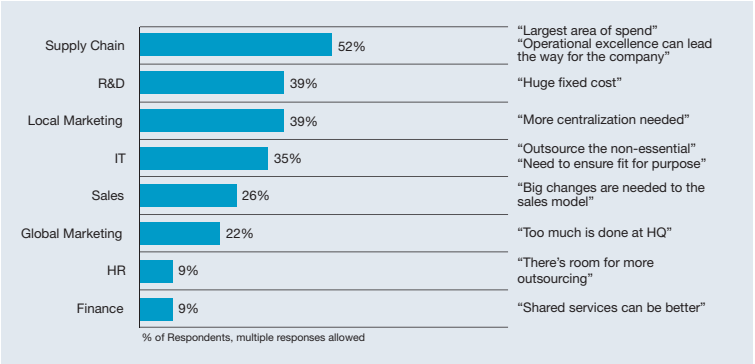
1 **Fix the basics** Here we seek to lower costs by challenging a company's current spending patterns. The focus is mainly on improving the bottom line.

2 **Search for economies of scale** This imperative drives companies to make better use of their assets, and to spread risk over a larger number of stakeholders.

3 **Innovate to save costs and grow the top line** In a rapidly-changing business environment, innovation is the key to remaining relevant so that products bring in the requisite revenue levels. Taking advantage of innovative technology and business approaches is also vital if costs are to be kept under control.

Capgemini sees these three imperatives as critical for surviving in a world of reduced margins; they make it possible for a company to move beyond transactional cost reduction and start getting more from less.

Figure 7: Respondents' views on departments with greatest cost reduction opportunities



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When asked which function within the business presents the greatest opportunity for cost reduction efforts, the interviewees in our study ranked "supply chain" first (see figure 7). According to one biotech supply chain head, "We are looking to lead the way with operational excellence and Lean manufacturing and hopefully to influence the rest of the organization to follow." For this reason, we address COGS first.

4.1 Cost reduction in COGS

This bucket contains direct costs associated with production of goods sold, including raw materials and staff costs.

Fixing the basics in COGS

Areas to consider when fixing the basics are summarized in figure 8.

The supply chain, in particular, is an attractive area for cost reduction efforts. The benefits are substantial and can also be achieved relatively quickly; for pharmaceutical companies the blockbuster decade allowed supply chain inefficiencies to creep in, with companies striving to get each product to market as quickly as possible almost regardless of cost, and then producing as much of the active ingredient as capacity allowed, without accounting for fluctuating demand.

The industry is not discovering demand planning, sourcing or Lean manufacturing for the first time. However, compared with other industries, it has significant potential for improvement. It is only recently that pharmaceutical companies have made supply chain optimization the focus of their COGS improvement activity, and they are still in the process of dealing with complexity built up over many years. (At the same time, in the case of biological products they are having to adopt supply chains that are intrinsically more complex, characterized by processes and analytical methods that cost more and are harder to master, products with shorter shelf lives, cold distribution chain, and so on.)

There are a number of areas for simplification and/or optimization. One option to consider is tax optimization of the manufacturing network: however in pharma factors to take into account when doing so include the potential impact on market access (in some countries, multi-national corporations are bargaining for market access with location of plant). Other options for simplification include specialization

Figure 8: The Capgemini Supply Chain Assessment Framework breaks down the supply chain into four main areas

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of sites by product type and limitation of the number of SKUs, which have often grown explosively as a result of lifecycle management decisions and country-specific requirements. Companies can also re-evaluate their manufacturing and quality control (QC) processes, and their outsourcing arrangements, but especially in pharma they should where possible avoid the need to rerun clinical trials or submission of complex product variations.

Despite considerable efforts in recent years, then, there are still significant opportunities to fix the basics and generate savings across the four areas Plan, Buy, Make and Move in the life sciences industry.

Plan: Historically, high margins hid costs inefficiency. By conducting more thorough demand and supply planning, companies can reduce costs while maintaining efficiency and flexibility. Demand planning involves understanding the consumer or customer, and hence assessing true market demand. It then becomes possible to plan supply, drawing on a comprehensive understanding of network capacity and lead times throughout the supply chain.

Historically, the industry has been built on the principle "never miss a sale". Now, however, the emphasis has shifted away from product availability to reduction of excess inventory at all stages of the supply chain. Clearly, success here is likely to depend on more accurate matching of demand and supply: effective sales and operations planning (S&OP) is important, and should interact closely with marketing and sales plans. This matching of supply and demand could be even more important in a future with lower product volumes and, perhaps, even greater demand fluctuations.

Buy: To achieve lasting cost reductions, companies should focus on supplier relationship management, using the disciplines of procurement, strategic sourcing and supplier risk management.

An approach that is both popular and viable in the current economic climate is renegotiation of existing contracts; however, for active ingredients and certain raw materials, caution is required. Risk management revealed to one company that a particular supplier was the world's only manufacturer of a certain active ingredient, the loss of which would have an impact of nearly $500m on its sales. The company accordingly switched from trying to negotiate further discounts with this supplier to ensuring continuity of supply. A complication exists for pharma, where these suppliers have to be named in the registration file, which means that this issue must be addressed as early as the product development phase.

Multi-sourcing is not necessarily a straightforward solution to securing supplies. One pharmaceutical company used two sources of PVC for blister packs, but found that, even though the PVC was bought on a single specification, switching from one vendor's supply to the other required lengthy tuning of the packaging lines.

Make: In addition to closing redundant facilities and considering outsourcing, companies should improve their manufacturing processes by implementing process excellence and/or Lean manufacturing programs. While respondents' interest in these initiatives has been increased by the recession, there are long-term opportunities to improve supply chain efficiency while maintaining or improving service levels. Doing so implies that QC and Quality Assurance (QA) document flow must be included in the scope of any process improvement initiative.

Many companies have started to move manufacturing to lower-cost locations, in some cases setting up their own manufacturing capabilities off-shore. While most are obtaining significant

cost benefits, some companies are also noticing drawbacks – such as a need to reinforce quality controls, especially when they use outside partners in lower cost base countries to do the manufacturing (for pharma this has been typified by the well-reported Heparin case[11]). Questions have also been asked about the potential societal, regulatory and environmental impacts associated with some offshore facilities: areas of concern include use of child labor and non-compliance with environmental policies or even with current Good Manufacturing Practices (GMPs).

Move: When it comes to transporting and delivering their products[12], companies must look for opportunities to consolidate the supply chain and rationalize stock holdings. Especially in pharma, manufacturers are questioning whether the classic logistic channels involving wholesalers and distributors are cost-effective, and are considering ways to reduce their numbers, or in some cases to bypass them altogether. For example, in Europe some pharmaceutical companies are experimenting with using third party logistics providers to sell and deliver products directly to pharmacies. This practice avoids the pools of inventory associated with the wholesale model, increases supply chain responsiveness and also helps life sciences companies recapture some of the margins currently paid to wholesalers. Other upcoming programs include direct-to-patient distribution.

However, certain countries look unlikely to allow direct sales because they suspect it limits the possibilities of parallel import, which allows drugs to be obtained at lower cost: certain governments, like Germany's, are therefore trying to mandate the use of wholesalers. (The public interest argument for parallel imports is challenged by the fact that direct sales and delivery could help to eliminate potentially dangerous counterfeit drugs from the supply chain; the debate continues.)

Where local regulation permits it, consolidated distribution allows rationalization of stock. If the company limits the number of wholesalers or distributors authorized to handle its products, then stock is held in fewer places and is much more visible; demand can also be better understood, an especially relevant point for OTC drugs where volumes are high and margins low. In this way, consolidated distribution allows the company to make better-informed decisions on safety stocks and production levels and hence achieve a lower cost base. A trade-off should be noted here, though: using fewer wholesalers might jeopardize market share, which is usually the more important battle.

