

OLIVER WYMAN

Executive briefing: Pharma trends

Beyond the blockbuster

Finding the next profit zone in Pharmaceuticals through Business Design thinking

Executive summary

- The rapid growth of pharma companies in the 1990s was driven by a 'blockbuster' model
- This model is under pressure: Slowing scientific innovation and rising development costs combine with prescribers, payors and patients becoming tougher customers
- But investor expectations remain high as much of the value of companies is still derived from products yet to be launched
- Finding a way through this situation calls for some deep thinking around new business models and different 'customer' relationships
- Oliver Wyman's approach is to identify new or adapted Business Designs that make money in distinctive ways that enable senior leaders to frame the questions they need to ask to find the profit zones¹ of the future
- This approach shows that some company strategies are beginning to move away from the traditional blockbuster model and are, in fact, becoming very different

¹ 'The Profit Zone', by Adrian J. Slywotzky and David J. Morrison was named by Business Week as one of the ten best business books in the year it was written. Currently in its fifth printing, The Profit Zone has appeared on several top 10 bestseller rankings, including The New York Times business hardcover bestseller list, and the Amazon.com non-fiction hardcover bestseller list. Adrian is a prolific book writer, his most recent – co-authored with Richard Wise – is entitled 'How To Grow When Markets Don't' and was published in April 2003.

Prologue: The triumph of the blockbuster

The consistent growth of the pharmaceuticals industry in the 1990s was built around the ability to consistently bring efficacious new therapies to market to satisfy large unmet medical needs.

Not only was this growth rapid, but it was also spread widely across many companies in the industry. The enterprise value of the top ten players grew fivefold from \$200bn in 1990 to \$1,000bn today. The underlying Blockbuster business model that drove this stunning performance was in essence very simple: discover efficacious compounds that address large areas of unmet medical need, and develop them fast and market aggressively via (mostly) large primary care sales forces.

'Finding the compound' was perceived as the key to the strategy and, on the whole, most big pharma companies were able to achieve this consistently,

profiting from a wave of scientific innovation that started in the 1970s and bore fruit in the 1990s. Even those that were slow to 'find the compound' could prosper by being good secondary movers, producing compounds that closely copied the method of action of competitors' drugs. Such was the level of unmet medical need that these were often more successful than the first entrants which had to carry the market-building burden of pioneering a new category.

The blockbuster model under threat

Recently, the blockbuster model has come under pressure from a number of factors that will limit its ability to generate substantial profits for all players.

1. New scientific innovation is taking longer than expected to bear fruit

(Exhibit 1)

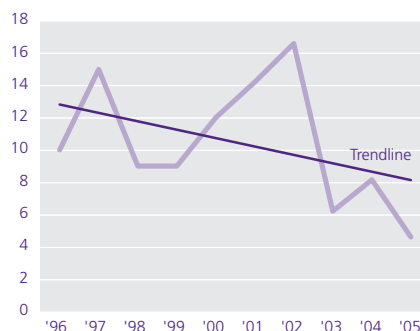
Many of the blockbusters launched in the mid to late 1990s were the product of discovery activities started in the 1970s and 1980s. These efforts focused on commercialising a wave of scientific knowledge that had been maturing for some time. More recent scientific advances such as high throughput screening and genomics have increased productivity but their impact has yet to feed through to the bottom line. For the time being, at least, many pipelines promise only single figure growth after the impact of patent expiries.

2. Development costs continue to rise (Exhibit 2)

At the same time that research is becoming less productive, development costs continue to rise, driven by falling success rates, greater clinical costs per patient and the need to perform larger trials to satisfy ever more stringent regulatory hurdles. In their recently published survey, DiMasi et al estimate that the overall costs for a successful compound rose over 2.5 times throughout the 1990s, amounting to over \$800m today inclusive of capital (opportunity) costs. We believe that these numbers are conservative, especially for highly competitive blockbuster categories.

