


PHARMAVITAE SECTOR ANALYSIS

Benchmarking the Pharmaceutical Market by Drug Delivery to 2014

Growth from injectables will mitigate the generic-driven decline of the dominant oral drug segment

Delivery technology can readily enhance the therapeutic value of a drug and, in doing so, helps companies add commercial value across all stages of the drug lifecycle. Physiochemical (e.g. controlled release, bioavailability enhancers) and biomolecular (e.g. protein/peptide, lipid vehicle) delivery platforms are the most prevalent in the drug delivery space, while in terms of route of administration, orals and injectables make up more than 80% of the prescription pharmaceutical market, which is also reflected in their prominence in the delivery technology space.

Looking at the leading prescription pharmaceutical companies, Datamonitor expects there to be a shift in market share away from orals and towards injectable drugs out to 2014. Injectables will see an increase in annual sales of \$49 billion over 2008–14, whereas annual sales from oral drugs will decline \$10.9 billion. This reflects a number of underlying factors driving each delivery type, such as therapeutic focus, molecule type and lifecycle stage. On the whole, companies overly exposed to oral therapeutics will see weak sales growth over the forecast period, whereas companies positioned in the injectable drug segment will exhibit the fastest growth out to 2014.

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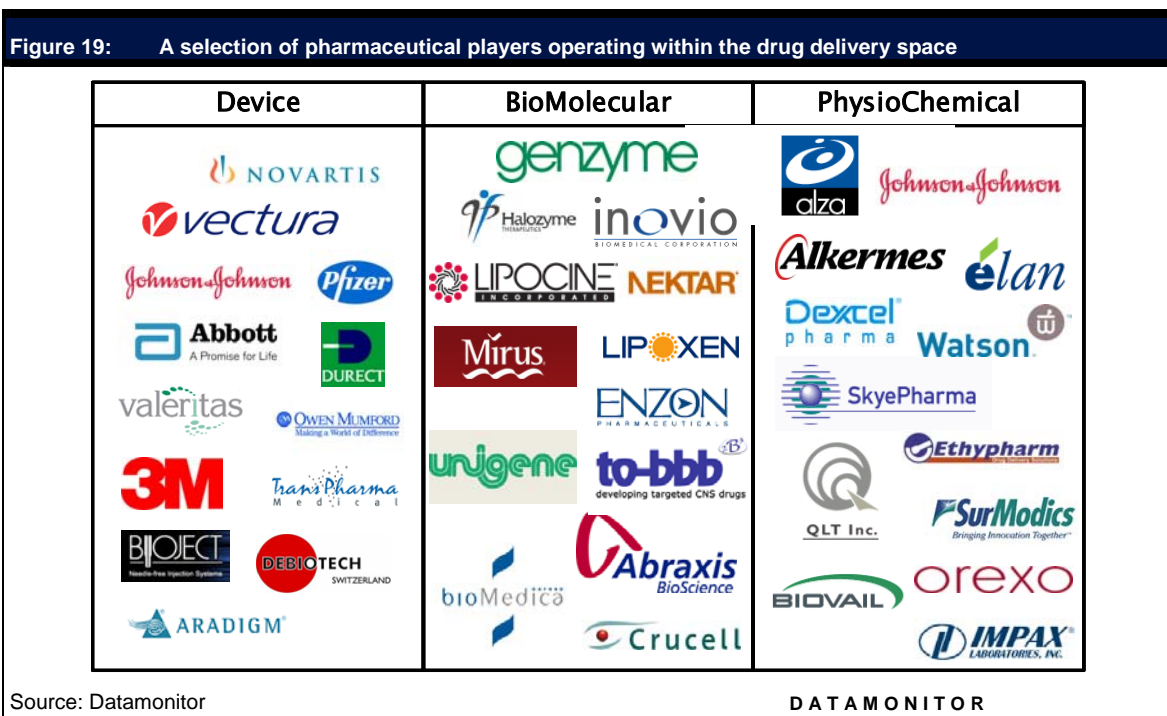
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Accessibility to drug delivery technology signals entrants from across the pharmaceutical spectrum

There are currently a large number of players, both established and forthcoming, operating in the drug delivery space. Some play the role of pure drug delivery players and have not yet expanded their focus towards manufacturing biopharmaceutical products. However some companies, such as those in the pulmonary drug delivery segment, are in a transition state from being pure drug delivery players to specialty pharma companies. This means that they are expanding their focus to manufacture products or in some cases market their own products, in order to strengthen their financial position.

