Business Growth: Bespoke Strategists Lead the Way

The last five years has been one of significant evolution for the pharmaceutical industry.

In a context of significant industry restructuring, cost-cutting and patent expiries, 26 of the world's top pharmaceutical companies have managed to grow their top-line revenues by more than 50% over the last 5 years. Some of the companies have achieved this growth highly profitably, some have sacrificed profits to grow top-line revenue. Some have invested heavily in R&D, some have chosen to avoid heavy R&D investment. So what can we learn from their diverse successes? In this paper we identify the 26 top-growing companies and classify them into three segments to illustrate the contrasting dominant strategic philosophies that have been applied to achieve business growth. We explore the success stories of selected companies within each of the three segments, and then conclude by examining the common theme that we believe has had a key role in driving business growth: that of 'bespoke strategy'.

Introduction

The last five years has been one of significant evolution for the pharmaceutical industry. In terms of new drug product approvals, the trend is upwards in terms of both number and quality, yet the largest companies have been ruthlessly cost-cutting and reducing investment in both commercial and R&D infrastructure. Furthermore the cost of making new drugs is escalating: whatever you think about the most recent $2.6 billion[i] estimate for developing a drug (the many assumptions behind this figure can be debated at length, and are outside the scope of this paper), there is no doubt that the trend in cost per new drug is up. Furthermore the pharmaceutical industry continues to face pressure to defend its stance on R&D investment and still remain profitable. This is especially true when considering that R&D decisions made today take time to be fully realised in the future. So is R&D investment still central to achieving business growth, and if so what is its role in securing business growth?

In this paper we explore the roots of growth for the top-growing pharmaceutical companies for the last five years. We specifically explore Revenues, EBITs (profitability), R&D investment[1], NME[2] Launches and Acquisitions[3] for each of the companies and draw conclusions of relevance to all pharmaceutical companies seeking to grow their businesses over the next five years.

We identified the top pharmaceutical companies that have grown revenues by over 50% in the past five years (2008-2013). Utilising Scrip Intelligence's "The Scrip 100 List," Novasecta's proprietary database and Forbes' "Worlds Biggest Public Companies List" we selected 118 companies. From this list we excluded 19 companies that: (a) are wholesalers, service organisations and other service providers, (b) publish minimal or no financial data and (c) had less than $500m in revenue during 2013. From the remaining companies, we chose the 26 companies that have had a revenue growth from 2008 to 2013 greater than 50%.

Three strategic philosophies of the top growers

As a proxy for the R&D investment philosophies that are currently applied by the 26 top growing companies, we examined the relationship between each company's R&D Spend as a % of 2013 Revenue and its revenue growth over the last five years (Figure 1). Three segments of companies are evident, which we have characterised according to the dominant strategic philosophy that they have been applying to grow their businesses:

- **'Build'** companies typically invest 10-25% of revenue in R&D and have maintained excellent profitability through focusing on what they uniquely do well.
- **'Breakthrough'** companies have typically invested more than 25% of revenue in R&D and have achieved success from a limited number of highly innovative products.
- **'Buy'** companies have taken a primarily acquisition-oriented approach to growth, typically investing less than 10% of revenue in R&D and achieving relatively low annual profitability as a % of revenues.

Top Pharma Growers Classified into Three Segments: Breathrough, Build and Buy

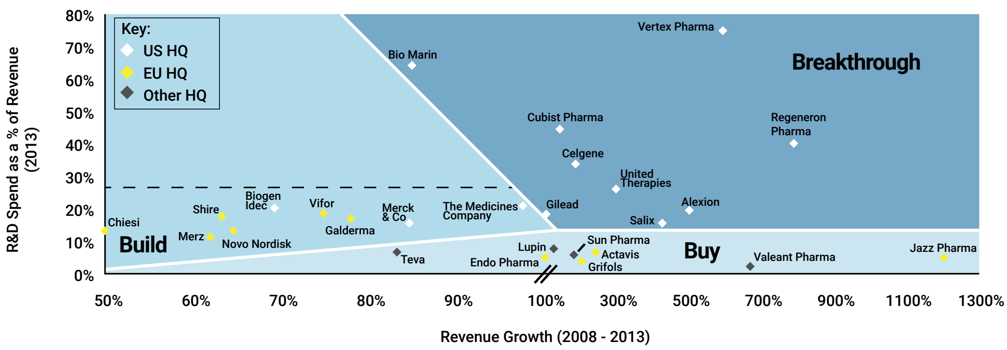

Figure 1 – R&D Spend as a % of 2013 Revenue against Revenue Growth over the five-year period; The Build pharmas typically do not invest more than 25% of Revenue in R&D spend, represented by the dotted line.
Source: Financial data obtained from GlobalData and Novasecta Proprietary Database.

