

Accenture Life Sciences

Patient Inspired. Outcomes Driven.

# TIME TO CHANGE

BRINGING OUTCOMES TO MARKET IN A NEW ERA  
OF BREAKTHROUGH SCIENCE



 **accenture**

**The pharmaceutical industry has entered a new era with more and larger specialty products than ever before. The industry has generated a wave of exciting new science that has driven it back to profitable growth, with the ability to offset current and future patent expiries. However, the market is more informed and demanding now—patients’, payers’ and providers’ expectations are rising with a different set of requirements—not just for great science, but for proof of effectiveness in the form of improved health outcomes at economically viable prices. As we get deeper into this new era, success will require more than just breakthrough science (with the possible exception of a cure or significant improvement in the standard of treatment). But even in those instances, the window for success may be limited with industry pressure coming from all sides for more affordable healthcare and more rapid product substitution.**

Just two years ago, the pharma industry faced an inflection point, when just as new science was starting to drive a return to growth, rising concerns over pricing and reimbursement and market reforms were looming. The summer 2015 accusations of ‘price gouging’ precipitated the start of a sharp fall in biotech and pharma share prices, and was followed by a stream of announcements from governments and payers committed to new measures being put in place to lower drug price inflation and drive greater scrutiny of the impact of new drugs on patient and economic outcomes.<sup>1</sup> Since then, the Nasdaq Biotech and ARCA Pharma Indices have seen sustained pressure and remain 16% and 9% below mid 2015 levels today, while the S&P500 index has risen 17% to new highs.<sup>2</sup> The first quarters of 2017 are showing some signs of net price decreases in the US market—which if played out through the entire year would present a first in several decades.<sup>3</sup>

However, the fundamentals of the pharmaceutical industry remain strong. The output of new drugs has increased and looks set to remain elevated over the next five years, largely based on exciting new science in hard to treat specialty indications. After four years of falling or stagnating revenue from 2011-14, the industry returned to growth in 2015 with acceleration and improved operating margins in 2016.

But, the new science coming to market faces a persistent affordability gap between payers and governments budgets and the sales forecasts for new products. Some notable, recent new launches have performed below analysts’ expectations in their first two years on the market, and the 2020 sales forecasts of the peer group companies we analyzed have been pared back in response to concerns over the prevailing price sensitive climate.

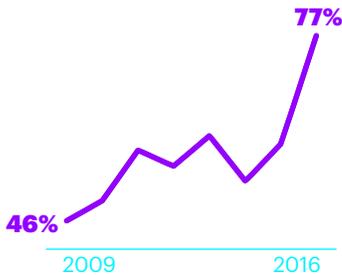
The key question for pharma companies today in their pursuit of high performance is “what sort of business do I need to have, to ensure my new science delivers quantifiable value to patients and the broader healthcare community, as well as investors?”

Our 2017 High Performance Business study of the biopharmaceutical industry reveals new insights into the market climate today, the opportunities and challenges ahead and what the High Performers are doing to outperform the market.

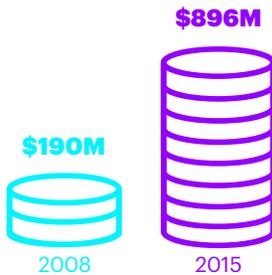
# KEY FINDINGS SUMMARY

## 1. THERE IS A PROFOUND SHIFT TO SPECIALITY DRUGS BACKED BY A STRONG PIPELINE.

**More Specialty Drugs:** The proportion of NME approvals in specialty indications increased from 46% in 2009 to 77% in 2016.<sup>4</sup>



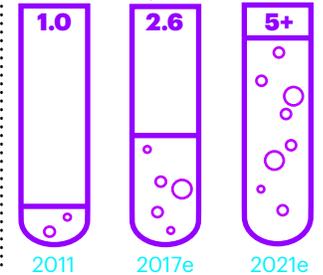
**Bigger Specialty:** Average sales of specialty NME approvals in first two years' post launch has increased over four times from \$190M in 2008 to \$896M in 2015.<sup>5</sup>



**Robust Pipeline:** The late stage industry pipeline is forecast to be sustained at a minimum of 40 NME approvals annually over the next five years.<sup>6</sup>