Well-established players in the drug delivery segment, such as Elan and Biovail, are retaining a greater control over their technology and their applications to pharmaceutical products in order to increase the profits of their business in an otherwise challenging environment.

Further still, while technology licensing is often the cheapest option, some companies that operate at the fully-integrated end of the business model spectrum are adopting internal approaches to developing drug delivery technology, thus ensuring maximal returns from their reformulation efforts. In the case of generic players, this allows them to differentiate their product offerings in crowded generic markets. The presence of established players from the Big Pharma, Biotech and Generics peer sets, alongside emerging specialty pharmaceutical players, serves to highlight the diverse nature of the drug delivery segment, as well as its overall accessibility to those across the industry. The figure below provides an illustration of some of the companies operating within each space.



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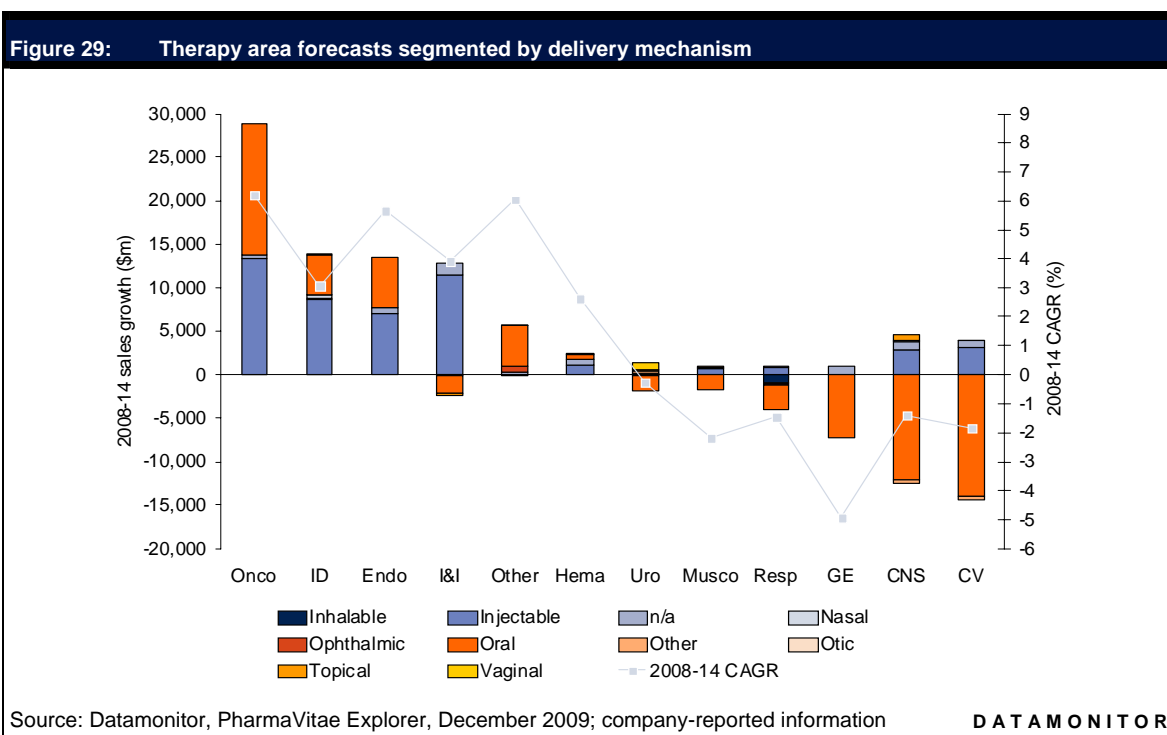
Therapy area view

Slow growth therapy areas are entrenched in orals, fast-growth therapy areas in injectables

By aligning product level growth expectations to a therapy area and delivery mechanism, it is possible to assess the therapy areas where each major delivery type will exert their commercial influence.

Looking at the chart below, a clear pattern emerges highlighting the importance of oral therapies in determining the performance of the slowest growing therapy areas, and the importance of injectables in driving sales growth across the fastest growing therapy areas. The slowest growing therapy areas, cardiovascular (CV), central nervous system (CNS), gastroenterology (GE) and respiratory (Resp) will suffer from steep sales declines as a result of falling oral sales, despite positive growth contributions from novel delivery types in the case of CV and CNS. Sales from respiratory drugs will also be driven down by falling inhalable product sales, where innovation will be unable to stem the tide of generic inhalable.

