Putting the Science back into Life Sciences

High Performers deliver science-based innovation through patient outcome-driven commercial models

Accenture Research Note: Biopharmaceutical High Performance Business Study—2013 Update
Since Accenture’s last High Performance Business (HPB) Study of the Pharmaceutical Sector released in October 2012, the industry outlook has continued to improve with Enterprise Value rising—driven by improved future growth forecasts. Entry in emerging markets and expedient product launches are still driving the markets, however, investor sentiment has shifted and science-based innovation strategies are now eclipsing diversification.

Our analysis reveals that a select group of High Performers is breaking away from the pack by focusing on innovation-driven growth strategies substantiated by patient outcome focused commercial models. These strategies are bringing the right products, with the right level of disease focus and differentiation to market through value-focused commercial models that are welcomed by reimbursers and appreciated by patients and the scientific community.

As the industry "pivots to the patient", winning companies are those that excel in putting science back into Life Sciences by transforming cutting edge discoveries into market viable products, applying equally rigorous science and analytics to deliver successful product launches, and demonstrate improved patient outcomes.
Key Findings Summary

Clear evidence of continued recovery in industry performance

Enterprise Value continued its recovery, up 14 percent in the first 10 months of 2013. Nearly half of the companies in our peer set (7 of 16) now have positive Future Value. Recent and upcoming launches are forecast to drive up to $148 billion in growth over the next 5 years.

Some companies are breaking away from the pack through science-based innovation strategies

Five companies are now a step change above the rest of the pack. This is largely driven by product launches based on scientific innovations versus diversified strategies.

The High Performers are putting science back into Life Sciences

Three metrics distinguish the High Performers:

- Higher replacement revenue ratio forecast
- Higher five-year revenue growth forecast
- Higher proportion of forecast growth from new products

The High Performers are leading the industry’s pivot to the patient

The High Performers display five key attributes:

1. Harness collaborative R&D models.
2. Commit to applying science to product launches focused on outcomes for specific patient groups.
3. Use flexible pricing strategies to meet patient population needs.
4. Master multi-channel marketing and patient services to reinforce patient outcomes.
5. Fine tune local operations to succeed in emerging markets.

$148B

EV

14%
Clear evidence of continued recovery in industry performance

Our research shows a continued recovery in the first ten months of 2013 with Enterprise Value (EV)1 up 14 percent and reaching 11 percent above the pre-recession peak of 2006 (see Figure 1). Recently, share prices have generally rebounded strongly and the Pharma Sector Index (ARCA Pharma Index ‘DRG) has outperformed the S&P 500 (^SPX) by approximately six percent over a three-year period. This improvement in valuation has increased the industry’s Future Value (FV)2 from -47 percent last year to -15 percent this year. This reflects improving investor confidence that the pharma sector is finding a path back to growth following the patent cliff of 2012.

However, the fact that it is still negative shows significant headwinds remain. But the true picture lies beneath the headline industry numbers, with a wide range of performance among individual companies. Nearly half the peer set (seven of 16 companies) showed a positive Future Value as of October 2013, up from just three companies in last year’s study. Meanwhile, the Future Value of 11 of the 16 companies improved in the last 12 months compared with just two in last year’s study. This highlights the splintering of the recovery underway in the biopharmaceutical industry with some companies on a strong path back to growth, and others stagnating and struggling against the impact of patent expiry.

FIGURE 1. Enterprise Value ($ billion) for pure play pharmaceutical peer set (2005–2013)

Note: 16 pure play biopharma companies only. Japanese companies have March year end (YE12 = Mar-13). Constant USD FOREX used from December 2012. October 31st share price used in latest EV and Q3-13 NOPLAT.

Source: Accenture Research, November 2013.
It is well known that emerging markets are forecast to sustain double digit growth rates over the next five years and contribute more than 70 percent of the global pharmaceutical market growth (IMS November 2013 report). Meanwhile, owing to patent expiries and austerity measures, the growth rate forecast is low for developed markets (typically zero to four percent over the next five years depending upon the country). Yet, those numbers can be deceiving as beyond the impact of patent expired products, they also include up to $148 billion in new global growth coming from recent and upcoming new launches (see Figure 2). This highlights the potential for new launches to restore profitable growth and replace revenue lost by recent and upcoming patent expiries.