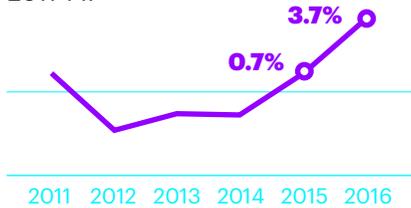


**Healthy Pipeline Replacement:** The Pipeline Replacement Revenue Ratio has bounced back strongly and is expected to double by 2021.<sup>7</sup>

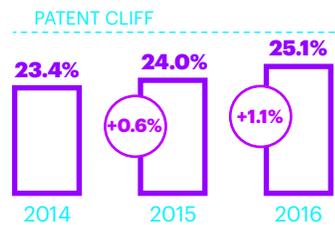


## 2. REVENUE GROWTH IS BACK AND PROFITABILITY IS IMPROVING, BUT VALUATIONS ARE DOWN.

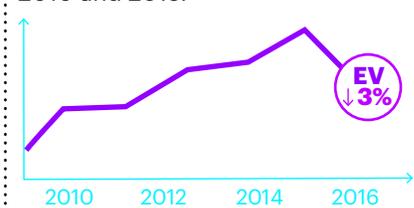
**Accelerating Revenue Growth:** Peer group revenue growth accelerated from 0.7% in 2015 to 3.7% in 2016 after four years of decline or stagnation from 2011-14.<sup>8</sup>



**Improving Operating Margin:** The peer group core operating margin improved 1.1% in 2016 building on a rise of 0.6% in 2015.<sup>9</sup>

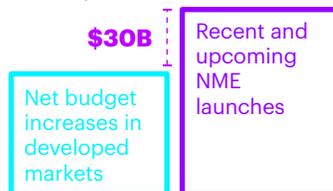


**Falling Enterprise Value:** Enterprise Value (EV) fell 3% in 2016, ending a five-year growth trend and wiping out nearly 8% of the value increase between 2010 and 2015.<sup>10</sup>

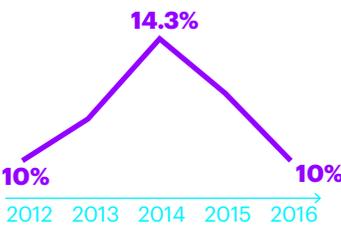


## 3. AFFORDABILITY AND PRICING CONCERNS PRESENT A CHALLENGE TO NEW LAUNCHES.

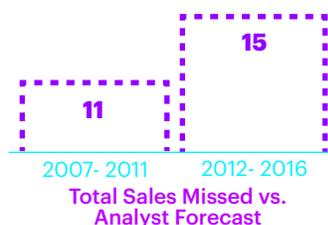
**Affordability Gap Persists:** There is a \$30B affordability gap between 2016-21 analysts' sales projections for NME launches and the net budget increases forecasted in developed markets.<sup>11</sup>



**Pricing Pressure Mounting:** List prices have seen double digit inflation in the US between 2012-14, but growth rates are slowing fast and increasingly offset by price discounts.<sup>12</sup>



**Some New Launches Struggling:** Between 2012-2016, 15 NME launches significantly missed analyst sales forecast for the first two years' post launch.<sup>13</sup>



**Analyst Forecasts Cut:** Total peer group sales forecast for 2020 have been pared back by 5% between 2016 and 2017, with 14 of 16 companies seeing revenue forecasts cut.<sup>14</sup>

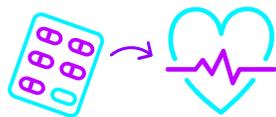


## 4. HIGH PERFORMERS DEVELOP BREAKTHROUGH SCIENCE, BUT BRING OUTCOMES TO MARKET.

**Building Market Dominance:** Committing to continuous portfolio assessment and active deal making to access the best science.



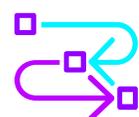
**Shifting from Volume to Value:** Being in the business of delivering patient outcomes.



**Building Patient Empowerment:** Personalizing through creating a data-rich patient interface.



**Creating New Simplified Business Models:** Leveraging technology collaborations and driving operational efficiency in "the New".