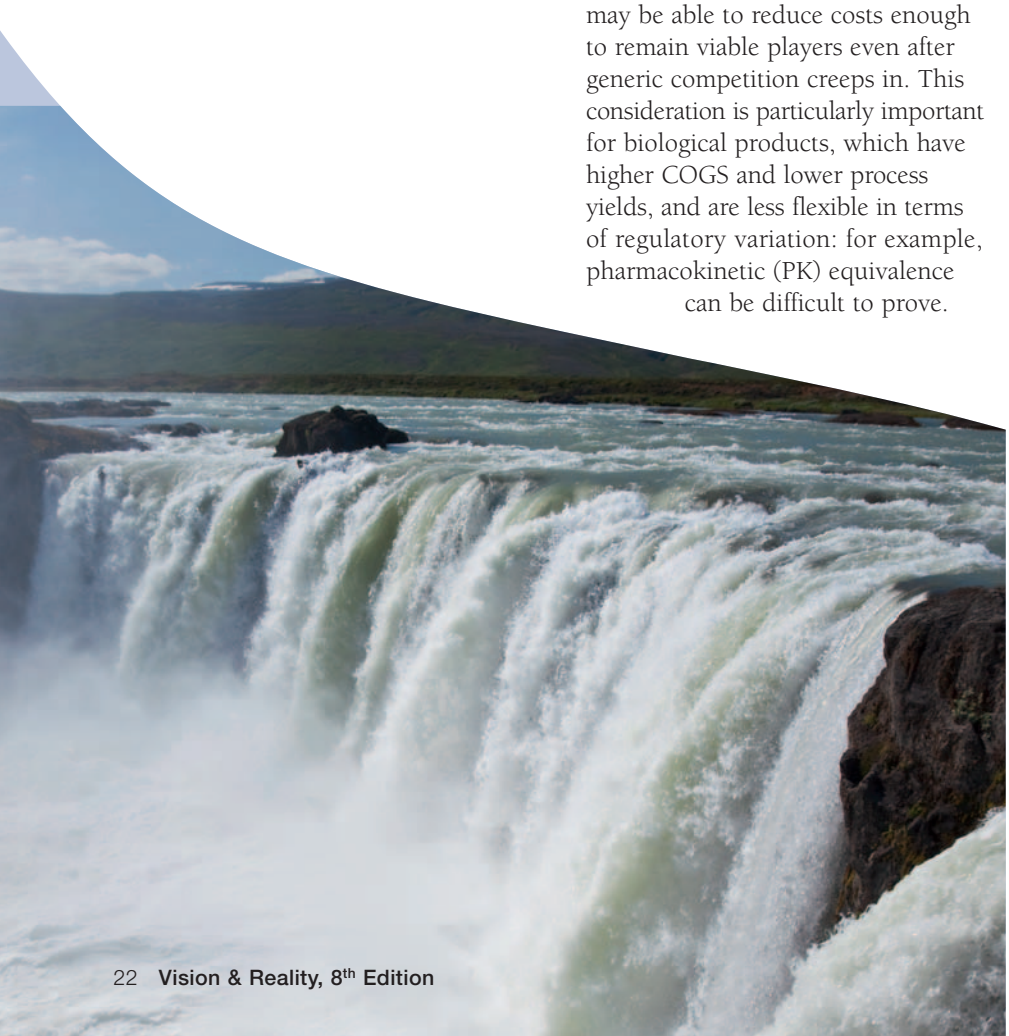
Overall: As well as improving the supply chain for existing products, patent holders should seek to optimize COGS early in the lifecycle of each new product in order to increase profits while the product is still patent-protected; later, this optimization will also help it continue to generate revenue when it goes off patent and

Our engagements often uncover optimization opportunities in several of these areas for a single product. With one client, we undertook a profit recovery initiative to prolong the life of a product that had returned diminished profits for several consecutive years and was projected to decline further. We found that profitability could be improved by between eight and 14 percentage points over a five-year period, largely through measures to increase manufacturing productivity ("make") and reduce distribution costs ("move"). We identified and initiated these improvements in just a few months.

11 Supply Chain Digest, March 18, 2008: "Global Supply Chain: Monitoring Quality in China isn't Easy, as Heparin Problem Shows"

12 While the "move" costs of the supply chain appear in the SG&A portion of companies' accounts, it makes sense to discuss all supply chain issues together, which is why they appear under the COGS heading

has to compete against generics. While this early intervention is probably the best way to fix the basics, it will require a revolutionary shift in mindset. Life sciences companies need to learn from other industries, such as consumer goods, where the focus is on achieving the lowest possible COGS – a radical departure from the "blockbuster" model which is designed to bring high volume, high margin products to market as quickly as possible. A relatively minor investment early in the life of the product can optimize supplier sourcing, manufacturing locations and processes (including assays (QA/QC)), and distribution networks. In this way the company may be able to reduce costs enough to remain viable players even after generic competition creeps in. This consideration is particularly important for biological products, which have higher COGS and lower process yields, and are less flexible in terms of regulatory variation: for example, pharmacokinetic (PK) equivalence can be difficult to prove.



Economies of scale in COGS

Economies of scale can be found in several areas. In the **buy** area, strategic sourcing will provide opportunities to negotiate discounts based on volume. In the **make** area, either after a merger or when productivity improvements have been achieved, it makes sense to consolidate manufacturing activities to gain economies of scale in production. Increasing the company's reliance on contract manufacturing lets you share in the contractor's economies of scale, obtained by consolidating the requirements of several other customers with your own. In the **move** area, as we have seen, some companies are looking at using third party logistics to bypass wholesalers; an additional benefit here is to share in the economies of scale associated with the high-volume activities of the logistics providers.

Innovation in COGS

The biggest potential for innovation with respect to COGS lies in the application of Lean to business processes in all areas of the life sciences supply chain. By looking at the processes, and the supporting organization, from the perspective of the customer, and considering what it is that the customer values, we can strip away everything that the customer does not value, releasing large amounts of labor or latent capacity and dramatically reducing costs. Because it drops cash out quickly to the bottom line, this approach is very attractive. However, Lean initiatives tend to disappoint if they focus exclusively on processes. To succeed, Lean requires a people-centered approach such as Capgemini's **Be**Lean™, which can deliver productivity improvement of 20% or more. For more details please refer to our paper "How

to implement Lean successfully and deliver results that last"[13].

In the **buy** area, creativity in forming strategic supplier relationships makes it possible to reduce costs without disadvantaging or alienating the supplier. The aim should be continuous improvement of supplier performance and proactive management of business relationships. Partner collaboration portals or EDI (Electronic Data Interchange) can increase the accuracy of capacity information and avoid the delays and costs associated with manual interaction.

Innovative approaches to decision support can help companies achieve end-to-end supply chain improvement, by using software models to de-risk activities like optimization of industrial operations, productivity and planning, and Lean supply chain management.

In the **make** area, technology is enabling improvements in a range of areas including QA, where we are seeing a move to Process Analytical Technologies (PAT), developed by the FDA and the industry as part of the work on Good Manufacturing Practices (GMP). PAT uses technology (such as statistical and process analysis software) to validate that each batch coming off the line meets the specification. Since batches no longer need to be warehoused pending QA, PAT reduces manufacturing costs as well as improving lead time.

In the **move** area, the industry is also already testing innovative ways to secure the supply chain and protect itself from counterfeit or parallel imports. In pharma, relationships with distributors and pharmacists are paramount in maintaining the integrity of the supply chain, but technology can help: for example, new generation barcode and RFID tags are being used in various ways to authenticate products. EFPIA, a European pharmaceutical industry association, is piloting a coding and identification solution in Sweden whereby pharmacists will scan a 2D data matrix barcode for a valid serial number before dispensing products to patients. For biological products, the industry has started to use temperature probes to secure the cold chain which for some countries is already mandatory. In the near future, scannable "smart" probes will probably be widely used.

Capgemini has recently partnered with Ortec Brightrivers to offer specialist decision support solutions to life sciences companies. For one major client, the solution was able to redesign the entire supply chain by simulating alternative network designs and strategies and analyzing and developing trade-offs (flexibility, cost, inventory, lead time, service level). Ultimately, updated production management practices were found that minimized operational costs and working capital, delivering cost savings of 29% or $19m per year.

13 Obtainable via http://www.uk.capgemini.com/services/ceo-agenda/how_to_implement_lean/

Overall – across the plan, buy, make and move areas – pharmaceutical supply chain groups need to devise innovative strategies to address the expected transformation of the product portfolio. Not only is the industry moving away from manufacturing large volumes of pills and towards more complex biopharmaceuticals and diagnostics, but it will also need to manufacture targeted treatments, perhaps delivered directly to the patient. This transformation can only be achieved with an extremely agile and sophisticated supply network and strong quality assurance. The entire manufacturing and supply chain philosophy of pharma will need to be redefined, with challenges to existing capabilities across the entire production network, both internal and outsourced. This will also be the case for other parts of the life sciences industry when implementing new, highly innovative, products and solutions.

4.2 Cost reduction in R&D

This bucket includes all expenses involved in discovering and acquiring new knowledge, and in the development of knowledge into a new product.

Fixing the basics in R&D

The life sciences industry is well aware that it faces a productivity challenge in R&D, particularly for the pharmaceutical and biotech industries. For some years investment increased while output declined, and today's commercial pressures mean that these trends urgently need to be reversed. As figure 7 showed, 39% of respondents mentioned R&D as offering substantial potential for cost reduction.

Fortunately, fixing the basics can bring considerable improvements, both reducing development costs and increasing productivity. The best results are typically achieved in development, which is the most costly aspect of bringing a product to the market. Development is often an area that can be industrialized. The key to cost control is cycle time reduction. This reduces on-going development costs and generates the revenue stream sooner. R&D improvements can be achieved by better planning, redesigning for process optimization, adopting technology to reduce manual operations and redundancies across divisions, improving portfolio management and reconsidering the location of operations. It is also possible to go further and entirely rethink the development model. We discuss each of these options in more detail below.