Exhibit 1

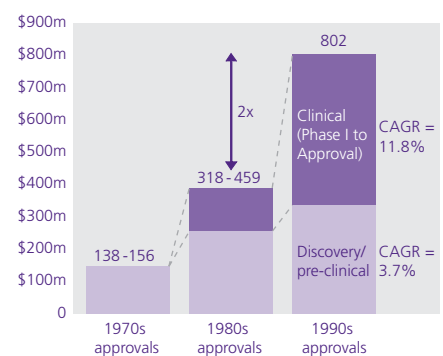
Number of blockbuster products launched per year is declining (number of products with peak sales >\$800m)



Source: Lehman Brothers

Exhibit 2

Development costs per drug, including cost of failures and opportunity costs



Sources:
 1970s: Hansen 1979; Wiggins 1987
 1980s: DiMasi et al 1991; OTA 1993; Myers and Howe 1997
 1990s: DiMasi et al 2003

3. The prescriber has become a tougher customer (Exhibit 3)

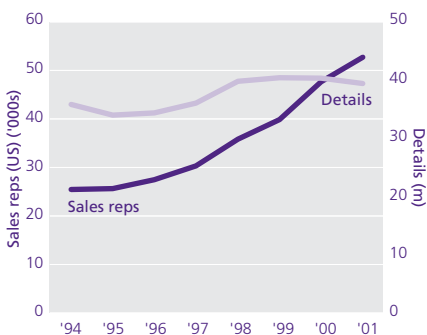
The blockbuster model also faces pressure at the customer end of the value chain. Throughout the 1990s, pharmaceutical companies relied heavily on building ever larger primary care salesforces to drive revenue and gain competitive advantage over competitors while still achieving good marginal returns for every new sales representative hired. This strategy is running out of steam. Doctors are saturated with sales calls as ever more reps chase ever fewer doctors who are willing to accept a visit. Moreover, many of the products that sales reps are promoting are 'mature' blockbusters that have already been promoted on many previous occasions.

4. The payors and patients have become tougher customers (Exhibit 4)

In the early 1990s, nearly 60% of drugs were paid for by private individuals. Today over 70% of drugs are paid for by insurance companies/HMOs who are leveraging their scale to exert downward pressures on prices. Payors are also demanding that new drugs have health economic benefits as well as enhanced efficacy. Organisations such as the 'National Institute of Clinical Excellence' (NICE) in the UK have been set up to do just that. The rise of the internet and dramatic increase in direct-to-consumer (DTC) advertising, where allowed, has meant that patients are becoming ever more informed about their treatment choices. As a result pharmaceutical companies are increasingly having to re-think their traditional marketing strategies.

Exhibit 3

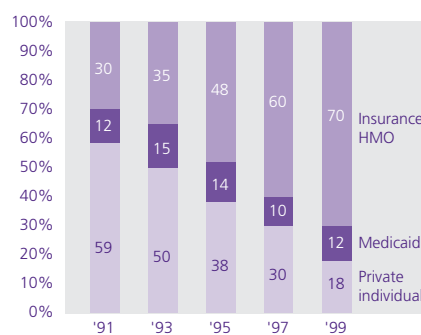
Sales reps have grown in number, but detailing activity is stagnating



Sample of Top 10 detailing companies in the US: Pfizer, BMS, Pharmacia, GSK, Wyeth, Schering Plough, J&J, Eli Lilly, Astra Zeneca, Merck
Source: Scott Levin

Exhibit 4

Sources of payment for ethical drugs



Source: S+P Industry Profile June 2001

Investor expectations remain high

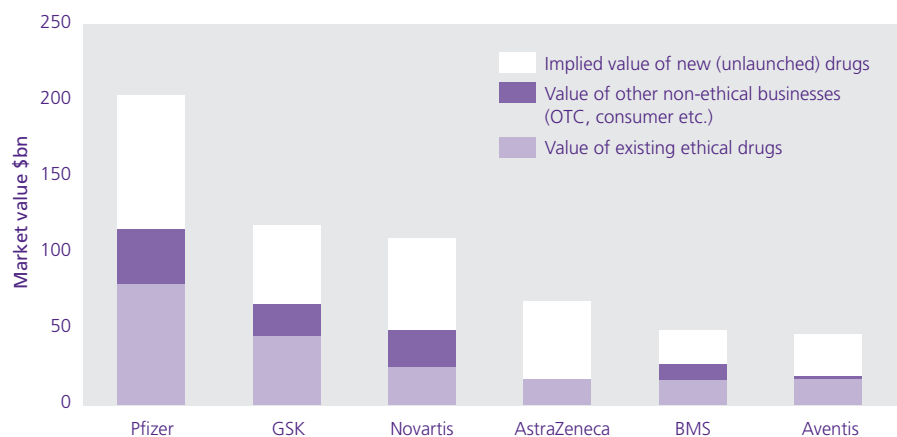
Despite these pressures, investor expectations remain high. Although valuations have declined significantly from their peak in 2000, average revenue multiples of the 10 leading players remain in the 4-6 range.