# KEY FINDING #1

## THERE IS A PROFOUND SHIFT TO SPECIALITY DRUGS BACKED BY A STRONG PIPELINE.

Recent years have seen a wave of exciting new science come to market, with an average of 49.8 NMEs approved per year from 2013-16. This is a 16% increase from the approvals in 2009-12, and a 23% increase from the 2005-08 average (see Figure 1).<sup>15</sup> While NME approvals were down to 36 in 2016 compared to 58 the previous year, the industry's late stage pipeline continues to look robust with 491 NMEs having the potential for regulatory approvals between 2017-20 (before probability adjustment) which could bring NME approvals up to level of at least 40 per year over the next five years.<sup>6</sup>

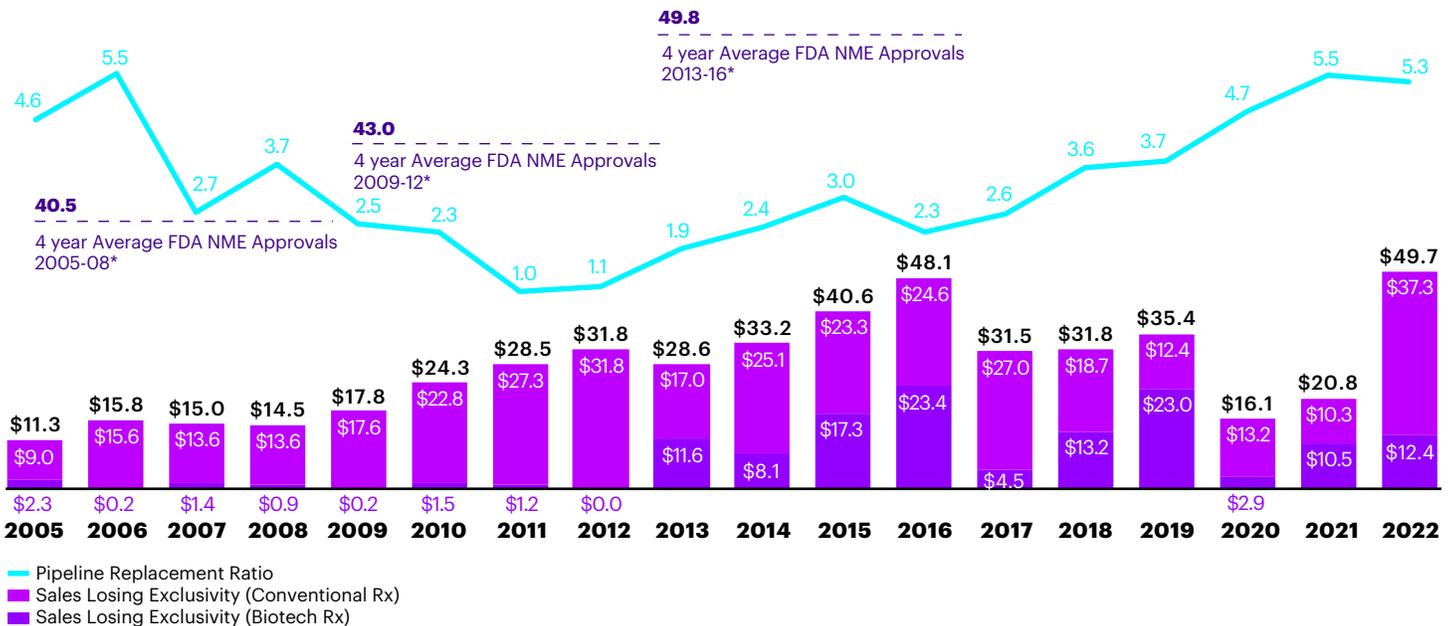
Looking at the composition of NME approvals, we can see a marked shift to specialty indications, representing 77% of the output in 2016 compared to only 46% in 2009 for the group of

sixteen pure-play pharma companies we analyzed (see Figure 2a).<sup>4</sup> Similarly, the proportion of NMEs which are orphan drugs has been rising, exceeding 40% in the last three years, while the proportion of first-in-class drugs fell to 36% from 51% in 2012.<sup>16</sup> Not only are there more specialty drugs coming from the pipelines of pharma companies, they are on average becoming bigger selling products. Between 2008-15, the average sales of specialty NMEs in the first two years' post launch increased roughly four times, with sales at five years forecast to have risen 165% (see Figure 2b).<sup>5</sup>

This shift to larger specialty NME approvals has improved the industry's growth prospects. Despite being in a second 'patent cliff' at present, with \$48.1B of sales losing patent cover