**FIGURE 2. Drivers of global pharma market growth 2013-2017 (estimated)**
IMS Health Methodology and adapted EvaluatePharma launch forecast

Notes: Pharmerging Market Forecast based on IMS methodology & Gross Sales. Brand forecast based on IMS Global Market Forecast.
*Forecast 2013-2017 and Recent 2008-2012 Launches based on EvaluatePharma forecasts of Net Sales, adapted to compare with IMS Forecasts (assuming Rebates~10% Gross Sales). The majority of NME Launch Revenue Growth will be in Developed Markets.
Source: Accenture Research based on IMS November 2013 and EvaluatePharma, November 2013.
Some companies are breaking away from the pack through science-based innovation strategies

Our HPB rankings for 2013, based upon the first three quarters of 2013, show significant and rapid improvement in performance for a handful of companies. Bristol-Myers Squibb, Amgen and Roche rose three, eight and six places respectively since last year’s study using year-end 2011 financials. These three companies now form the “near high” performers below Novo Nordisk which has remained the only High Performer. Additionally, Astellas jumped eight places to just behind the near high performer group.

All of these companies have faster average growth forecasts than the peer group, largely driven by recent and upcoming product launches based upon scientific innovations as opposed to truly diversified strategies (see Figure 3). Companies growing through more diversified portfolios are now being rewarded less by investors in our most recent analysis.

**FIGURE 3. High Performers strategies for growth**

Recent and upcoming launches are from 2008-2012 and those forecast for 2013-2017.

Source: Accenture Research based on EvaluatePharma, November 2013.
The High Performers are putting science back into Life Sciences

The High Performers are more successfully bringing new science to the market in key areas of unmet need as demonstrated by their performance in three key forward-looking metrics:

- **Higher replacement revenue ratio forecast**—5.6 average for the High Performers versus a 1.5 average for the rest of the peer group.
- **Higher five-year forecast revenue growth** average of 4.2 percent (in line with overall global market) versus -0.4 percent average for the rest of the peer group.
- **Higher proportion of forecast growth from new products** (the percent of five-year forecast dollar growth from recent/upcoming launches)—32 percent for the High Performers versus 13 percent average for the rest of the peer group.

The High Performers have been able to successfully launch and grow these new products against a tougher payer environment.

For example, Germany’s Health Technology Assessment body IQWIG conducted its first benefit assessment of a whole drug class (DPP-IV inhibitors & diabetes) which led to Boehringer Ingelheim’s new drug Tradjenta, and Novartis’s older Galvus not receiving additional benefit status. Also, in the diabetes area, US prescription benefit manager Express Scripts announced it will drop formulary coverage of Novo Nordisk’s Victoza for cheaper GLP-1 agonist drugs Byetta and Bydureon, produced by AstraZeneca. Express Scripts has also dropped formulary coverage of 48 established and newly launched drugs including Pfizer’s Xeljanz, Johnson & Johnson’s Stelara and GlaxoSmithKline’s Breo Ellipta.

As these moves show, new launches are entering into a radically more competitive and crowded market than ever before, elevating the importance of building excellent launch capabilities to demonstrate whole system patient outcome benefits to payers. The difficulty presented by this tougher payer environment is reflected in our finding that six of 12 selected New Molecular Entity (NME) launches from 2011 missed analysts’ pre-launch sales target for their first two years by $2.7 billion. Additionally, our analysis showed that 12 of the 38 significant NME launches studied from January 2011 to November 2013 have had 2016 sales forecasts revised downward from original pre-launch expectations, totalling $6.2 billion in lower 2016 revenue estimates.

Our analysis further shows that portfolio complexity of global pharmaceutical firms is also evolving (see Figure 4). There are still many drugs that generate more than $1 billion in revenue in the market, but they contribute a smaller proportion of the global market and its growth. Furthermore, comparing FDA NME approvals from 2006-2010 to actual 2012 global sales, the proportion reaching $1 billion and the average sales is noticeably down from those gaining approval during 2001-2006 compared to actual 2008 global sales.

**FIGURE 4. Declining average sales of new launches**

**FDA NME Approvals**

Fewer have made >$1B in sales, and their average size has fallen sharply.

The High Performers are more successfully bringing new science to market through launch capabilities that demonstrate whole system patient outcomes.
The High Performers are leading the industry’s pivot to the patient

High Performers, however, are translating innovative new science into higher growth replacing revenue exposed to patent loss; these companies display a rapid recovery in analysts’ growth forecasts over the last three years (see Figure 5). They have been able to bring these new products to market with a clear articulated view on how the drugs improve patient outcomes and are consequently able to carve out a unique place in today’s price and value-conscious health market.

High Performers display a handful of attributes and capabilities that set them apart. Specifically, they:

1 **Harness collaborative R&D models.**

This means finding and developing the best science, wherever it arises—Academia, Biotech or other pharma companies. This includes having processes to expedite early decision making when choosing the best candidates and pathways to successfully bring differentiated products to market in areas of significant unmet clinical need. Examples include:

- **Bristol-Myers Squibb’s (BMS) “String of Pearls” strategy** sought to build a leading pipeline across its focus disease areas through partnerships and acquisitions with both small and large companies which in turn enhance the internal capabilities within BMS. The company has made 11 transactions to affect its strategy thus far, including the 2009 acquisition of Medarex which consolidated BMS’s leading position in developing new cancer immunotherapies. Today the company estimates 50 percent of its revenue and 40 percent of its pipeline come from external alliances.