The results and value drivers by segment show clearly contrasting strategies in relation to how the companies have chosen to grow their businesses – and the consequences of those choices in terms of profitability and growth (Table 1):

		Build (9 companies)	Breakthrough (9 companies)	Buy (8 companies)
Business Results	Average Revenue Growth (2008 - 2013)	71%	346%	350%
	Median Profitability as % Revenue (2013)	34%	28%	17%
Value Drivers	Average R&D Spend (as % of 2013 Revenue)	17%	38%	6%
	Average Acquisition Deal Value (2008 - 2013) (as multiple of 2013 Revenue)	0.3	0.7	1.1
	Average NME Revenue (2013) (as % of 2013 Revenue)	12%	41%	0%

Table 1 – Summary of key business results and value drivers for growth for each segment; Profitability measured by EBIT (data available for all companies except for Galderma); NME Revenue relates to the 2013 Revenue generated from sales of NME products launched between 2004-2013 where available (NME revenue data availability by segment: Build – 16/22, Breakthrough – 14/16, Buy – 0/3).
Source: Medtrack, Novasecta Proprietary Database, GlobalData and Scrip Intelligence.

The Build companies conform to the classic pharmaceutical model: moderate R&D investment as a % of revenue with little investment in acquisitions compared to the revenue they generate – and a 12% share of revenues from NMEs that were launched in the last 10 years. By contrast the Breakthrough companies invest and receive more from R&D, often complementing this with significant acquisitions. And the Buy companies spend significantly on acquisitions, invest little in R&D, do not rely as much on their recent NMEs for revenue, and have much lower profitability than the Build and Breakthrough companies. In the remainder of this paper we explore the companies within each of the three segments then draw some conclusions and implications for pharmaceutical companies seeking growth now.

Build: Focused strategies for growth and consistently strong profitability

The Build companies have grown through a variety of strategies: organically, inorganically or international expansion all with R&D at its core. This group typically invested 10%-25% of revenues in R&D whilst maintaining a respectable revenue growth of 50%-100% over the five-year period. Notably, a mixture of public and private companies based in Europe dominates this segment. Companies in this segment have launched on average 2.4 NMEs in the last ten years, but do not rely on these for their 2013 revenue. Indeed half of the Build companies had no NME launches and Merck's 11 launches during the period skews the average. These companies typically have portfolios of historical products such as LCM products and other legacy products that are still generating top-line and growth. The group also invested less than half of their 2013 revenue into acquisition deals. By maintaining both revenue and R&D growth, this group has remained profitable with EBIT as a percentage of revenue (2013) typically ranging between 20%-40%.

Focused strategies bound by commitment to R&D and innovation

This is a diverse group with respect to drivers for growth, yet each has focused on a particular strength and built carefully from that, as illustrated by the following four examples:

- **Novo Nordisk** has shown a strong commitment to R&D that has been reflected in its output, launching four NMEs during 2004-2013. The company is primarily focused in developing insulin treatments for diabetes, both patented and generic products. The CEO of Novo Nordisk has stated that "the insulin market is big enough and growing fast enough that Novo Nordisk does not need to make acquisitions."[ii] As such, there is room for innovation in this field to fuel organic growth for the company. Establishing presence in obesity is now complementing this field in addition to expanding the haemophilia and growth disorders franchises.
- **Chiesi** has been growing internationally, stating that international sales outgrow national: 75% of 2013 revenue represented international sales. Chiesi also stated that 70% of 2013 revenue is due to internal growth (i.e. generated from products developed in the internal R&D pipeline), the remainder is a result of acquisitions. Chiesi strives to capture value from existing brands through an LCM pipeline ("Foster and Nexthaler and related brands continue to be the main driver behind the company's development"), as well as investing in innovative technologies.

- **Shire** recently underwent an R&D transformation, resulting in an R&D strategy centered on rare diseases. Consequently, Shire's commitment to its new strategy is illustrated by the plethora of acquisitions it has secured; a total of six acquisitions in the last five years, four of which were completed in 2013. These acquisitions brought in a portfolio of commercial and pipeline products to strengthen Shire's position in the rare disease field.
- **The Medicines Company** focuses on providing solutions in three areas: acute cardiovascular care, surgery and perioperative care and serious infectious disease care. More recently it has pursued growth aggressively with three acquisitions being completed in 2013 alone (four in total over the last five year period). These have enabled The Medicines Company to complement its existing marketed portfolio and facilitate its entry into the European market.