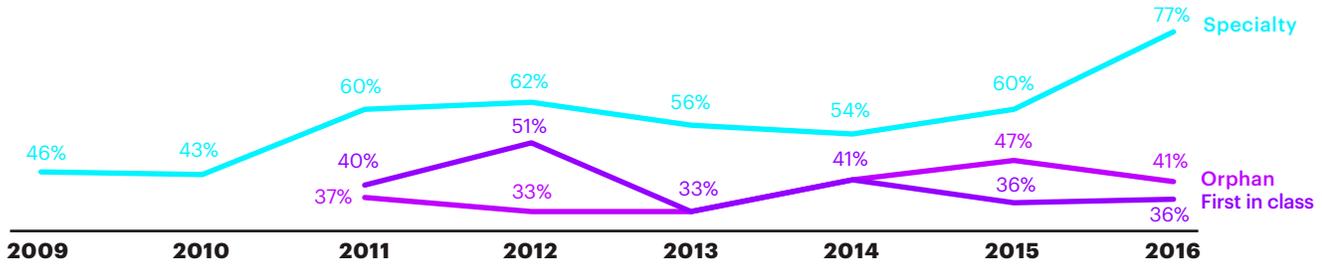
in 2016, the strength of new product sales coming to market is forecasted to more than cover the expected losses.<sup>17</sup> The Pipeline Replacement Revenue Ratio stands today at 2.6 and is expected to increase to above 5 in the next five years, having fallen to 1 in the last 'patent cliff' of 2011-12 (see Figure 1).<sup>7</sup> But, this time around, the strength and depth of the pipeline growth prospects is dramatically better and approximately half the products with expiring patents are biologicals. This second "biologicals patent cliff" does enter some uncharted water, as the extent and pace of biosimilar erosion is not fully known. This, along with companies having to achieve the sales forecasts from new product launches, indicated some growth forecasts are not without downside risks.

**FIGURE 1.** PIPELINE REPLACEMENT REVENUE RATIO 2005-2022E

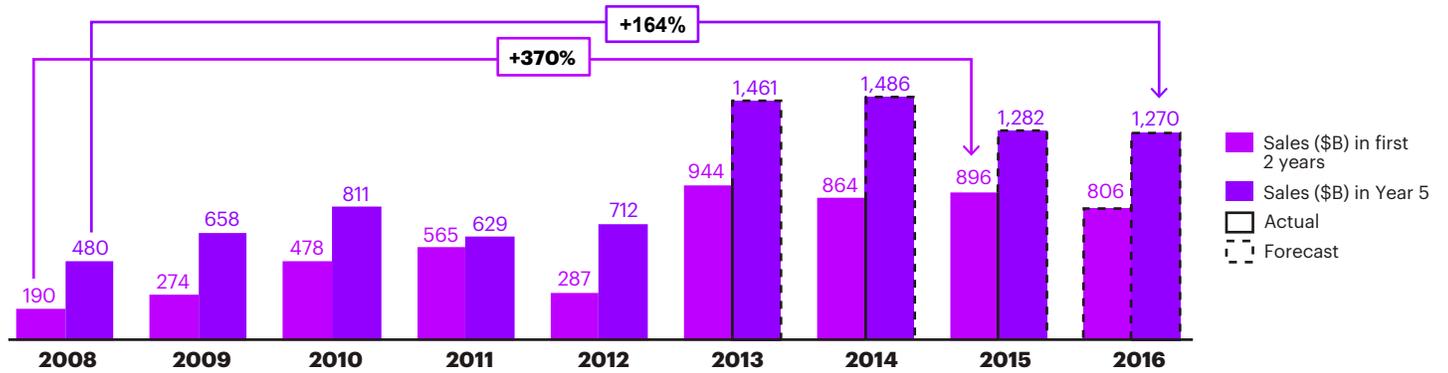


\*Total Peer Group Revenue and Earnings (Core EBIT) in USD with no adjustment for FOREX fluctuations. Larger companies performance does skew trends observed here. A simple Avg of CER Growth by each company also shown. Source: Accenture Research Jan-17, based on EvaluatePharma data.

**FIGURE 2A.** NMEs APPROVED BY FDA CDER 2009-2016—PROPORTION OF SPECIALTY, ORPHAN AND FIRST IN CLASS DRUGS



**FIGURE 2B.** SPECIALTY NMEs APPROVED BY FDA CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) 2008-16 —SALES IN FIRST 2 YEARS POST LAUNCH AND AT 5 YEAR POST LAUNCH



Source: Accenture Research Jul-17, based on FDA reporting, CDER division only. \*Harvoni and Sovaldi are excluded from average sales analysis.