The speculative value placed by the capital markets on unlaunched drugs in companies' long term 'distant' pipeline surprises us. Research carried out by Oliver Wyman suggests that the value of existing products and other non-ethical pharmaceutical businesses constitutes on average less than half of the market capitalisation of the major players. We believe that a significant proportion of the remaining 'gap' may be accounted for by high expectations for longer term unlaunched drug

prospects. To maintain these steep valuations, pharmaceutical companies will have to maintain existing margins and grow sales by over 10% per year, even in the face of patent expiries. This translates into the need to launch three blockbusters a year, a difficult challenge when viewed in the light of the industry's past performance. Few of the leading players managed to launch consistently more than one major blockbuster per year in the 1990s.

Exhibit 5

Investor expectations remain high: most of the value of pharmaceutical companies is derived from products yet to be launched



Source: Oliver Wyman analysis

The challenge of strategy

Given these negative trends in the industry, how should pharmaceutical companies think about new strategies that address the pressures on the blockbuster model and meet shareholder expectations?

We believe that developing high level strategies is a tough task for leaders in this industry. Unlike some other sectors, the time taken for strategy decisions to hit the bottom line is very long indeed. An initiative to, say, focus on a particular therapeutic area in drug discovery can take up to 15 years to bear fruit. Even a supposedly shorter term initiative to in-license a given compound in late stage development can take up to three years, assuming the approvals process runs smoothly. Leading players have to be outstanding at anticipating trends early and positioning themselves to take advantage quickly.

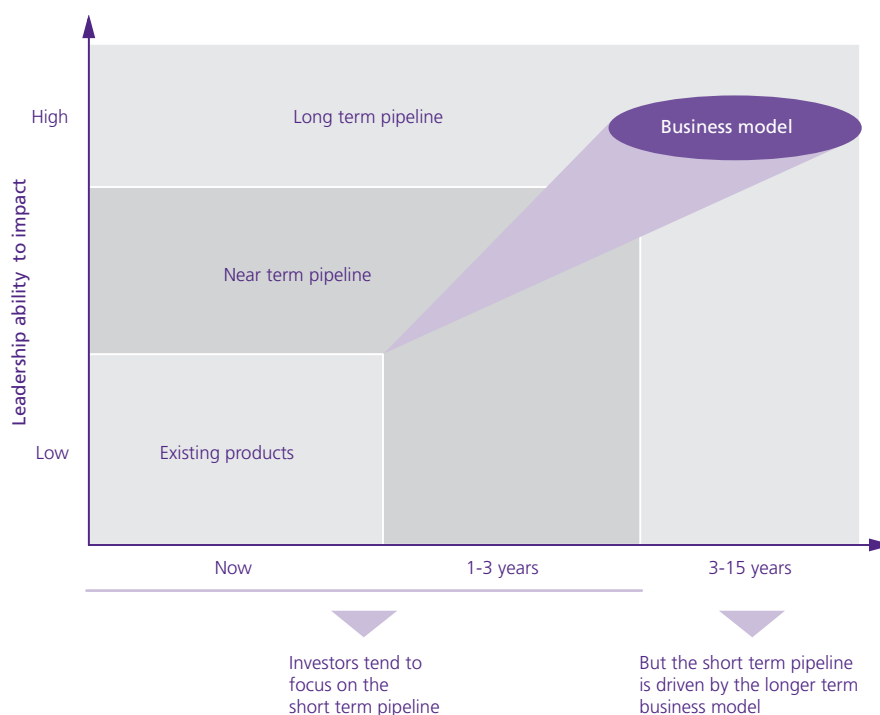
Another difficulty is serendipity. Even the most deliberate, well planned and executed strategies are hostage to events (fortunate or otherwise) in drug development that are impossible to anticipate. Who could have foreseen Pfizer's erectile dysfunction success with Viagra, a compound originally developed as a cardiovascular drug. Or B-MS's success in type II diabetes with Glucophage, a 'forgotten compound' originally discovered and used successfully in Europe since the 1950s.

Leaders in this industry are also under continuous short term investor pressure to focus on running better the businesses they have today, rather than finding answers to the longer term issues needed to build the businesses they need in the future. There is always a critical development decision to be made about a particular drug, the efficiency of the salesforce regularly requires improvement, and biotechs always want face to face discussions about an in-licensing deal.