Planning

More time spent on planning means less overall development time, which in pharma minimizes the number of studies and avoids duplication. Provided clinical practices outside Europe and the USA meet FDA and EMEA standards, studies do not necessarily need to be repeated for those regions. Good planning also ensures protocol development is well designed, includes specific objectives and clearly identifies planned analyses of primary and secondary end-points. Site selection is also critical to ensure speedy recruitment of investigators and patients. Another component of the planning phase is empowerment of the project team. This includes clarification of roles and responsibilities and the decision-making process.

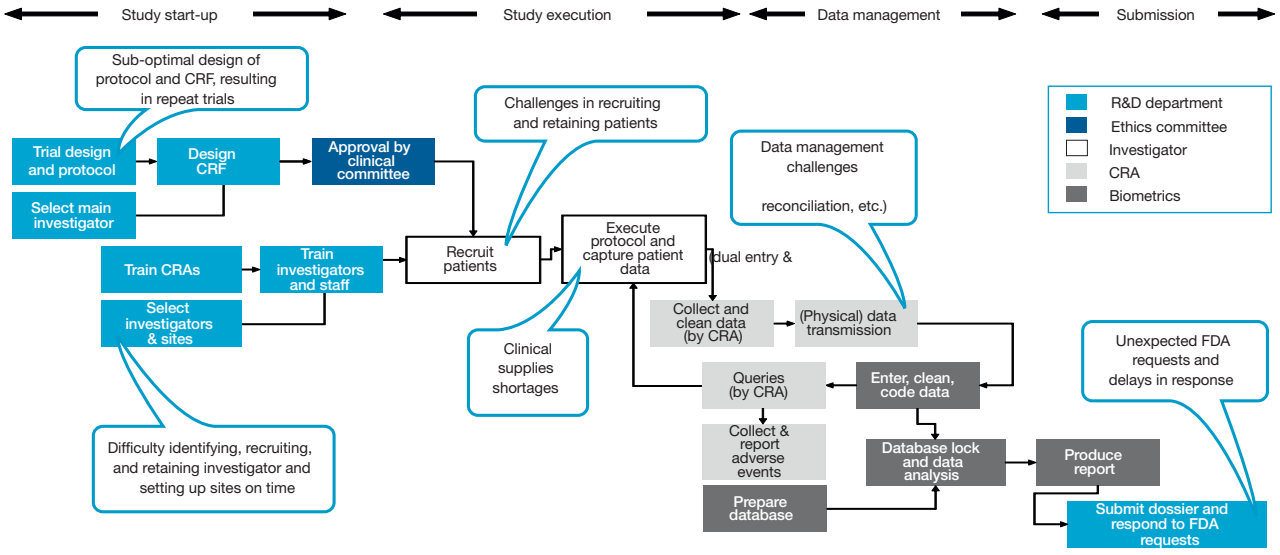
Process redesign

Industrialization of basic development processes, including standardization of roles and responsibilities, processes and supporting technologies, can yield significant improvement. It also contributes to successful collaboration with partners such as Contract Research Organizations (CROs). Strong and effective leadership and a good change management approach are required to ensure adoption of standardization across the firm's scientific community. Process redesign should aim to remove bottlenecks of the kind illustrated in figure 9.

Technology

Electronic Data Capture (EDC) in clinical research trials enables automation of many expensive and manual processes. With EDC, an industrialized solution can greatly reduce the cost of development and

Figure 9: Bottlenecks in the drug development process



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filings to regulatory authorities. This solution will typically define metadata and data standardization to enable interoperability, together with a single repository for submission data, accessible by all the appropriate business functions. Apart from the cost saving, additional EDC benefits include real-time data collection and monitoring, along with reduced error rates and better trending.

Another application of technology within the development process is to make modeling and simulation (M&S) or adaptive trials a component of the clinical development program. Adding these capabilities makes it possible to react to issues in real-time. For example, researchers could stop a trial early because efficacy end-points are met. Alternatively, they could modify the dose because of safety concerns or non-response data at the current dose level, without the need to stop the trial.

Internal mining of data, made possible with data and systems interoperability, can provide additional knowledge about a company's legacy product findings and previously failed product development efforts by tapping into what were previously "siloed" areas of data, information and knowledge. Mining external data (public information from pharmacy partners, health care providers and/or regulators) can enable the company to identify and proactively respond to trends, for example tackling safety issues before they are detected by regulatory authorities. External data mining can also yield important information on a competitor's product.

For a top-tier pharma company, Capgemini supported an R&D "Transformation Taskforce" which initiated a program to increase productivity and reduce cycle times in late-stage development. This two-year program, which was also strongly supported by Capgemini, designed and implemented new organizational roles, processes and technologies for late stage development. The program promoted collaborative working and fast decision-making, while also increasing the time scientists had available for clinical science and innovation. Processes were streamlined and common standards set in areas such as clinical data. These changes, combined with new technological tools, delivered the targeted benefits, including a reduction in the cost of executing clinical trials.

A new product development model: owning the disease

"Owning the disease" means becoming the authority the market acknowledges. It means that a company's scientists understand the disease mechanism and can genetically identify a subset of patients for whom a product has proved efficacious, so as to avoid non-responders and sub-populations with a risk of serious adverse events. The company's product dramatically outperforms the competition.

This paradigm shift requires tight integration with research. It is based on a deep understanding of a disease model that is tightly defined at the bio-molecular level, and of the genetic variations that determine a specific patient sub-population.

Owning the disease could also mean providing "before- and after-sales support" in the form of services that monitor patient compliance and management. Upfront diagnostics can be provided to identify sub-populations, thus reducing development costs and increasing revenues.

Portfolio management
Putting in place a lean, efficient development process, as described above, is particularly critical in view of the current proliferation of potential compounds in the early stages of the pipeline, for which it is vital to reduce costs and time to market. Even more critical, though, is management of the go/no-go decision as to whether to bring a product into development.

Currently, the pharmaceutical industry is poor at killing R&D projects, resulting in a serious bottleneck within development. Projects tend to be selected based on R&D managers' gut instincts and on existing resources and competencies, instead of on strategy, with the result that the wrong ones often go forward. Applied science has not kept pace with basic biomedical science: that gap needs to be filled if the go/no go decision is to be made on the basis of correct information.

The cost and other implications of a failed candidate in phase III are now so high that management has to be ready to kill a program early, even if it means challenging established industry behaviors or NPV predictions. Critical assessment of each potential new compound must take into account patient safety, efficacy predictions, alignment with the appropriate strategy, and a product's commercial potential, including the competitive landscape, pricing and reimbursement assumptions.

Location choice
Locating R&D outside the U.S. and Europe can benefit life sciences industries not only from a cost perspective but also from a talent pool perspective. In places like China, India, South Korea or even Latin America there are great scientists and great ideas, so companies can access excellent R&D capabilities by locating in these countries.

However, care is required when selecting centers and countries. For example, in the case of clinical research trials it is important to choose those locations with the best opportunity of patient recruitment. Executing clinical research trials outside the U.S. and Europe can not only reduce cost but also meet or accelerate recruitment requirements. There are, however, ethical considerations that must be addressed before moving forward. They include any requirements for additional education and training of site personnel.

Rethinking the pharma development model
As we noted, fixing R&D basics can reduce costs, but there are more fundamental problems with the current development model, which is still focused on blockbusters and me-too products. These problems include failures after Proof of Concept (POC), and difficulty in providing the statistical evidence for efficacy and safety to regulators and the reimbursement community. The current model is also ill-suited to identify potential safety issues early on, and to deliver on the promise of prevention or cure – increasingly sought by patient advocacy groups. From a commercial point of view, remaining with the current model will eventually leave the industry with an increasingly dismal market share.

Fortunately, companies do have an alternative: a paradigm shift to a new development model, in which the company "owns the disease", is becoming a necessity.

Economies of scale in R&D

Economies of scale can often be achieved by rethinking sourcing. Because CROs service multiple clients, they can pass on some economies, while also taking on some of the development risk. Outsourcing of trials and trial management to CROs has grown 14% from 2007 to 2008 and is expected to continue this growth rate up to 2013[14]. While in the past CROs provided services on individual clinical research trials, we now see complete service offerings that include protocol authoring, statistical analysis and reporting, and data management or site management. Additionally, the industry today is outsourcing complete clinical development programs and the provision of pharmacogenomics services to identify targeted treatment patient populations.