- Roche recently gained approval for the first drug to pass through the FDA’s Breakthrough Therapy pathway, set up to greatly accelerate approval in critical areas of unmet need. Roche’s Gazyva for chronic lymphocytic leukemia showed improvement in survival rates versus standard treatment.

- Amgen recently formed a long-term joint venture with Astellas to co-develop new medicines in Amgen’s pipeline for the Japanese and broader Asia Pacific markets. The partnership targets innovative new programs in cholesterol management, osteoporosis, leukemia and gastric cancer—the latter of which is particularly prevalent in Asian populations.

**FIGURE 5. Evolution of consensus analyst forecasts in the last three years**

Source: Accenture Research based on Capital IQ November 2013
2 Commit to applying science to product launches focused on outcomes for specific patient groups.

High Performers initiate and maintain dialogue with payers and other patient-oriented organizations starting early in the drug development process. This allows them to build payers’ understanding of patient outcomes for target patient populations.

- UK HTA NICE recommended Roche’s Zelboraf based on outcomes data in BRAFV600 mutation positive inoperable or metastatic melanoma patients, identified by its approved Cobras 4800 companion diagnostic test.
- The US FDA approved Kadcyla (Roche) in HER-2 positive patients becoming just one of a handful of antibody–drug conjugates (ADCs) to reach the market when it was approved for second-line metastatic breast cancer.

3 Use flexible pricing strategies to meet patient population needs.

High performing companies have more rigorous and varied approaches to ensure successful launches in both developed and emerging markets. For example, they have flexible approaches to pricing and generally have a range of strategies to maximize accessibility, while continuing efforts to support physicians and the patient. The depth and breadth of their efforts are a distinctive and necessary capability to maximizing revenue and returns.

- For several years, Roche has offered flexible pricing for Avastin in Italy, whereby the company pays back some of the cost depending on the patients response and duration of treatment. Additionally, Avastin pricing may be tiered differently for efficacy in different cancer indications.
- UK HTA NICE recommended BMS’s innovative new melanoma drug Yervoy when the company combined it with a flexible pricing and patient access scheme.
- GlaxoSmithKline consistently tops the independently judged Access to Medicines Index based on its commitment to improving access to medicines through tactics such as tiered pricing and Patient Access Programs run in some of the least developed countries.

4 Master multi–channel marketing and patient services that reinforce patient outcomes.

High Performers also demonstrate mastery of new channels geared towards the changing needs and behaviors of healthcare professionals and patients. Healthcare professionals have rapidly adopted technology and changed their communication preferences regarding how and when they want information. Similarly patients’ appetite for information and support is almost insatiable. Although questions remain about persistently low levels of adherence and the regulation of new information channels and sources, High Performers have become trusted (and value adding) information partners through new digital channels.

- As part of its Dawn2 program, Novo Nordisk provides diabetes patients with online resources including personalized feedback for disease management and information resources, as well as providing healthcare professionals resources to better understand and manage their patients.
- Sanofi developed the iBGStar blood glucose monitor that syncs with an iPhone app, enabling patients to view, analyze and store blood glucose test results and better manage their disease. The company is working on connecting results to healthcare professionals. Sanofi has also partnered with online patient network PatientsLikeMe to access its clinical trial awareness tool and expand the digital recruitment of patients to its clinical trials.
- Novartis launched a Count on Us board on Pinterest to promote infographics that raise awareness of breast cancer, alongside other social media initiatives on YouTube and online patient communities.

5 Fine tune local operations to succeed in emerging markets.

Finally, High Performers bring a portfolio of appropriately priced products tailored to the local patient needs, as opposed to offering entire portfolios. This more focused approach is often accompanied with financial assistance and patient services which together maximize accessibility and value.

- Novo Nordisk was an early investor in India, opening its first local manufacturing facility in 1995 and a R&D center in 2002. More recently it has invested widely in physician training, patient screening and communication initiatives, such as the Changing Diabetes Bus, physician surveys and the specialist staffed Novocare patient telephone hotline. Novo Nordisk has also developed a leading market position in China for insulins (China is the second largest global market), and has enjoyed double digit growth in recent years.
- Patient services are a pillar of Sanofi’s strategy in India. The Saath7 diabetic patient support program has a team working closely with physicians to help patients and families understand the disease and attain desired treatment goals. Sanofi is also working on making blood glucose monitoring and insulin injector devices more affordable to Indian patients.
- Roche works closely with payers in emerging markets to drive greater accessibility to its expensive specialty drugs. For example, MAbThera was recently approved by Brazilian HTA CONITEC and the drug was placed on the public reimbursement list. Roche has also teamed with local manufacturer Emcure to bring locally produced, lower cost rebranded versions of MAbThera and Herceptin to Indian cancer patients. Roche also offers patient assistance programs in China for Herceptin, as well as supporting education programs with local cancer organizations.
Conclusion