Breakthrough: High-risk innovation driving growth when it pays off

The Breakthrough companies have clearly been driven by R&D and innovation; typically committing over 25% of revenue to R&D in 2013. Simultaneously they have achieved high revenue growth within the last five years (greater than 100%). Impressively seven out of nine of these companies had at least one NME launch over the last ten years, feeding substantial revenue growth. For Regeneron, Celgene and Vertex, over 70% of their 2013 revenues relates to these NME launches thereby highlighting their revenue-dependence on 2-3 key products on the market. Certainly for Regeneron and Vertex revenue has grown year-on-year with significant increases observed between 2011 and 2012 for Regeneron and 2010 and 2011 for Vertex. Both increases in revenue can be attributed to the launch of NME products Eylea and Incivek respectively.

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It is notable that all of the Breakthrough companies are stock-market listed companies headquartered in the USA. This reflects the history of successful biotechs in the USA over many years (Genentech, Amgen et al.) and the capital market's willingness to invest in innovation and R&D in USA, which contrasts significantly with Europe and Asia, at least for now. Clearly the scientific and technology capabilities are what ultimately create innovation and growth, but it is hard to imagine a company that is not publicly-listed in the USA replicating the Breakthrough phenomenon.

For the future, additional stakeholder pressure to remain innovative and launch new products could be driving these companies to maintain high investment in R&D, raising concerns about the sustainability of this business model. When considering profitability (measured as EBIT as a percentage of revenue in 2013) the group is varied, possibly a consequence of the scale and/or stage of the company. Moreover while almost all of the companies completed acquisition deals over the past five years, investment in such deals totalled less than the 2013 revenue. This is a relatively small investment and emphasises that R&D is still a strong driver for growth for this group with a focus on making targeted acquisitions.

Transitioning from the US Biotech model to more a established Pharma Company

With scale and maturity and the need to continuously create new products and manage the lifecycles of existing products, we believe that the Breakthrough group will inevitably transition over time into either Big Pharma or Build companies or both. Meanwhile the commitment to R&D is impressive. For example despite rapidly bringing five products to the market (four in-house), Biomarin continues to invest up to 65% of revenues in R&D with a respectful revenue growth of 85%. By contrast Alexion's high revenue growth relates solely to one product, Soliris, which is marketed for two ultra rare diseases. Its clinical pipeline is dominated by Soliris label expansion and LCM studies and has a low R&D spend relative to the group – more like a normal pharma company – but is this sufficient for future sustainability and growth? Finally Gilead has built its business through a mixture of in-house innovation in infectious diseases (HIV/AIDs) and targeted acquisitions, more recently moving into oncology. It is now transitioning into Breakthrough company to more of a Build company, achieving a steady R&D spend as a percentage of revenue; 19% in 2013 compared to 79% in 2001.

Chasing breakthrough innovation leads to more creative investment

Another example of how the Breakthrough companies have pursued growth is through their eagerness to accelerate drug development. Both Regeneron, with its collaborate Sanofi, and Gilead have bought FDA priority review vouchers to fast-track regulatory reviews of late-stage assets. The former bought a voucher from Biomarin for $67.5m[iii] in July 2014 while the latter paid $125m[iv] to Knight Therapeutics in November 2014. The voucher entitles the holder a regulatory short cut where the FDA completes a six-month review of a new drug application.

Buy: An acquisitive approach to growth

Acquisition is clearly the key driver for this segment of companies; typically these companies made low investments in R&D (less than 10% of revenue) whilst achieving revenue growth of greater than 100% during the past five years. This highly acquisitive approach is demonstrated by a significant investment in deals and not only by the number of the deals concluded (typically more than four deals made in the last five years). Valeant, Actavis and Endo Pharma have completed 28 acquisition deals between them and invested more than double their 2013 revenue into these deals between 2008-2013. Such significant investment is now reflected in the long-term debt that these particular companies have accumulated; taking long-term debt as a percentage of revenue (2013) gives 172%, 62% and 48% for Valeant, Endo and Actavis respectively. Predictably, the three companies above have not performed positively with respect to profitability, which ranges between -5% to -15%. These companies have achieved high revenue growth in the short-term through the addition of commercial portfolios but the key question is whether this growth can continue mid- to long-term?