Having a clear strategy for R&D means that, by reorganizing around selected areas (e.g. therapeutic in pharma), companies can focus scientific efforts where there is a stronger market potential or significant advancement in science, and hence a better chance of viable products and improved ROI. Economies of scale in R&D, as in other areas, can also be realized with mergers or acquisition.

Setting up alliances with biotech companies and academic organizations not only strengthens the development pipeline but also provides economies of scale and increased access to basic research. An increasing number of innovative medicines have their origin at the biotechnology industry, and as these products are complicated and expensive to develop and test, external alliances can cut risk and costs. Late-stage candidates, whose costs were spiraling before the crisis, may now be affordable because of biotechs' funding difficulties. Partnerships with those engaged in basic research, like academic organizations, keep costs down and facilitate the early spotting of creative breakthroughs, which can then be exploited to bring new medicines successfully to market earlier.

Innovation in R&D

As well as seeking innovative products, there are many opportunities to use innovative R&D strategies, technologies and techniques to increase the pipeline and reduce development costs. Several examples have been noted earlier in this section.

We have just described how collaboration with organizations engaged in basic research makes it possible to bring the latest scientific knowledge and practice into the business. Our discussion of the new pharma development model showed how genomics, combined with increased knowledge of the disease state, enables the identification of patient sub-populations where a candidate product is safest and most effective. Also, in connection with the new development model, we discussed the possibility of looking beyond conventional products that alleviate symptoms and starting to address prevention or cure and added-on "after-sales service". Our

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Lilly set up Chorus as an independent division to get compounds to POC faster and with less cost. A lean team organization, located outside Lilly's laboratories, manages the process using a robust software package that gives all players instant access to key information about the candidate. Recognizing that not all products will reach the market, the team takes shortcuts that most Big Pharma organizations would not (for example it does not look at manufacturing or formulation feasibility as a key decision driver). This makes the process faster and cheaper by avoiding any extra opportunity cost.

This approach will not work in every case: for example, it is unsuitable for novel compounds that lack validated predictive biomarkers. With a positive POC Lilly is required to conduct more work prior to registration trials. But the net result is that Lilly gets more post-POC programs to choose from – and those that they decide not to take forward can be out-licensed.

In contrast with Big Pharma's normal mindset, Chorus assumes that most compounds will fail. The trick is to identify as fast and cheaply as possible those which are likely to fail. In fact, Chorus can be seen as an exercise for acquiring this decision-making skill.

discussion of fixing the basics described how data mining could provide better knowledge of our product line – both internal and external – enabling us to proactively manage and remediate risk.

Below, we discuss further opportunities for innovation in the areas of biotechnology, partnership and systems and data interoperability.

Biotechnology
New technologies can save development costs while improving the quality of the product. For example, increased understanding of the disease at the molecular level, together with biomarkers, gives us information on specific sub-populations where our product may be more efficacious and where the chance of serious adverse events is reduced. This information removes some of the guesswork from early decision-making.

Whereas the traditional development model is driven by "discovery push", the new model, incorporating "omics" technology, is focusing a shift toward "clinical pull." Genomics, proteomics and pharmacogenomics enable the segmentation of targeted treatment populations according to genetic variations. Proteome analysis enables us to identify the metabolic pathways of cells, identifying protein profiles for validating targets and initiating screening methods.

Pharmacogenomics is the global science of recognizing differences in disease phenotypes and disease disposition, which makes it possible to predict the efficacy and/or toxicity of a drug, explain inter-individual differences in pharmacokinetics (PK) and pharmacodynamics (PD), and monitor drug response and disease progression. All this can significantly improve success rates of novel products. As we saw earlier, adaptive trial design will enable real-time study changes such as moving a non-responder to a higher strength or reducing drug strength for a patient who experiences an adverse event.

Once again, use of these technologies requires a thorough understanding of the dis ease at the molecular level, and of the impact of individual genetic differences.

Partnership
As well as partnering with small biotechs, academic organizations and CROs, some companies are embarking on even more innovative relationships. Collaborating with patient advocacy groups and regulatory bodies can increase disease definition and knowledge. Since advocacy groups

have increasing political influence on regulatory authorities, both types of partnerships could be useful in obtaining fast-track approvals.

Collaborating with co-development partners with specific product expertise can provide knowledge and strategic insight. Some companies are even open to collaborating with others sometimes regarded as competitors, an example being Pfizer and GSK's work on HIV.

Interoperability
Collaboration, whether with or amongst development partners or within a single company, requires data and metadata standards and an IT platform that enables interoperability. The increasing focus on the patient in the world of personalized medicine will add to the need for companies to share and exchange data – both across internal organization boundaries and with partners. Sometimes the exchange of data and interoperability of systems will not be enough, and systems and data stores will need to be integrated. The industry will therefore require IT frameworks to make this integration and interoperability possible.

4.3 Cost reduction in SG&A: Commercial

The SG&A bucket includes spend associated with selling and advertising the goods of the business, including staff costs of sales such as commissions and expenses. Historically, life sciences companies in general had a strong focus on commercial growth. A high profit margin promoted the pursuit of top line growth; cost was a secondary consideration at best. The new reality looks different: revenues are stagnating or even shrinking, the bottom line is attracting increased attention, and commercial ROI is top of mind.

Fixing the basics in SG&A: Commercial

Commercial functions usually have plenty of scope for fixing the basics. Until now the sales force has been the most prominent focus for cost reduction efforts, a focus that came about as a result of decreased productivity of sales reps. Across the board, pharmaceutical companies have announced sales force size reductions based on the straightforward calculation that lower productivity means a lower break-even number of sales reps in the field.

We are also observing a much stronger focus on cost and ROI. Where previously the majority of commercial ideas got funding, companies are now dealing with reduced budgets, reduced funding and fewer initiatives. Companies are demonstrating their focus on ROI by asking "how is this initiative (or this incremental sales rep, this campaign, this channel, this customer, etc.) helping with the bottom line?" – and they are looking for a contribution sooner rather than later. They are adding controls and metrics to track marketing and sales spend. Analytics are being upgraded to target now-scarce resources better.

To help a large biotech achieve better monitoring and evaluation of its marketing activity, Capgemini developed an Accelerated Enterprise Marketing (AEM) solution in collaboration with Aprimo. This solution has helped the client update its marketing tactics and processes while reducing expenditures within its marketing operations. Benefits include improved visibility of marketing spend, standardization and automation of campaign and event management, and enforcement of industry leading practice.

A smaller sales force could mean less impact on the market, but with the help of these improved analytical capabilities, companies can enable a broad array of productivity measures to maintain or even improve their impact on the market despite the reduction in resources.

Value-based selling and key account management put the interest of the customer first – which in pharma includes those of the prescriber, who is currently being rediscovered as a customer. These techniques are also helping companies abandon the mindset of repetitive detailing. Better segmentation can identify what message, and message delivery, works best with what customer. Tablet PCs allow tailoring of messages and provide richer interaction.

Orchestrated multi-channel campaigns can reach the market broadly and quickly, and segmentation will help companies focus their costly sales force on high value customers, while lower value customers are served through e-detailing, video-detailing, call centers, emails, or other channels. Information can be captured from all relevant interactions with the help of technology (Closed Loop Marketing in the broadest sense). This information gathering, together with analytics, provides a richer and clearer picture of the customer. Predictive analytics will be next.

In a downsizing environment, Capgemini helped a leading pharmaceutical company to design a commercial model where the customer comes first. Founded on the Closed Loop Marketing approach, a program was designed and implemented to increase customer focus, improve analytical decision-making and accelerate commercial processes. It encompasses value based selling, tablet PCs, e-learning, multi-channel campaigns, improved analytics and segmentations, and other related initiatives. Our team has delivered a path to the creation of high-value customer relationships that benefit the physician and the client organization alike.

Given life sciences companies' high dependency on subcontractors, one other obvious cost reduction area is that of sourcing. We will look at this area separately in the next subsection, and focus on the core commercial functions in this section.

While the majority of SG&A resources in pharma are currently focused on the prescriber as a customer, the future will require a different approach: the rising importance of payers will require a reduction in prescriber-focused

efforts and resources, and an increase in payer-focused efforts. To work effectively with payers, companies need to learn to negotiate effectively; a structured, analytical approach to discount negotiations will be a significant profit lever.

First and foremost, however, they will need to provide comparative effectiveness and cost benefit data for their innovative products. For products competing with generics, given the aggressive switch being pushed by payers, pharmaceutical companies will need to revisit their contracting agreements, and shift their expenditure towards consumers (where permitted) and towards promotions and programs aimed at pharmacists.

Economies of scale in SG&A: Commercial

The changing focus of sales and marketing, with smaller sales forces and increased multi-channel marketing activities, will predominantly benefit larger life sciences companies. The need for basic detailing activity is reduced; sales reps will be mostly employed for important events like product launch or disseminating newly available information. The new paradigm for the large sales force is that of flexibility – companies need to leverage a sales rep across the entire portfolio. Similarly, analytical capabilities need to be flexible and scalable enough to adapt to rapidly changing needs.