Thinking about Business Designs as the right units of strategy 'raises the vantage point' for senior leaders, enabling them to make real strategic choices. Our Business Design analysis shows that despite the 'interference' of serendipity or long time lags, company strategies have begun to move away from the traditional blockbuster model and are in fact becoming quite different, whether strategically or serendipitously. This emerging evolution can be instructive.

Exhibit 6

The challenge of strategy: getting the business model right over the long term



Business Designs:

Our starting point

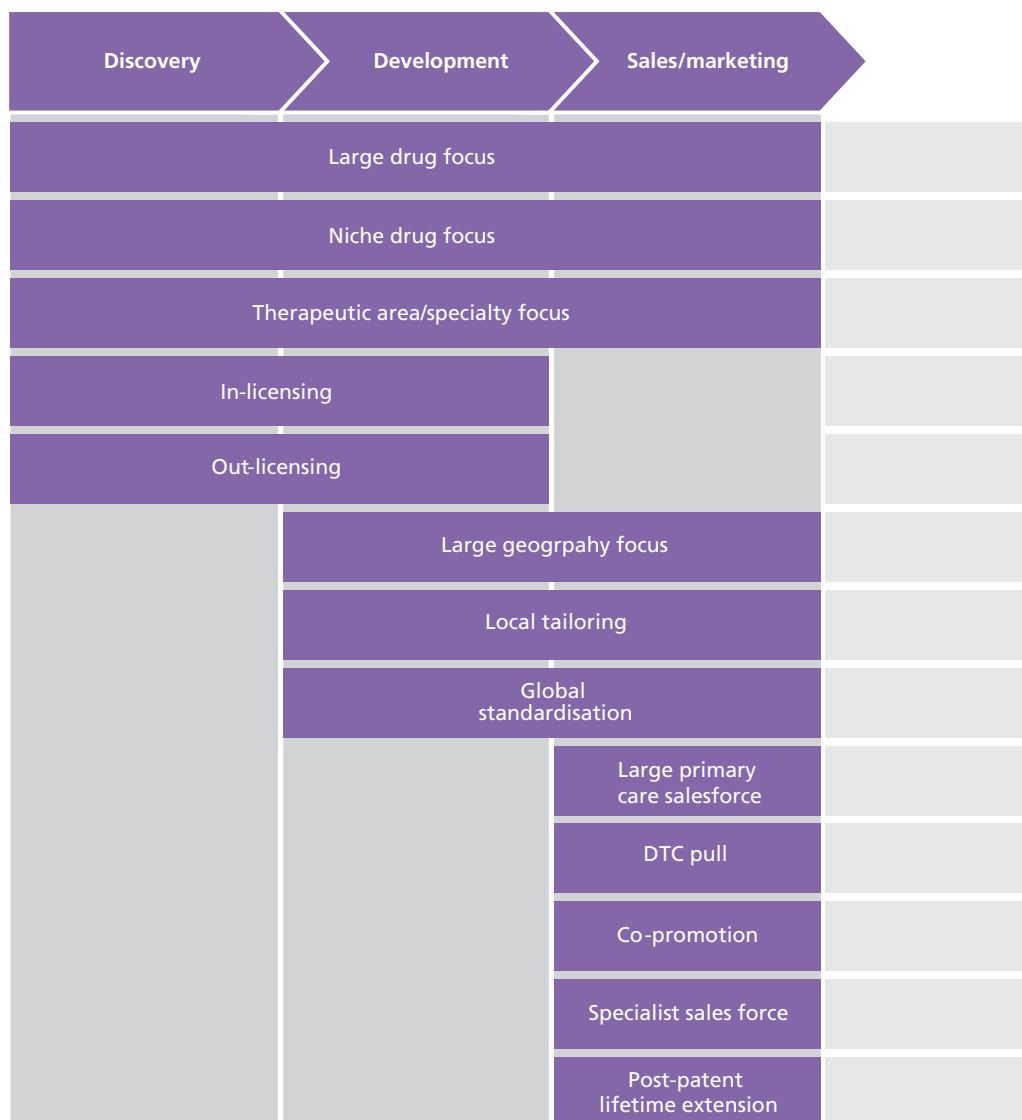
Our view of the industry revolves around looking at the different 'Business Designs' that pharmaceutical companies might or might not operate.

A 'Business Design' is how you make money; what you do for whom that earns a profit, and how you protect the cash streams. A Business Design is more than just a value proposition, a particular profit model or a source of competitive advantage. It is the customers you choose,

the problems you solve for them with the drugs or services you offer them, how you access these, how you get paid, why this is defensible and the sort of organisation that is required to make it all happen.