## KEY FINDING #2

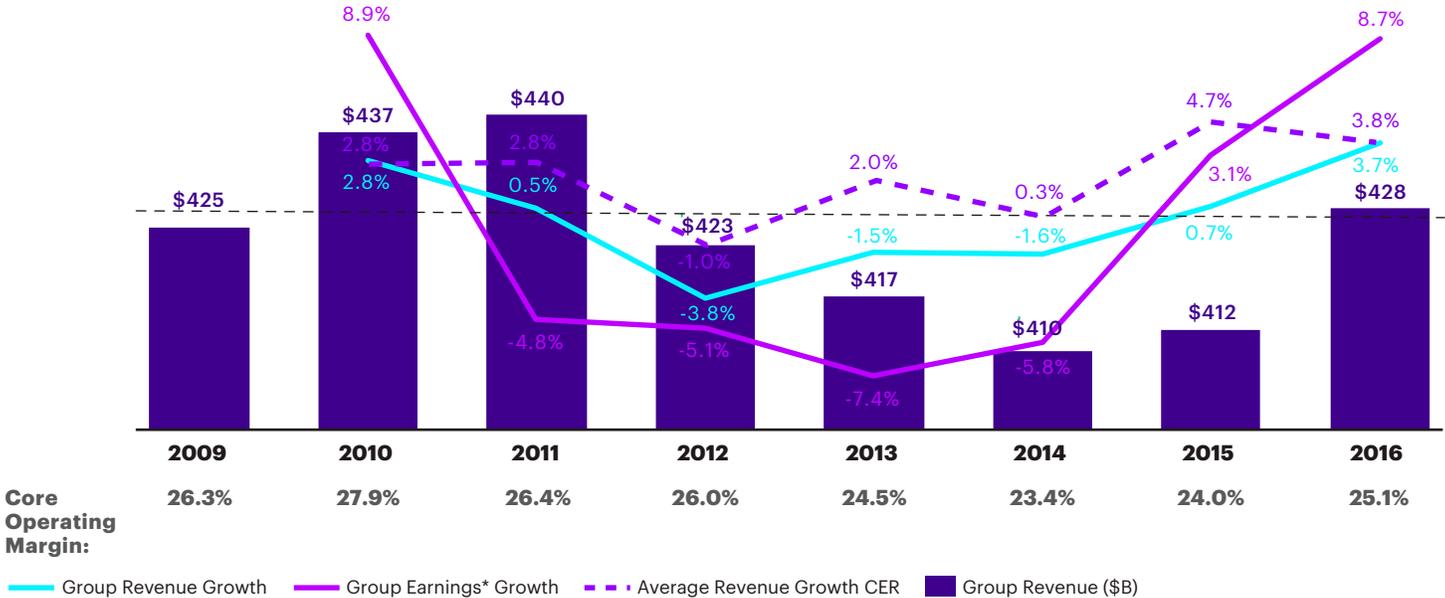
### REVENUE GROWTH IS BACK AND PROFITABILITY IS IMPROVING, BUT VALUATIONS ARE DOWN.

Our analysis shows that after four years of stagnant or declining revenue growth (2011-14), the pharma peer group overall returned to growth of 0.7% in 2015, which accelerated to 3.7% in 2016 (see Figure 3).<sup>8</sup> The peer group also saw its average Core Operating Margin improve to 25.1% in 2016 after falling 2011-14, but remains below the 2010 pre-patent cliff levels where the average stood at 27.9% (see Figure 3).<sup>9</sup>

Set against these encouraging signs of a sustained return to profitable growth, our research shows that the peer groups' Enterprise Value (EV) is down 3% in 2016, marking an end to a five-year growth trend between 2010-15, with an estimated 8% of the gains made in those years wiped out in 2016 (see Figure 4). Current Value (CV) has fallen and pushed Future Value (FV) more positive, albeit only mildly so compared to historic levels prior to 2009 (see Figure 4). Future Value levels vary widely by individual companies, pointing to their differing earnings growth prospects. Eight of the sixteen companies studied had positive Future Value in 2016.<sup>10</sup>