Smaller companies may need to reassess their make-or-buy decisions: they may want to use contract sales forces. We are also seeing an increase in the outsourcing of commercial operations like forecasting, sales and market analytics, and also of more strategic marketing and sales activities like knowledge services, competitor intelligence and market research management. As one of the pharma sales executives in our survey says, "We will continue to feel the pressure on the top line and our margins, so we will constantly be looking for new solutions, and here outsourcing will be key."

Another commonly used lever for cost reduction due to scale is the consolidation of marketing activities at a regional or even global level; this is becoming increasingly feasible as country customization is tending to be seen by companies as less important than cost savings and a globally aligned market approach. One of our respondents, a director of transformation in Europe, said, "We are centralizing the creation of marketing content, using one agency per brand across all countries, outsourcing tactical commercial activities and centralizing marketing research, sales ops, and CRM."

Innovation in SG&A: Commercial

In the past, the commercial models of pharmaceutical and big biotech companies have been fairly homogenous, benefiting from a quasi-monopoly on patented products that were pushed into the market through intense prescriber marketing and sales. It is commonly accepted that this blockbuster model is not sustainable. However, while we can observe many experiments to tweak this model, we have yet to see a more fundamental shift. Capgemini believes that there are a number of opportunities for companies to differentiate themselves through innovation in the commercial area.

Most fundamentally, companies can work with three main go-to-market models: innovative product offerings, customer focus, and cost leadership.

The first model, innovative product offerings, is closest to the traditional pharmaceutical model. It implies the ability to develop products that give extra value to patients, payers and healthcare providers. This might mean creating a product that treats a condition for which no therapy was previously available, or one that works much better than existing products. Products need to come with convincing health economics and evidence of high value to ensure that they secure reimbursement (see section 3 for a discussion of reimbursement issues). Once a pharmaceutical company has established the reputation of its product with the relevant health authorities, then it will secure guaranteed access (for example the product will be listed on formularies). This model is particularly applicable to specialty drug portfolios, and requires a best-in-class approach to defining the development and in-licensing portfolio, solid capabilities with respect to health outcomes, and an effective, science-savvy sales force.

The customer focus model is about putting the customer first. The whole organization needs to adopt a customer-oriented attitude, together with the disciplines of account management. The sales force should be organized and managed on a regional basis, with each sales team or individual executive responsible for a limited number of accounts about which they can develop deep customer understanding and insight. Marketing, too, should be both account- and customer-focused: for example, marketing managers should liaise with account or customer segment managers to see how the company can promote itself to these customers. Instead of simply offering individual products, companies should think about offering key customers a tailored portfolio of products that meets most of their needs, which for pharma include holistic solutions for physicians, payers and patients, beyond the products alone. Given the pressures on existing pharmaceutical models, many pharmaceutical companies are experimenting with this model.

A contrasting model is that of cost leadership, which is similar to the current generics model but applicable to products both on-patent and off-patent. Here, the aim is to become a leader on price and as a result to sell in high volume. Payers in turn push the product to physicians. This approach is particularly appropriate for "me-too" drugs; companies with a significant portfolio of these drugs might decide to complement it by in-licensing more drugs from other companies. Some companies may choose to adopt this model for all their products, which would result in a very lean profile since it virtually eliminates expenditure on drug promotion. So far, ethical pharmaceutical companies have shied away from this model as it requires more drastic change. Generics companies, on the other hand, could use it as a push into the ethical pharmaceutical market. However, it is dependent on a health system where costs have a significant impact on the prescription decision, which is not yet the case for all the major countries.

In general, companies should realize components of all the three options. An example of a composite, collaborative model is a solution that we call "Superior Innovation with Authority Intimacy". Here pharmaceutical companies and healthcare authorities collaborate closely so that when a new product is about to be launched they get together to agree prices, volumes and other market parameters (there are signs, particularly in Europe, that authorities are becoming more receptive to this type of negotiation). Typically these agreements will have some element of shared risk and benefit, and will be staged. For example, a product might be launched to a limited patient segment and later, once benefits and safety are proven, be launched to a wider patient base on revised terms. Because the authority is happy with the price, it pushes the product to physicians so that there is no longer any need for physician-level negotiation or selling, though the pharmaceutical company will still provide education about the product (but on a train-the-trainer basis). The commercial function can become very lean and its focus will be on negotiating with healthcare authorities.

This is just one model, applicable mainly to companies with high-value products emerging from R&D. In the future no single model can be expected to dominate: the three basic models above must be mixed and matched according to company strategy, product portfolio, company culture, and so on. However, there is no doubt that close collaboration between stakeholders (including regulators, payers and health providers) will be the key to the success of any commercial model.

4.4 SG&A: Shared services and use of outsourcing

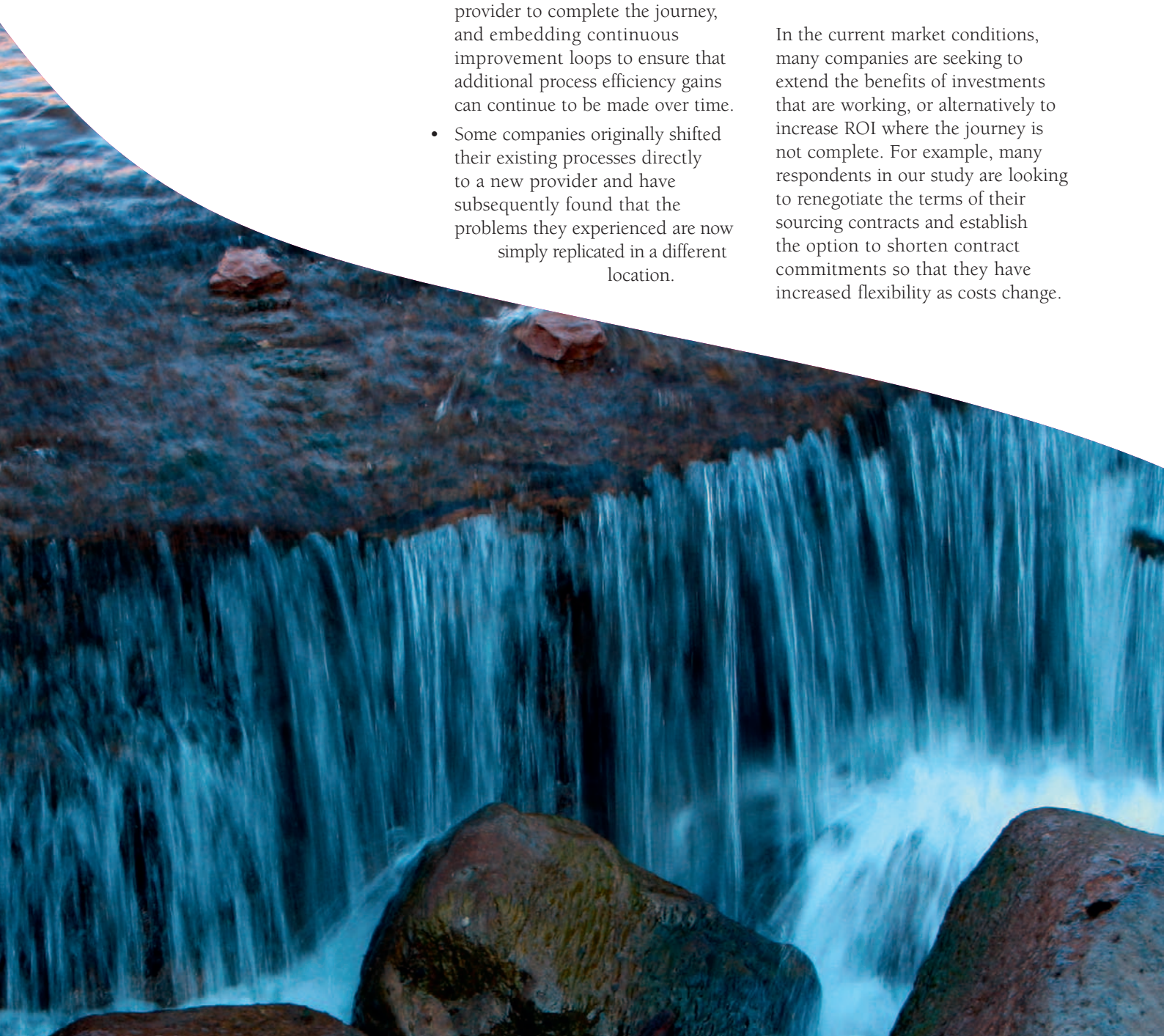
Shared services and the use of outsourcing have been looked to for years by many industries as ways to reduce costs, largely in the general and administrative (G&A) areas.