Exhibit 7

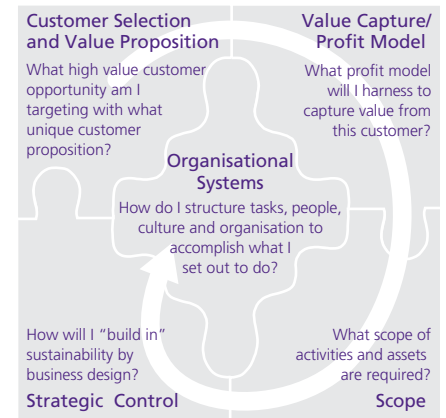
'Business Designs' - the common building blocks of every big pharma company (not at all exhaustive)



After studying a variety of big pharmaceutical companies and new entrants, like biotechs, we believe there are at least 13 major Business Designs in the industry today, as shown in Exhibit 7. This exhibit provides a brief, high level but not exhaustive description of the Business Designs. These boil down to the different ways companies can access, develop and market drugs. Some of these can exist at multiple points from discovery through to sales and marketing. For example, an

integrated pharma company can choose to focus on large drugs all the way across the value chain. But a biotech could do this just at the discovery stage, a contract research organisation (CRO) during development and a contract sales organisation (CSO) during marketing. We observe that all companies are unique mixes of these Business Designs, employing different ones at particular points of the value chain that add up a unique 'tone of voice'.

The components of a Business Design



Description

What's the 'bet'?

<ul style="list-style-type: none"> Rigorous focus on markets and compounds that have the potential for >\$1bn/year sales (irrespective of therapeutic area) 	<ul style="list-style-type: none"> The risk/return profile of one large drug is better than many small ones
<ul style="list-style-type: none"> Focus on lower potential areas/conditions largely ignored by other companies e.g. orphan markets (irrespective of therapeutic area) 	<ul style="list-style-type: none"> New compounds for small, 'un-addressed' markets are easier to develop and require less marketing push (no competition)
<ul style="list-style-type: none"> Focus and build scale in a particular therapeutic area (broadly or narrowly defined) 	<ul style="list-style-type: none"> The scale and customer synergies within a therapeutic area are substantial
<ul style="list-style-type: none"> Purchase promising early stage compounds at a price below their full potential and develop them successfully 	<ul style="list-style-type: none"> Can identify value in licenses that the current holder cannot see or cannot create
<ul style="list-style-type: none"> Capture value through selling partially developed compounds 	<ul style="list-style-type: none"> More value will be created by selling the compound than developing it further internally
<ul style="list-style-type: none"> Tailor drugs only to major global markets to increase development speed and reduce regulatory risk 	<ul style="list-style-type: none"> Lower risk/faster launch in a few major markets outweighs the revenue opportunity loss from other markets
<ul style="list-style-type: none"> Tailoring compounds closely to local needs at the expense of development speed, consistency and regulatory risk 	<ul style="list-style-type: none"> Revenues from smaller markets outweigh regulatory risks / launch delays in major markets
<ul style="list-style-type: none"> Sales and development strategies focused towards swift rollout to one standard 	<ul style="list-style-type: none"> Speed and consistency is worth more than local tailoring
<ul style="list-style-type: none"> Create strong sales 'push' through large sales force scale with resulting efficiencies 	<ul style="list-style-type: none"> Sales forces have large scale efficiencies
<ul style="list-style-type: none"> Create sales 'pull' through DTC brand building 	<ul style="list-style-type: none"> The returns on DTC spending are high
<ul style="list-style-type: none"> Promote another company's products for share of revenue, risk 	<ul style="list-style-type: none"> Increased sales/marketing scale creates a win-win for both partners
<ul style="list-style-type: none"> Build strong relationships with specialist physicians via a dedicated and focused salesforce 	<ul style="list-style-type: none"> Specialist physicians are more responsive to highly focused salesforces
<ul style="list-style-type: none"> Extend the value of a drug beyond its patent expiry via line extension, brand building etc. 	<ul style="list-style-type: none"> The post patent value increase justifies the investment

Business Designs **in practice**

How can a Business Designs approach be used in practice to evaluate current strategies and build the winning ones needed in the future?

1. Catalogue and describe existing Business Designs

Which Business Designs operate within the business today and how much are they worth? How does this compare to competitors? Finding answers to these questions requires the re-casting of internal management accounts or publicly available data into discrete Business Designs. While this is not conceptually straightforward, it is possible with the application of the right analytical tools. Taking, for example, an integrated company with a 'Large Drug Focus' we would isolate the costs and revenues associated with all the large drugs in the portfolio and carry out a DCF valuation.