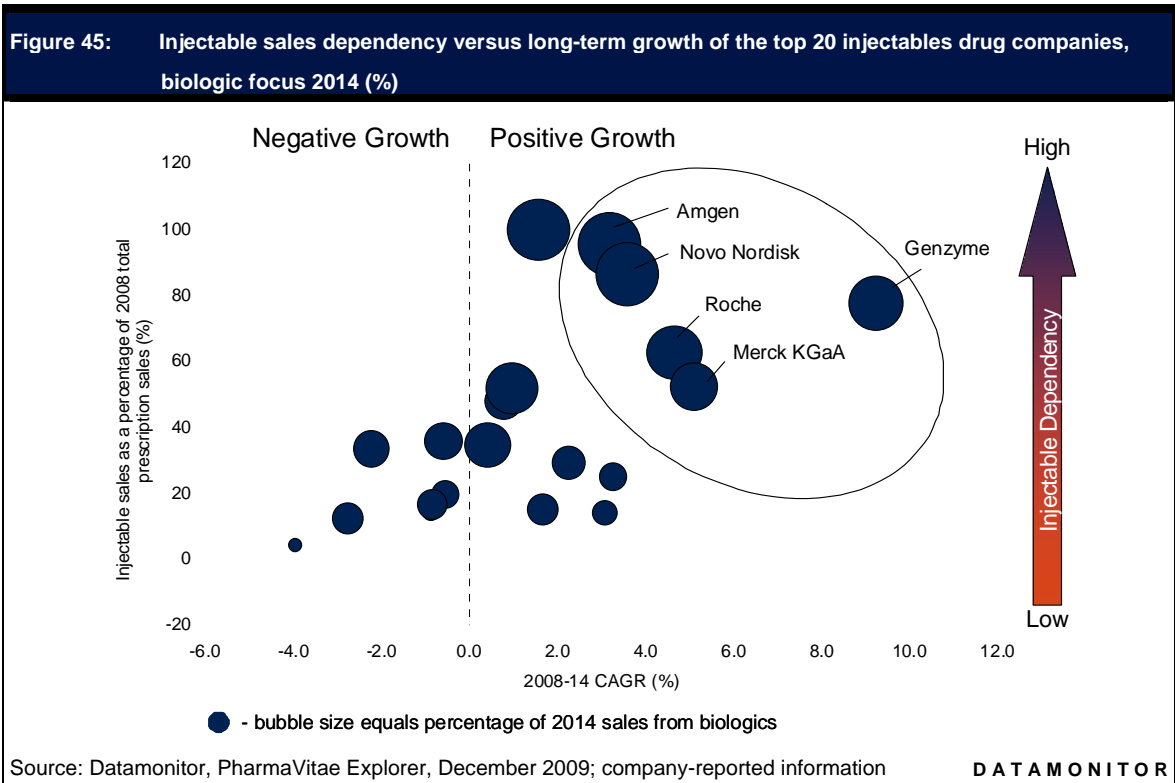
These dynamics are completely mirrored by expectations within the fastest growing therapy areas, namely oncology (onco), infectious disease (ID), endocrinology (Endo) and inflammatory & immunology (I&I), where the growing contribution from injectable drugs will be vital in driving up sales. While oral sales are also expected to exert a positive effect on the oncology market, where significant unmet need remains, the growing prominence of injectable drugs within these fast expanding therapy areas is clear. This largely reflects the role of the parenteral route of administration in opening up novel targets for today's cutting edge treatments to exert their therapeutic affect, crucially in areas where outcomes have been historically poor with oral therapeutics.



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The chart below is the same as the previous plot with the exception that it shows the proportion of each company's forecast 2014 sales expected to come from biologic drugs, as depicted by bubble size. Interestingly, companies with a high injectables focus that are set to record the fastest growth rates to 2014 are also heavily positioned in the biologics segment. Amgen, Novo Nordisk, Genzyme, Merck KGaA (through its acquisition of Serono) and Roche all have impressive biologic portfolios and since a high focus on biologics is not mutually exclusive from a high focus on injectables, companies operating in injectables will be able to reap the benefits from a drug portfolio populated with biopharmaceuticals. Although compliance is a key issue with injectable biologics compared with oral therapeutics, the clinical benefits of biologics as well as the relative insulation they provide from generic drug manufacturers makes them valuable members of any company's prescription drug portfolio.

Conversely, while strong growth is likely to befall the leading injectable players with a high focus on both injectables and biologics, companies with a low focus on injectables and an equally modest positioning within the biologics segment display less impressive growth prospects than their more biologic-focused competitors in the injectables market. This comes down largely to generic exposure, although demand, innovation and clinical excellence are also key determinants when entering the realms of biologics.



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