Fixing the basics in SG&A: Shared services and use of outsourcing

Given the worldwide operating footprint common among life science companies, they have often been among leading adopters of outsourcing services in their core business. R&D has long been partially outsourced to CROs, manufacturing agreements have been in place for many years, and to some extent selling activities have been outsourced to Contract Sales Organizations (CSOs).

Surprisingly, the industry has been lagging in the area of shared services and Business Process Outsourcing (BPO) for IT and support functions. It is catching up now, as part of its response to the challenges and opportunities of running a global business under cost pressure.

The extent to which life sciences companies have, in general, embraced outsourcing should mean that they are well placed to "fix the basics" of their existing setups, as they should have a partner – internal or external – who is looking for ways to improve processes and optimize service. However, the degree of maturity varies greatly from company to company:



- Good practice is to set, and deliver against, a clear route map to achieve the advantages of co-location from a cost and common operations perspective. That means building an alliance with an internal or external provider to complete the journey, and embedding continuous improvement loops to ensure that additional process efficiency gains can continue to be made over time.
- Some companies originally shifted their existing processes directly to a new provider and have subsequently found that the problems they experienced are now simply replicated in a different location.
- Others aimed to optimize the processes before transferring them, but have struggled to achieve local standardization and process improvement, and are still at the start point in terms of leveraging off-shore or shared models.

In the current market conditions, many companies are seeking to extend the benefits of investments that are working, or alternatively to increase ROI where the journey is not complete. For example, many respondents in our study are looking to renegotiate the terms of their sourcing contracts and establish the option to shorten contract commitments so that they have increased flexibility as costs change.

Some are also re-evaluating their choice of locations and/or model utilized. Companies are increasingly looking to consolidate more processes and transfer them into existing shared service centers or outsourcing partnerships. Companies that have been conservative in their choice of service locations are looking to take advantage of the larger opportunities that exist in off-shore locations. Outsourcing and shared services offerings are becoming increasingly sophisticated, with the rise of more hybrid strategies and the spread of operations beyond the traditional off-shoring locations, opening up even further potential. India and Eastern Europe have for some time been popular outsourcing destinations, but increasingly educated workforces, together with government policies favorable to international business, are opening up attractive opportunities in other countries. Malaysia was named in our study as a country to watch, while Morocco is seeing inward investment as a potential location for companies with French language requirements.

With regard to shared services, the overarching objective for decision makers must be to ensure that support functions are "fit for purpose", meeting the service needs of the business at the correct price point.

Economies of scale in SG&A: Shared services and use of outsourcing

Economies of scale are already a common motivator for outsourcing and shared services. Companies should seek to gain additional economies by consolidating existing outsourcing and shared services arrangements so that fewer providers are used, operations are spread across fewer geographies, or scope of services covered under the existing arrangement is expanded. Furthermore, moving to common platforms for all shared services can increase standardization as well as potential cost savings.

Following acquisitions in the diagnostics market, a major healthcare provider decided to migrate financial shared services in three countries to a single shared service center running SAP. Capgemini designed standard migration paths and provided project management services together with specialist resources and advice. Areas addressed included standardizing policies and processes, migrating groups onto a common ERP platform, and consolidating accounting and transactions processing activities into a single shared services center. The migration was completed in just five months and brought improved customer service as well as substantial cost reductions.

Innovation in SG&A: Shared services and use of outsourcing

Most companies have considerable scope for innovation around the way that outsourcing and shared services are set up. For instance, they can seek competitive advantage by feeding information from service providers, who often have considerable data mining capabilities, back into their internal functions. The information gained will enable further innovation: for example the company can improve its go-to-market model, better segment the customer base, expand service offerings, and design better products and supporting services.

Leading the way in outsourcing innovation are certain providers who have, together with the outsource customer, defined the input and outputs of the outsourced process, and then been granted flexibility to define how the service is delivered. The approach makes the outsource feel much more seamless to the life sciences company, and puts more of the onus for delivery and simplification of processes onto the outsource partner.

Organizations should also consider applying alternative sourcing approaches to activities beyond the "usual suspects" like finance and HR. Candidates for outsourcing and shared services considered by our respondents include commercial operations and support services like sales conference management, sample distribution and marketing publication management.

5. Performing beyond the Downturn

As we have seen throughout this report, most companies interviewed in our survey are currently seeking to cut their costs, and at the same time to make those costs easier to control and vary, for example through outsourcing.

These moves are responses to factors like lower profitability levels in shrinking markets, and, in the case of pharmaceutical companies, the impact of patent expirations on the top line.

We found much less evidence of companies seeking to transform their business model. Rather than drastically change the way they operate, most life sciences firms seem to be waiting for the next innovation cycle. Indeed, the current wave of M&A activity in pharmaceuticals can be seen as the industry's attempt to bridge the gap between two innovation cycles. The trouble is that if we do not seek to transform ourselves now, by the time the next innovation cycle arrives it may be too late.

In this section we survey the future and discuss some strategies that companies can adopt to ensure they achieve optimum performance through the downturn and beyond. First we look at pharmaceutical and medical device companies, next at biotechs and finally at agribusiness companies.

5.1 Transforming pharmaceutical and medical device companies

Transformation is, perhaps, even more difficult for the pharmaceutical industry than for other branches of life sciences, because it has so many unknowns. Will the successful pharmaceutical company of the future adopt a diversified model with separate arms for prescription drugs, branded OTC, and generics, or will it be a higher-margin company focused on innovation? Will the current focus on specialty and oncology offer an escape from the downward spiral, or are these areas just going to become the next crowded space for pharmaceuticals? What should the core capability of a pharmaceutical company be: an integrated model spanning everything from research to commercialization, or lifecycle management with outsourced operations?

These are the questions that pharmaceutical companies need to be asking themselves now. Our research allows us to make some confident predictions and recommendations.

What will the future look like for pharmaceutical and medical device companies?

Impending changes to science, markets and society add up to an urgent need for industry transformation which cannot be postponed any longer. Here we look at some of the most important of those changes.

Continued cost pressures will force life sciences companies to fundamentally reassess their business model

In established markets, cost pressure will continue to increase, reflecting higher demand for care and insufficient GDP growth to fund the system. Similar demands will be seen in developing markets, which will expect the same sophisticated care that is already available in the west. And, even though only a minority of healthcare expenditure goes on drugs, nonetheless drug manufacturers will become the prime targets of payers' attempts to get more for their money.

These societal pressures for more healthcare coverage at the same or lower cost leave pharmaceutical and medical devices companies with no choice: they must dramatically modify the way they operate. However, changes to the competitive landscape are making this task more complex. Pharmaceutical companies' current cost structure does not allow them to compete efficiently with generic firms, which will come to own mass market segments as patents expire. A pharmaceutical company could decide to strengthen its own generic arm, but should be aware that this strategy will dilute profitability ratios. Competition from low-cost

countries will also weaken the position of medical devices firms with a strong presence in "commoditized" products (syringes, gloves and so on).

A growing emphasis on safety, comparative effectiveness and a clear cost-benefit case

Already, public and private payers' willingness to fund treatment is increasingly based on measurement of outcomes rather than just on the amount of product used. In future, payers can be expected increasingly to base reimbursement on a cost-benefit assessment, which will have to include a longer-term perspective.

Recently, we have seen major pharmaceutical companies drop products in phase III as they were considered to be "me too" drugs and therefore not likely to obtain reimbursement with the stricter requirements from payers. In line with this, companies have also significantly reduced the number of R&D projects that they fund, selecting the products to go forward based on an assessment of value. In future, demonstrating value will require a much broader use of head-to-head trials as a basis for proving comparative effectiveness.

In addition to demonstrating value, manufacturers are having to guarantee safety to higher levels than ever before. With the rise of complex molecules, Risk Evaluation and Mitigation Strategies (REMS) will become part of the core requirement for pharmaceuticals.

Dramatic expansion of network-based collaboration

There will be opportunities for increased stakeholder collaboration. Life sciences firms will grow their external networks in two main ways: downstream expansion and extension of capabilities.

Downstream expansion will make it possible for companies to promote end-to-end health solutions rather than just a single product. Partnering with payers, pharmacists, distributors, advocacy groups, and so on can improve companies' ability to reach specific patient types and to meet their needs. Pharmaceutical companies can for example use their contacts with advocacy groups to identify patients who could benefit from niche products. This ability will become increasingly important with the rise of personalized medicine.

The second way in which companies will use external networks is to extend their capabilities within a function (such as research) by accessing a worldwide pool of innovation. The previous section's discussion of R&D revealed how some companies are already collaborating in this way. In the Lilly Chorus example, we saw how Lilly has formed alliances with many external contractors instead of maintaining internal expertise in every aspect, as would happen in the traditional pharmaceutical model.