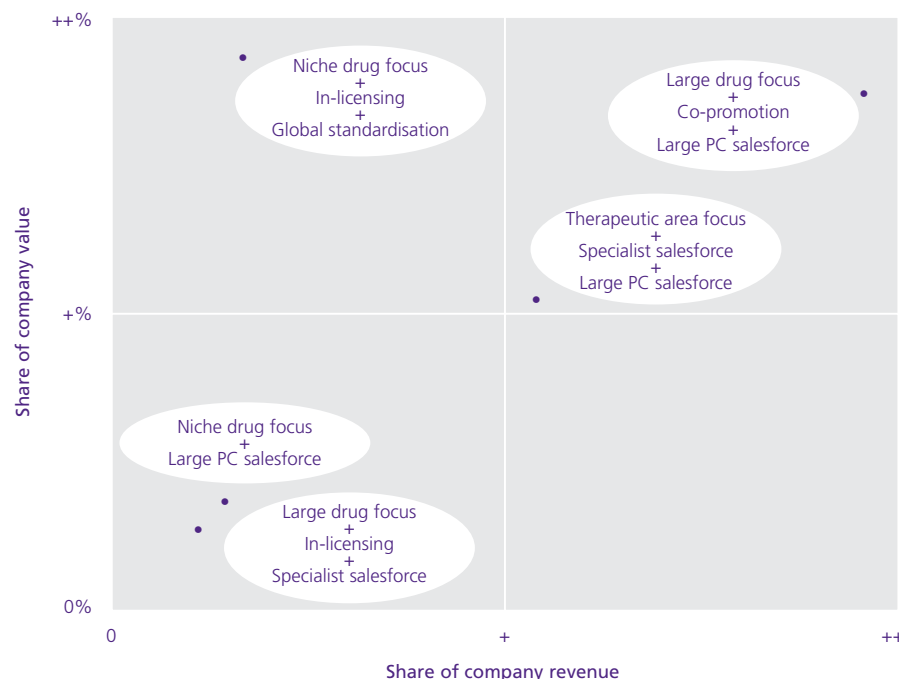
We would then break this value out by each step of the value chain. If this process is repeated for each potential Business Design a detailed picture of the size and structure of the portfolio begins to emerge.

2. Understand how Business Designs can be mixed and matched to either create or destroy value (Exhibit 8)

Most pharmaceutical companies, except perhaps for some very focused specialists, operate more than one Business Design. But if you mapped out the discrete value created by each one it would be only half the picture.

Exhibit 8

Valuation of different mixes of Business Designs operating within a company



Here's why. Let us assume that the integrated pharmaceutical company with a 'Large Drug Focus' begins to bolster its pipeline by in-licensing drugs from biotechs. The value of this activity is superficially simple: The sales revenues of the in-licensed products less the purchase price, royalties, marketing costs and so on. But if the company has a large primary care salesforce that it used to persuade the biotech that it was the best partner for the deal, the picture becomes less clear. How much value was created by combining in-licensing with a big salesforce – certainly more than doing either on its own.

These sorts of questions can be answered by thinking deeply through the logic of combining different Business Designs and applying a range of sophisticated analytical approaches. But it is not straightforward. Nor do we think it is only of academic interest to senior leaders. Pfizer became the industry leader it is today because it understood early the economic value of linking in-licensing with a large primary care salesforce and made some large bets. The race is on to mix and match the right Business Designs that will create value in the future.

3. Understand the organisational constraints on different mixes

We define organisation here in its broadest sense: the types of people, culture, processes and structures required to ensure a business operates effectively. Just as mixing Business Designs has economic implications, it also has organisational implications. Obviously no organisation can accommodate an infinite amount of Business Designs. But at a more practical level, the more Business Designs you begin to add, the greater the compromises that have to be made within the organisation to accommodate them. A good example of this is the commonly advanced argument that biotechs have better R&D productivity than large integrated pharmaceutical companies because they are more focused on basic research activities. What this really means is that the single Business Design

that they operate is not organisationally compromised by the need to co-exist with a range of other Business Designs within the same company. But equally as important as the number of Business Designs is their type. Simply put, some mixes of Business Designs work better together within an organisation than others.

Viewing pharma companies...



What can we learn from looking at pharmaceutical companies from a Business Design perspective? How do they mix and match the Business Designs to gain competitive advantage?