Generic players are building R&D credibility in speciality pharma

This segment also features a number of growing generic players that are building a presence in speciality pharma, such as Lupin and Sun Pharma. Teva can also be classified in this category. All three of these companies have pursued growth from generics businesses while moving into speciality pharma through acquisitions. Moreover, Teva states that it "pursues robust organic growth" applying its R&D capabilities in the generics/OTC field into NME. For these particular companies, a gradual move into specialty pharma through this route allows them to build credibility in R&D while simultaneously continue to be profitable.

Jazz Pharma: the top grower of our sample

The largest revenue growth amongst the top 26 pharma growth companies over the last five years was achieved by Jazz Pharma, which represents a unique example of growth within this segment. Incorporated in 2003, Jazz now sells just two main products, Xyrem and Luvox CR, for narcolepsy and obsessive-compulsive disorder respectively. Jazz has exploited the orphan disease status of the former drug, which was obtained through the acquisition of Orphan Medical in 2005, enabling it to increase prices. Astonishingly Jazz has raised the price of Xyrem at an annual average rate of nearly 40%[v]. Coupled to the fact that R&D spend decreased between 2008 and 2011 and now represents just 5% of revenues means that Jazz achieved a highly respectable profitability of 39% of revenues in 2013. The question, as with all the Buy companies, is what next? By seeking innovation from acquisitions, the risk is lack of availability or overpaying or both. With the notable outliers of Valeant and Actavis, the other Buy companies are transitioning in some way to sustain themselves and mitigate the risk of being acquired themselves. It will be interesting to see how they all evolve over the next five years, but we believe that they do not represent a model that more conventional pharmaceutical companies can follow easily.

Is R&D required for pharmaceutical business growth?

The Breakthrough companies show that growth is contingent on NME launches that require significant R&D investment – still with the possibility of growth and high returns albeit with high risk. We believe that such companies cannot survive indefinitely by investing such a huge proportion of revenues into R&D, so will evolve to become established pharmaceutical companies with levels of R&D investment that are much lower as a proportion of revenues, as has been more recently achieved by Gilead and Alexion.

In contrast the Buy companies have shown that embracing an acquisitive approach can lead to immediate revenue growth without the need to invest in R&D. However the long-term sustainability of this business model is also questionable as demonstrated by the fluctuating and sometimes negative profitability of these companies over time. In short, chasing after acquisitions is an expensive game and though at an industry level it may be an efficient way to accelerate (arguably necessary) cost-cutting, sustainably profitable business growth may be more elusive. Indeed, a relatively recent example of this reality is that following Allergan's strong defence against a takeover, Valeant has visibly cooled off its buying spree in an effort to relieve its debt and increase internal R&D output.

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So perhaps the most valuable lessons can be learned from the Build companies. These companies have achieved not only respectful revenue growth year-on-year but also remained consistently profitable. They have leveraged their strengths to accomplish their goals, albeit by following different paths.

Bespoke Strategy: The common thread

The Build companies have demonstrated that significant growth does not necessarily depend on the new NME launches of the Breakthrough companies or the major acquisitions of the Buy companies. There is therefore hope and inspiration for all pharmaceutical companies that cannot realistically expect many NMEs or acquisitions. And the common thread to the success of the Build companies is their smart and focused choices. For example, Shire recently announced that its current pipeline is estimated to generate sales of $3 billion by 2020[vi], a pipeline that was constructed from a number of targeted acquisitions during the past five years.

The common thread that we therefore believe has had a key role in driving business growth for the Build companies in particular (and the Breakthrough and Buy companies in a different way) is that of 'bespoke strategy'. Bespoke strategists focus on exploiting and evolving from the unique and distinctive capabilities that they each alone possess – whether these are related to customer/stakeholder relationships, science/technology skills or financial market relationships/skills. The successful growing companies typically have best-in-class capabilities in one of these areas, for example Build companies typically have excellent customer/physician relationships and networks in focused domains, Breakthrough companies often have incredible science in specific fields, and Buy companies typically know and work their investor community better than even the financial institutions. So each of the 26 top growing companies has successfully developed and executed bespoke strategies that exploit their relative competitive strengths while ensuring that they have access to the necessary capabilities for growth for all other areas. They are indeed inspiration for successful pharmaceutical companies world-wide.