Some companies are working with academia – and even sometimes competitors, as in the case of Pfizer and GSK's collaboration on HIV – to share knowledge during early-stage R&D. The advantage here is that the network's ability to find a promising compound collectively is much higher than any single organization's ability. In the same way, cross-pollinating ideas about manufacturing best practices, or entering into co-marketing agreements, can reduce resource output while increasing top-line benefit.

Acceleration of efforts towards personalized and targeted medicine

The development of targeted therapies and the move to personalized medicine, enabled by genomics and similar technologies, is inevitable. This trend will in fact be eagerly accelerated by pharmaceutical companies themselves, since they see it as an opportunity to strengthen innovation and re-create a profitable market space.

However, these approaches will force a full redesign of all operations across the value chain, affecting all stakeholders. Operations (including supply chain and distribution) will need to adapt from mass production to the provision of complex molecules in much smaller batches. Marketing and sales activities, too, will change their emphasis from marketing a product to promoting a complete health solution (including diagnostic, treatment and monitoring). This trend will also alter the role of professionals, including pharmacists: with the development of genetic testing as a means of selecting the most appropriate therapy, the advisory roles of these professionals are likely to become increasingly important.

The rise of genetic testing, and of personalized and targeted medicine, will bring further challenges to reimbursement processes, since these treatments are likely to increase

Cost reduction strategies

The current cost reduction wave, as described in section 4, is just the first wave of more to come. We predict that deeper cuts will be required in future, and will force strategic choices such as an increased focus on a limited number of therapeutic areas. Whereas interviewees told us that their cost initiatives to date have mostly focused on carrying out essentially the same operations at lower cost, the future will be about doing more with less.

Figure 10 summarizes some of the major cost reduction approaches that we expect to see companies adopting. All are focused on "fixing the basics", in the terminology of section 4.

Business process outsourcing, together with other forms of outsourcing, will continue to grow in scope and scale. Companies will adopt a more strategic approach to sourcing that focuses on value, in contrast with today's initiatives which are often strongly cost-focused. However, outsourcing and shared services will remain vital sources of economies of scale, and companies will look for further sources of such economies.

Figure 10: Summary of cost-limiting measures

Examples

	Research and Development	Supply Chain	Marketing and Sales	Support Functions (IT,HR, etc.)
Easy	• Clinical supplies rationalization • Renegotiation with CROs • Clinical trials in lower cost locations	• Contract negotiations • SKU rationalization • Inventory reduction • Third party logistics outsourcing • Demand planning • Supply planning • Strategic sourcing	• Sales force resizing / territory realignment • Contract negotiations • Marketing materials sourcing • Monitoring product sensitivity to marketing spend • Lowering spend on items such as dinner events and samples	• Contract negotiations • Service level rationalization • Group size rationalization • Company wide procurement initiative
More difficult	• Better and earlier clinical planning (e.g. protocol design , endpoint definition) • Cost of clinical trials • Submission process improvement (e-submission) • Project rationalization (reduce the size of project portfolio) • Therapeutic area rationalization • R&D site rationalization • IT enablement of research and early development • Outsourcing of clinical data management and site monitoring • Clinical data and new technologies integration	• Supplier risk management • Supplier relationship management • Site rationalization • Manufacturing outsourcing • Lean manufacturing / process excellence	• Channel optimization strategy/ alternative channel utilization • Implementation of marketing spend management systems • Contract management (rebates, chargebacks, selling price, etc.) • Marketing operations centralization (more responsibility at global) • Public and private payer strategies • Product/portfolio rationalization • Efficient ROI measurement and tracking	• Set-up of shared services • Set-up of outsourcing and BPO arrangements • Off-shoring for outsourced or shared services functions • Companies setting up their own off-shore capabilities (moving functions to lower cost geographies) • Setting up common platforms across shared service centers

Capgemini Consulting 2009

short-term costs for a given individual with the promise of a longer-term benefit. Some regulatory authorities are already starting to adapt their approval processes to deal with targeted therapies or personalized medicine. An example of progress towards this goal is the FDA's partnership with Medco, a large pharmaceutical benefits manager. Medco will provide the FDA with access to test results, prescription data, and clinical outcomes, positioning the FDA better to assess treatment outcomes initially, and later to evaluate the benefit of basing treatment decisions on genetic testing.

For personalized and targeted medicine to succeed in a given area, the industry needs to offer an effective combination of diagnostics, medical devices, drug and monitoring services. This requirement will necessitate a range of alliances to facilitate both R&D and also the recruitment of patients in hard-to-reach groups.

What steps should pharmaceutical and medical device companies take to advance their journey towards transformation?

We have identified 10 major actions that the industry can take to respond to the conditions just described. Some are aimed at helping companies to transition to the new world of personalized and targeted medicine, while others are ways to deal with current or imminent market conditions.

1. Implement the next wave of cost reduction in order to adapt to the next round of price pressure.
2. Increase business model flexibility and build strategic networks across the value chain.
3. Adapt the internal organization, implementing appropriate business models for each therapeutic area and product. This move will facilitate strategic decisions e.g. spin-off or divesture when the new wave of innovation takes off and margins recovery becomes a priority.
4. Recognize that, pending the next wave of innovation, patient compliance is the industry blockbuster. All stakeholders should promote disease management programs (including payers who have a direct interest in preventing the effects of non-compliance).
5. Build end-to-end health solution capabilities to serve patient needs (diagnostics to compliance) and to prepare for personalized medicine.
6. Proactively set up risk management capabilities across the portfolio to protect the company and support the drug approval and monitoring process.
7. Develop partnerships with all stakeholders – patient advocacy groups, regulatory authorities, hospitals, pharmacists, HCPs and payers – to test new approaches to innovation and care (e.g. Alzheimer's Disease, HIV and so on).
8. Rebuild goodwill, for instance by becoming more focused on patients and their needs. Companies should make upcoming healthcare reforms an opportunity to improve their standing among the broader population.
9. Strategically evaluate existing internal capabilities and compare them with those required in future.

Build a roadmap for equipping the workforce with the skill sets required for success.

10. Review information infrastructure across the value chain to ensure it can support the upcoming changes (customer, regulatory authorities, research and development networks, supply networks and so on).

In the "cost reduction strategies" panel on page 39, we elaborate the first of these recommendations, which has been a major theme of this report.

5.2 Transformation and biotech companies

What does the future look like for biotech companies?

There is no question that the current economic downturn will hurt some biotechnology companies, mostly because debt financing is so difficult to secure these days. Most sources of investment funding for biotechs have dried up. Nearly two-fifths of British biotech companies have been unable to obtain any financing over the last year, while funding for French biotech companies fell by 79% in 2008. Germany's biotech industry saw funds raised in 2008 from both venture capital and public capital markets decrease by a third compared with 2007. In the U.S., too, 38% of 370 listed biotech companies are operating with less than a year's worth of cash, and nearly 100 publicly traded biotech companies have less than six months' cash.

Inevitably, the financial crisis is making the biotech business model less sustainable. At least 10 European biotechs have declared bankruptcy since November 2008. The crisis is having strongest impact on EU biotech firms because most are still at an early loss-making stage of development, whereas U.S. firms tend to be more mature. It is estimated that one in five of Europe's small biotech companies risk bankruptcy in 2009; some analysts predict that up to 100 European biotechs will go bankrupt by the end of the year[15].

The challenge is for companies with great science to be as creative as possible in sustaining their product development, by leveraging all possible sources of traditional funds and non-traditional funds – including government contributions, charities and disease foundations. Partnering and merger opportunities may also offer a lifeline. However creative it becomes as to funding, though, the biotech industry may struggle over the next couple of years. In this sector, a company's future depends on its ability to achieve and advertise success for a product while it is still in development.

On the positive side, some current healthcare trends offer special opportunities for biotech companies. For example, the fact that both regulators and payers are calling for more targeted and more effective therapies means that biomarkers and tests will increasingly be needed, and biotech companies can play a major role in delivering them. The challenge here is that the majority of the payers see diagnostic tools for testing the effectiveness of therapies as an additional cost of the therapy and not as a driver for healthcare savings. It is up to biotechs, along with pharmaceutical companies, to prove them wrong by providing clinical evidence that the tools can in fact deliver value in their own right.

Diagnostic developers tend to be focused on the opportunity here, but there is an emerging risk that pharmaceutical companies will see the diagnostic products as a threat to their own product – for example, if a diagnostic reduced the size of the eligible patient population for a product – and respond aggressively. If pharmaceutical companies feel forced to mount a fierce defense of their labels, it will be to the detriment of diagnostic companies.

Fortunately, the introduction of personalized medicine provides an opportunity for biotech companies to partner with pharmaceutical companies, pre-empting such confrontations. Pharmaceutical companies rarely have the necessary diagnostics experience so many of them will be dependent on partnering. The future looks bright for biotech companies who are open to these alliances.