There are a range of distinct models that are unique collections of Business Designs

Research carried out by Oliver Wyman suggests that there are very real differences in how companies do this, from integrated 'big pharma' right down to smaller players who are focused on particular areas of the value chain. What is most striking is not just the way companies have made choices about which Business Designs to operate, but how they are linked together to create value.

In big pharmaceutical companies, it is clear that all players have employed all of the Business Designs to a greater or lesser extent, but if we filter out some of this 'noise' and focus on those that form a significant part of their business an interesting picture begins to emerge. We think that there are a range of distinct models that are unique collections of Business Designs, each with their own internal logic and unique 'tone of voice'.

... through a Business Design lens

The 'R&D Driven Blockbuster'

The heart of this strategy reflects a fastidious focus on the in-house discovery of large drugs for high prevalence, mostly primary care prescribed disease areas.

In some traditionally successful competitors, we see over 80% of sales are derived from in-house originated compounds and over 90% of revenues come from products with yearly sales of over \$850m. This is a high risk, high return model predicated on the ability to consistently do the outstanding science necessary to find the next large drug, in whatever therapeutic area.

The larger the average drug size becomes, the more it pays to increase the speed of development and minimise risks throughout. As a result, this type of company employs two other Business Designs. First, a 'Large Geography Focus' in development and marketing means that the speed of product commercialisation is not affected by distractive efforts to get the product exactly right for smaller markets. This approach also reduces risks since clinical trials do not have to be complicated by the need to test a broader range of indications within the context of very different local disease treatment 'philosophies'. Second, a 'Large Primary Care Salesforce' ensures that each drug is supported by a high level of promotional activity, ensuring rapid market penetration.

All of these Business Designs are wrapped in a highly centralised organisation that keeps all activities tightly aligned.

The 'Customer Driven Blockbuster'

Superficially, this approach appears very similar to the R&D Driven Blockbuster. Its product portfolio is centred on large, blockbuster drugs targeted at high prevalence disease areas, in large geographic markets and primary care.

However, we believe that this approach is an 'enhanced' R&D Blockbuster model and that it operates three additional Business Designs with a centre of gravity closer to the customer, rather than in the science of R&D. The key to this approach is a leading primary care sales force, large enough relative to competitors to have advantage in physician access.

The approach can leverage its scale in this area to carry out 'In-licensing' and 'Co-promotion', signing attractive deals because of its ability to offer a bigger promotional effort at lower cost than its peers. Typically, over two thirds of all revenue comes from products that have been sourced in this way, as other companies see this Customer Blockbuster as the partner of choice for new product launches.

This is a high risk, high return model

Although the drug sizes might be smaller, the development and marketing costs are lower too

The ‘Niche Drug Player’

This strategy is centred around the ‘Niche Drug Focus’ Business Design – targeting small ‘niches’ that have not been fully addressed by competitors. Although the drug sizes might be smaller, the argument here is that the development and marketing costs are lower too, because of limited competition and regulators’ unwillingness to discourage novel therapies that address rarer diseases. In essence, the opposite of the high risk blockbuster strategy. There are many different approaches to what constitutes an attractive niche, in terms of economic size and structure. A low prevalence, high value per treatment niche is very different from a high prevalence low value per treatment niche, even if their overall sizes are the same.

The basic model is often enhanced with the ‘Local Tailoring’ of drugs closely to the requirements of a broad range of geographies, the bet being that getting the niche right everywhere is worth the resulting slower development times. Companies also appear to have some success at extending the life of their drugs beyond patent expiry – niches tend to be more defensible from generics manufacturers. Typically companies tend to have decentralised organisational structures, with local operations having the freedom to pursue their own approaches to targeting niches.

The ‘Therapeutic Area Focus’

The underlying principle of this strategy is a focus on just a few targeted therapeutic areas. In practice this means providing a broad range of drugs (both large and small) and potentially ancillary services to offer an overall ‘therapeutic solution’ to customers. The underlying premise here is that there are synergies within certain therapeutic areas from early drug discovery, through development and right up to forming customer relationships. This strategy has been pursued by some small and mid-sized companies as a way of negating their overall scale disadvantage versus larger competitors.

We see a broad range of variations around this strategy with companies mixing in many additional Business Designs, often driven by the particular characteristics of their chosen therapeutic areas. Most companies tend to structure themselves around therapeutic area units to realise the full benefits of focus. Overall, it is unclear today whether this type of model is sustainable over the long term or whether the current positions are a result of serendipity and will evaporate with the loss of a key compound.