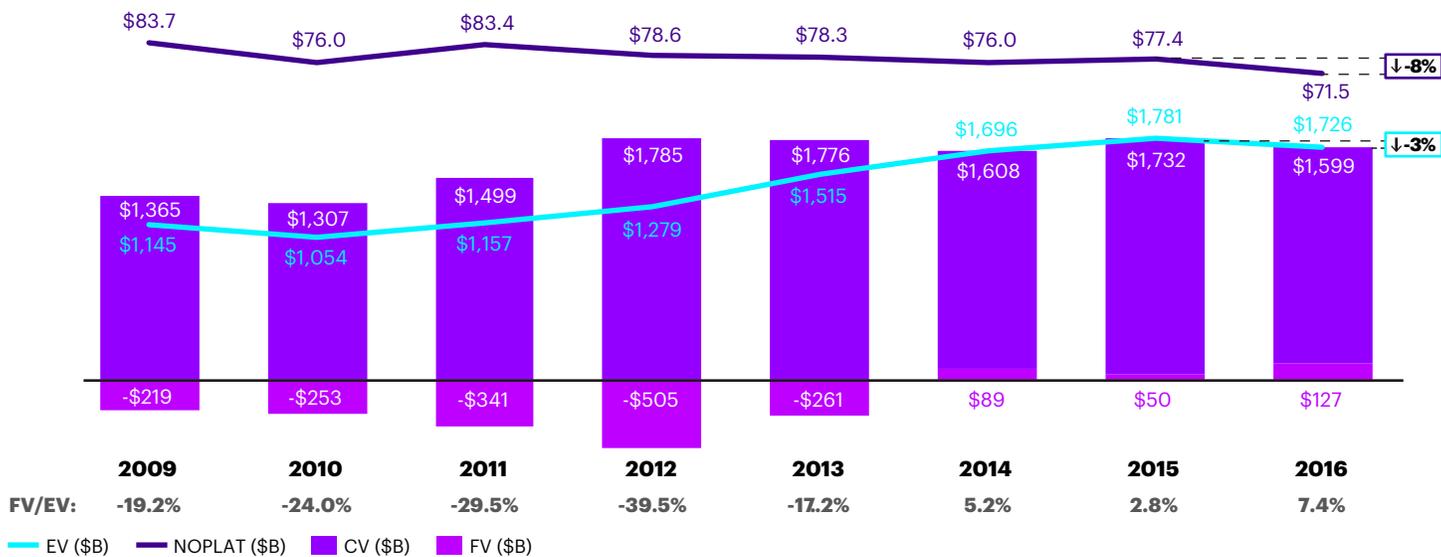
The fact that Enterprise Value has fallen back and Future Value is only mildly positive, when set against encouraging signs of a return to sustained profitable growth in 2016, demonstrates that investors still see considerable threats to the industry growth story today. Indeed, the ARCA Pharma and NASDAQ Biotech Indices have fallen -9% and -16% respectively since September 2015 (when Hillary Clinton's 'price gouging' tweet enlisted scrutiny onto drug pricing and reimbursement) compared to a 17% in the S&P500 which has recently reached new record levels.<sup>2</sup>

**FIGURE 3.** PHARMA PURE PLAY PEER SET: TOTAL REVENUE & EARNINGS GROWTH 2009-2016



\*FDA CDER and CBER division Approvals of NMEs (NDAs and BLAs).  
 Note: CER = Constant Exchange Rate  
 Source: Accenture Research Jul-17, based on Evaluate Pharma.

**FIGURE 4.** ENTERPRISE VALUE FOR "PURE PLAYS" 2009-2016



Note: 16 pure play biopharma companies only. Japanese companies have March year end (YE15 = Mar-16). Constant USD FOREX used from Dec 2016. Nov 30<sup>th</sup>, 2016 share price used in latest EV and TTM Q3-16 NOPLAT.  
 Source: Accenture Research, Jan-17.