15 "Surviving difficult times ," Drug Discovery and Develop ment, 2/1/2009; "Funding dries up for biotechnology start-ups --- Bankruptcies rise for drug incubators;" Wall Street Journal Europe, 3/17/2009; "Fifth of European biotech firms could fail in 2009," Reuters News, 3/16/09; "Europe Bio SME platform, 5/27/09; Biotechnology Industry Organization,. "The German biotech sector 2009", biotechnologie.de, 5/6/2009

What steps should biotech companies take to advance their journey towards transformation?

We have identified eight major actions that biotechs can take in response to these challenges.

1. Find alternative sources of capital. Evaluate spin-off or divesture opportunities that can bring capital into the company. Wherever a suitable opportunity arises, raise as much money as you can. At a time when cash is king, don't worry too much about dilution. Also, don't assume that each development milestone will bring new rounds of capital, at higher valuations; instead, fund your company beyond the next milestone if you get the chance. Finally, pick your venture capital (VC) partner wisely: as your lead investor you need an experienced VC with deep pockets.
2. Proactively set up risk management capabilities across the portfolio (for example, by managing cash flow and suppliers) to provide financial protection for the company.
3. Outsource for speed and for the flexibility to free cash resources. Potential partners include CROs, CMOs and IT vendors.
4. Exploit new partnership models and build strategic networks with both academic institutions and pharmaceutical companies.
5. Prepare for early partnerships with Big Pharma, and participate in building end-to-end health solutions to serve patient needs (diagnostics to compliance), especially in personalized medicine. However, think strategically about partnering. Each company and situation is unique so companies shouldn't simply follow generalized trends about when and how to partner.
6. To improve the company's negotiating position, invest in clinical data for POC, as well as in Intellectual Property (IP). Even though the crisis encourages a focus on survival, think strategically about IP and value creation for your product. IP and licenses are at the core of everything a biotech company does, so be clear about what you own and what you'll have to license from others to ensure your patent protection is strong enough to resist challenges from generic companies. This is the only way to ensure you'll have the freedom to operate later on.
7. Adopt portfolio management. Focus on core assets with a reasonable and timely path to approval and reimbursement. Understand the target market and ensure your expectations about market potential are realistic, given that healthcare costs are on the rise and expensive medicines are harder to get accepted. Take account of likely reimbursement decisions when you prioritize your pipeline, and enter into an open dialogue with the payers. A very expensive drug – even an effective one – may not be worth pursuing if there are alternatives on the market. Building the right stakeholder relationships is the way to anticipate (and sometimes influence) decisions that will determine the success of your product.
8. Even though funding difficulties may make it seem as if you have to focus all your efforts on getting drugs to the next phase, don't forget to develop processes for manufacturing and commercialization. If you fail to organize supplies for clinical trials, for example, you can waste valuable time.

5.3 Transformation and agribusiness companies

What does the future look like for agribusiness?

Several trends suggest that global demand for food is likely to increase. These include a growing world population, an expected continuation in the rise of incomes, and the likelihood of a longer-term return to global economic growth. With a finite amount of useful arable land available, it will be necessary to increase output per acre.

This need for greater productivity implies increasing demand for agribusiness's products, though there are uncertainties about the exact growth path, caused mainly by the knock-on effect of the economic crisis, food price inflation and doubts about the acceptance of Genetically Modified Organisms (GMOs). We shall briefly discuss the outlook for the industry's two main subsectors, crop protection and seeds.

Crop protection

We can expect continued growth in this market through to 2012. North America is expected to grow by 1.3% year-on-year (YoY), with growth mostly driven by the expansion of the fungicide market. Europe should grow by 1.6% YoY with Eastern Europe, including the Russian Federation, being a major source of demand. In Latin America, the shift from subsistence farming to professional farming, together with

Brazil's problems with the soybean rust fungus, will drive strong growth of 4.9% YoY. Asia Pacific is a difficult market for agrichemicals because of the high proportion of subsistence farming, but is nonetheless expected to grow by 2.8% YoY[16].

Seeds
Continued growth is again expected through to 2012, though North America, the largest market, is expected to see its GM corn, soybeans and cotton acreages remaining flat for the next few years. In Latin America, the growth opportunity is in Brazil, though so far only soybean and cotton insect resistance GMOs have been approved there; analysts believe there is a 55 million acre potential for soybeans, but progress is slow because of Brazil's weak IP protection[17].

India presents a great growth opportunity for genetically-modified (GM) soybeans and cotton in the next decade, but market penetration is difficult because India's farming industry is fragmented. Nonetheless, analysts expect the India GM cotton market to grow by 15-20% through to 2012.

While the overall European population size, and hence its probable demand for food, is relatively stable, its ability to import crops will be reduced because of demand in other geographies. It will therefore need to get better leverage from existing land, which may lead to a reduction in the resistance to GM crops in Europe.

The strong anticipated growth of these two subsectors in emerging markets will mean that most large agribusinesses will continue their drive to build their global presence in these markets. However, these companies face some challenges and risks as they do so.

Challenges
The biggest challenge will be to avoid the "growth at any cost" syndrome. When companies are expanding rapidly, the temptation is to hope that the growth in revenue will hide potential cost issues that will cause problems later. Companies must maintain their focus on cost control.

It will also be important to build and maintain a common organizational culture – a particular challenge in the context of a continuation of (and possible increase in) the level of M&A activity. At the same time companies must maintain standardization of processes, methodologies and key performance indicators. New employees must be quickly brought up to speed with the company's ways of working.

Rapid growth brings HR challenges, such as managing individuals' career development and Human Resource Planning (HRP) expectations when total headcount is changing significantly. In an expanding market with a limited talent pool, it can also be harder to recruit people with the right level of industry knowledge.

Risks
There is a significant risk that the level of counterfeiting will continue to rise[18]; already it is increasingly prevalent in the emerging markets where organizations expect to grow fastest.

At the same time, cost pressures may reduce brand loyalty and increase the

16 "The Global Agrochemical and Seed Markets," PhillipsMcDougall, Jul 08
17 "The Inevitability of GMOs & The Coming Surge in Ag Chems," Credit Suisse, Sep 08
18 See "Perspectives on Life Sciences", Spring 2009

use of generics. Worse, the economic crisis may mean that the expected increase in overall demand does not materialize, leaving all the big agribusiness companies in a head-to-head battle for customers. (In an expanding market there is generally room for all the companies to hit their sales targets, but in a stagnant or decreasing market this is not the case.)

What steps should agribusiness companies take to advance their journey towards transformation?

We see nine major responses open to the agribusiness industry, some of them related to strategies also recommended for the pharmaceutical and biotech industries.

1. Build end-to-end capabilities to serve customer needs in a more integrated way (for example, deliver a GM seed pre-coated with the appropriate herbicide).
2. Adapt the internal organization, implementing new operating models that make it easier to deliver these integrated product offerings to the customer.
3. Build the operating model to allow for growth – standardize wherever possible and look closely at how local markets are supported.
4. Tailor the marketing approach – both channel and message – to meet local needs.
5. Proactively set up risk management capabilities across the portfolio (for example, by managing cash flow and suppliers) to provide financial protection for the company.
6. Increase collaboration with other businesses (especially in the R&D area). Also collaborate with academic institutions.
7. Perform a detailed capabilities audit. Examine current capabilities and compare them with those needed in future. Find out which other sectors can offer any missing capabilities, and then recruit heavily from these sectors.
8. Build more goodwill: try to create a more positive public perception of the industry. For example, demonstrate how the industry is helping to deal with the demand for food, to counteract the negative vibes associated with GMOs.
9. Review information infrastructure across the value chain to ensure it can support the upcoming changes (for example, regulatory changes, the growth of networks for R&D and supply, and the bundling of products and services).

5.4 Conclusion: A call to action

Changes in the life sciences industry are here to stay, and companies need to make permanent changes to the way they operate.

In biotech, the major challenges are to maintain funding and to take advantage of the growing need for diagnostics and biotechnology-derived products; in both areas the key may be to form the right partnerships and alliances. In agribusiness, the challenge is to adapt to the needs of the newer markets that hold the greatest promise of growth.

For pharmaceutical and medical device companies, worldwide healthcare reform presents a great opportunity to revisit the role of life sciences companies in accomplishing their mission of better health and better care for patients, while reassessing all components of the existing business model.

Medical records and healthcare information will also play a major role in enabling change.

Transformation in the pharma industry will not be accomplished overnight. It will depend on innovation cycles, and on the ability of all stakeholders to change their mindsets. We all know the new model will be driven by personalized care. However, because the timeframe is unknown, no company can afford to wait for the new model to become clear. Now is the time to begin experimenting with new ways of collaborating and of managing innovation.

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