We see a broad range of variations around this strategy with companies mixing many Business Designs

Other Approaches

Many smaller players appear to be attempting more radical departures from the types of strategies followed by larger pharmaceutical companies. A key theme is the unbundling of the value chain as players stake out their own chosen areas of focus.

The first wave of this was the proliferation of drug discovery focused biotechs throughout the 1990s. The large amounts of capital that have been sunk into these players (nearly as much as the combined R&D spends of the top 10 big pharma companies over the last three years) means that a bigger and more liquid market for new compounds is beginning to develop. As a result, downstream players have greater scope to develop more innovative games. Some companies have positioned themselves as 'compound traders', making money by in-licensing undervalued compounds and out-licensing them later at a higher price, without necessarily having carried out any further development work.

Other companies appear to be focused on in-licensing, developing and marketing large drugs with limited discovery capabilities, similar to the ill-fated Marion Merrill Dow in the early 1990s. It is as yet unclear whether the market for compounds is large enough to provide enough 'feedstock' to sustain this model

– the success of some players so far has been based primarily on just one product.

At the sales and marketing end of the value chain contract sales organisations such as Quintiles appear to be dabbling in backward integration, taking on more risk sharing deals with customers for compound development. While all this is going on, biotechs such as Amgen are busy forward integrating into sales and marketing.

A more liquid market for compounds gives greater scope for more innovative strategies

Focus on a new horizon



How can pharmaceutical companies use Business Design thinking to set their future direction? We believe senior leaders should ask themselves a number of questions.

1. What Business Designs do I have today and how much are they worth?
2. How much will they be worth in the future if the trends in scientific innovation, development costs and the behaviour of patients, physicians and payors continue? Will they still be viable and will their current mix create best value?
3. What can I learn from the Business Designs operated by my traditional competitors and new emerging players? What new Business Designs should I consider 'importing'?
4. How should I mix and match existing and new Business Designs to create the business I need in the future? How do I get there and what 'bets' do I need to make a long the way?
5. What does this mean in terms of organisational practicality, and what trade-offs should I make?

Contributors



David Campbell Toronto

david.campbell@oliverwyman.com ■ +1 416 868 2101

David works extensively with pharma and device companies, academic research agencies, hospitals, clinics, and providers to these. His activities range from clinic management to negotiating research funding and acquisition due diligence. A frequent industry speaker and author, prior to Oliver Wyman David was at Procter & Gamble and a graduate of Queen's University, Kingston in Canada.



Andrew Chadwick-Jones London

andrew.chadwickjones@oliverwyman.com ■ +44 (0)20 7915 9233

Andrew is a key contributor to Oliver Wyman's Life Sciences intellectual capital. Andrew's work ranges from high level strategy issues to development process improvement, product launch strategies, marketing optimisation, compound due diligence and provider efficiency (hospital). Before Oliver Wyman, Andrew worked at HSBC and holds an MA in biological sciences from Christ Church, Oxford.



Andrew Pasternak Chicago

andrew.pasternak@oliverwyman.com ■ +1 312 902 7012

Andrew works across a variety of clients including large pharma, biotech, private equity, NGOs and government agencies. He is a recognised thought leader in vaccines and biopharmaceuticals and holds an MBA from the University of Chicago.



Adam Sabow Chicago

adam.sabow@oliverwyman.com ■ +1 312 902 7915

Adam works with life sciences clients on a range of topics, including operational economics, market entry, and growth strategy. He has particular expertise in biologics, speaking and publishing on that sector, and holds an MBA from the Kellogg School of Management at Northwestern University.



Mike Weissel Boston

mike.weissel@oliverwyman.com ■ +1 617 424 3752

Mike is the leader of Oliver Wyman's Health and Life Sciences team and has extensive experience in the insurance, payor and health outcomes area. His work on marketing effectiveness has been published in HBR and he holds an MBA from the Fuqua School of Business at Duke University.



Jim Hall Boston

jim.hall@oliverwyman.com ■ +1 617 424 3571

Jim has over 20 years experience in the Health and Life Sciences industries and his work includes strategic planning, marketing planning, new business creation, R&D optimization and product development.

About **Oliver Wyman**

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Oliver Wyman's proprietary Business Design techniques – combined with its specialised industry knowledge and global reach – enable Life Sciences companies to anticipate changes in customer priorities and the competitive environment, and then design their businesses and improve operations to seize opportunities created by those changes.

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