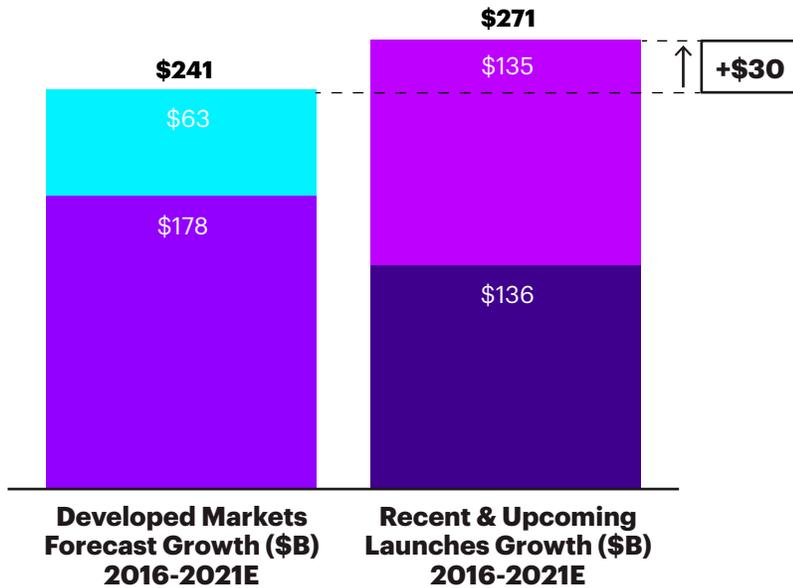
# KEY FINDING #3

## AFFORDABILITY AND PRICING CONCERNS PRESENT A CHALLENGE TO NEW LAUNCHES.

The 'Affordability Gap' we reported on in 2016 persists today. We see a \$30B gap from 2016-21 between the sales forecasts for recent and upcoming NME launches compared to the net pharmaceutical budget increases for developed markets.<sup>11</sup> Simply put, payers do not have enough budget to afford all the breakthrough science hitting the market at current analyst expectations. This means there will be winners and losers in the effort to secure favorable deal positions with payers (see Figure 5).

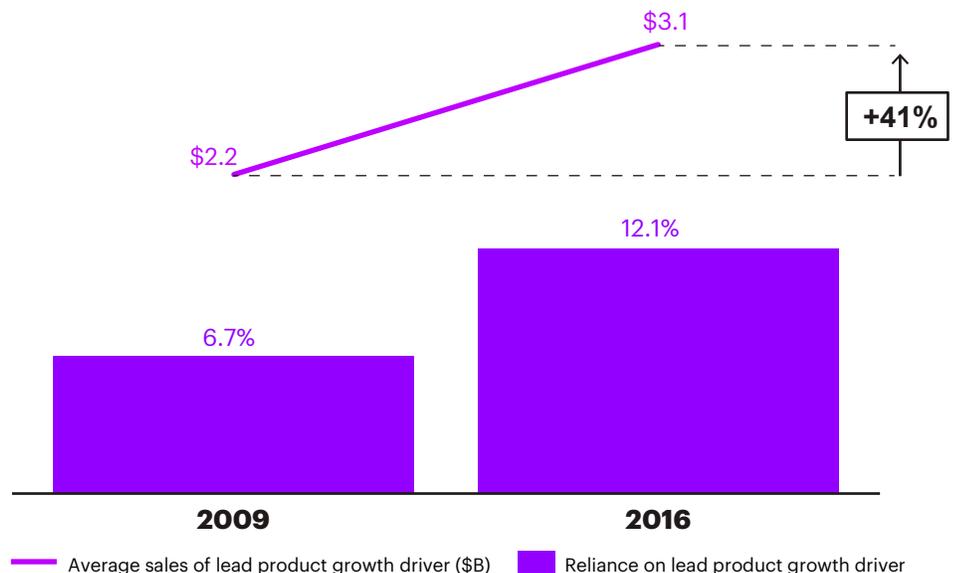
While it can be argued that analysts may have been over-enthusiastic in their forecasts, it is notable that pharma companies are becoming increasingly more reliant on the performance of just one or two lead products to achieve their growth commitments and generate a return on R&D investment. If we look at the largest product growth driver, in 2009 it represented 6.7% of the actual dollar sales growth seen between 2009-16 with average sales of \$2.2B at five years' post launch.<sup>18</sup> In 2016, the largest product growth driver accounted for an average of 12.1% of dollar sales growth forecast for 2016-21 with average 2021 sales of \$3.1B (see Figure 6). Companies are becoming increasingly reliant on lead product growth drivers to offset any patent losses and grow the overall company, which is notable when you consider the affordability gap described above.

**FIGURE 5.** AFFORDABILITY OF RECENT AND UPCOMING NEW MARKET ENTITY (NME) APPROVALS 2016-2021E



Source: Accenture Research May-17, based on Evaluate Pharma and IMS Health.

**FIGURE 6.** LEAD PRODUCT GROWTH DRIVER – AVERAGE SALES AT FIVE YEARS AND FIVE YEAR GROWTH AS A PERCENTAGE OF CURRENT SALES Pure-Play Peer Set 2009 versus 2016.