Since our study in October 2012 there has been continued tangible recovery in the pharmaceutical sector and increased confidence among investors that science-based innovation will deliver growth to replace patent losses. But this recovery is not equal, and is split between a group of High Performers (many jumping significantly in our performance rankings) that have great science innovation and the capabilities to differentiate new launches with payers, and the remaining cohort that are struggling to return to sustainable growth. New science-driven launches are a significant growth opportunity that complements ongoing growth in emerging markets. These new areas of innovation and new commercial models are not without risk; R&D productivity remains a concern and the elevated payer scrutiny is increasingly challenging reimbursement prospects. Even as payer pressures increase, High Performers will continue to prosper by delivering real, science-backed innovations that deliver improvements to patient outcomes, supported by evolving commercial capabilities.
Research Methodology

Accenture's High Performance Business Research Program

Accenture embarked on its High Performance Business Program in 2003. We have studied more than 6,000 companies across multiple industries and industry segments to come up with definitive answers regarding business performance. Our High Performance Business research methodology is a proprietary approach for analyzing relative peer company performance across five key metrics. For each company, we capture the metrics for profitability, growth, positioning for the future, longevity and consistency with scores graded along a curve. In our 2010 research, we added a forward looking dimension to our research methodology which analyzed a company’s top line revenue growth and strength of its pipeline relative to its intellectual property exposure. Composite scores demonstrate relative performance within the peer set and highlight the High Performers.

Accenture’s High Performance Business Research for the Biopharmaceutical Industry

Accenture’s study of the Biopharmaceutical industry is in its eighth year and has analyzed the long term performance of “pure play” pharmaceutical companies (those with more than 75 percent of their revenue derived from pharmaceutical products). Our 2013 update is based on year end trailing 12 month Q3-2013 financials and analyzes the 16 largest pure play pharmaceutical companies in the world over an 8-year period. Collectively these companies had $468 billion in aggregate revenue, representing over half the global pharmaceutical market by net sales. The results have been compared with our 2012 study (based on year-end 2011 financials) to identify relative movements in the performance rankings. The analysis pro forma adjusts for the impact of major M&A deals and removes the impact of exceptional costs to reveal an accurate (normalized) picture of ongoing business operations. A detailed analysis of historic financial performance averaged over 1, 3, 5 and 7 year timeframes is combined with consensus analyst forecasts to gain a forward looking picture of forecast revenue growth from portfolio and new product launches, as well as the impact of patent expiries and mature products.

Research notes and sources

1. Enterprise Value (EV) is the sum of Market Capitalisation and Net Debt, totalled across a peer set of 16 of the largest pure play Global Pharmaceutical Companies, and measured at constant USD exchange rates from 2005-2013.

2. Future Value (FV) is the difference between Enterprise Value and Current Value—and represents the implied portion of Company Enterprise Value that may be ascribed to growth. Current Value is calculated (CV) as Net Operating Profit Less Adjusted Tax divided by Weighted Average Cost of Capital.

3. The High Performance Ranking Methodology assesses financial performance of the peer group across an 8-year period using 5 different metrics, and ranks their performance according to a normal distribution of scores. “High” Performers have performed at least one standard deviation better than the average, “Near high” performers at least 0.3 standard deviations above peer average, while “Low” performers are performing at least one standard deviation below the average, the rest being “Average” performers.

4. The Replacement Revenue Ratio is calculated as 5 year Forecast Revenue growth from New Launches and existing portfolio, divided by 5 year forecasts sales lost to products already off patent or facing patent expiry in next 5 years (2013-17 timeframe)—sourced from EvaluatePharma, November 2013.
About Accenture

Accenture is a global management consulting, technology services and outsourcing company, with approximately 281,000 people serving clients in more than 120 countries. Combining unparalleled experience, comprehensive capabilities across all industries and business functions, and extensive research on the world's most successful companies, Accenture collaborates with clients to help them become high-performance businesses and governments. The company generated net revenues of US$28.6 billion for the fiscal year ended Aug. 31, 2013. Its home page is www.accenture.com.

About Accenture Life Sciences Practice

Accenture's Life Sciences practice is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better patient outcomes and drive shareholder returns. We provide consulting, outsourcing and technology around the globe in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing and the Supply Chain. We have a long history of working hand in hand with our clients to improve their performance across the entire Life Sciences value chain. Accenture's Life Sciences practice connects more than 8,500 skilled professionals people in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better patient outcomes for people around the world.

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