\*Reliance on lead product growth driver is calculated as 6 year Forecast \$ growth for product divided by Pharma Revenue in year in question. Adjustments have been made for major M&A transactions historically. Source: Accenture Research Jun-17, based on Evaluate Pharma and IMS Health.

Drug pricing has increasingly come under pressure from payers and governments who are seeking to mitigate increased cost of paying for expensive new treatments while managing growing demand from an aging and increasingly ill population. 2012-15 saw US drug list price inflation reportedly standing at double digit growth rates while price discounts have been mounting. The effect has been a widening gulf between rising list price inflation and falling net price inflation (see Figure 7a).<sup>12, 20</sup>

The first quarter of 2017 is reported to have seen US branded drug inflation fall to 6.5% compared with 10.9% in Q1-16, and net prices inflation fall negative to -1.2% compared to 4.1% in Q1-16.

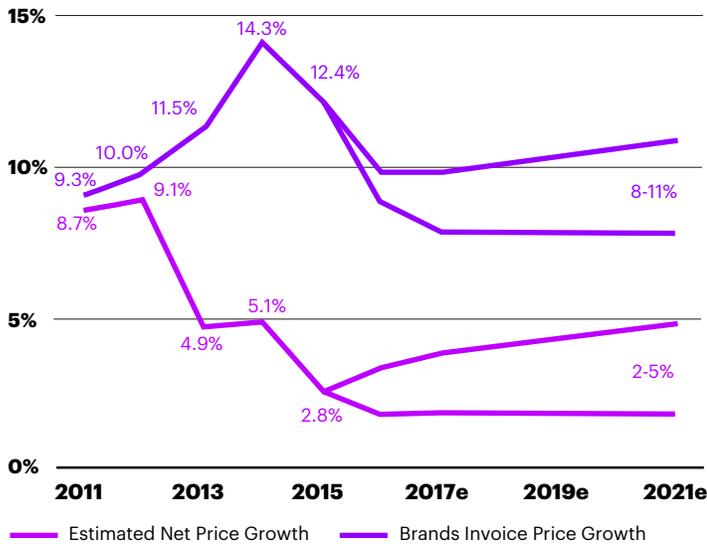
Our analysis of eleven companies showed that four had rebates running at more than 50% of gross US sales from 2015-16—and all companies have seen steep raises in rebates in recent years, demonstrating the more price pressured market climate that's evolved (see Figure 7b).<sup>19</sup>

Recent analysis by Credit Suisse has shown that a large majority of pharma companies were in large part or completely reliant on US price increases to deliver their earnings growth reported in 2016.<sup>20</sup> In the last five years, pricing growth has been the largest contributor to the reported sales growth. Pricing increases have come from both hikes to existing drug prices as well as new drug approvals.

**FIGURES 7A & 7B.** TRENDS IN RISING US LIST PRICES AND GREATER PRICE DISCOUNTING

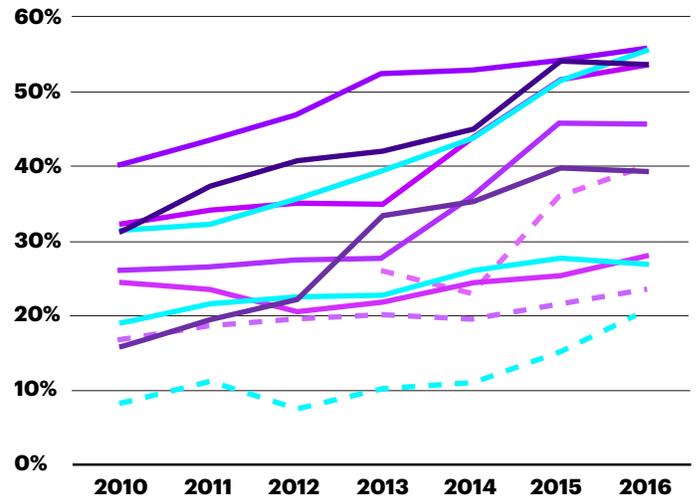
**US Protected Brands—Invoiced vs. Net Price Inflation**

Double-digit list price inflation slowing and net price difference widening



**Rebates as a % of Gross Sales 2010-16—11 Selected Companies**

Companies are having to offer higher price discounts, especially in US



Source: Accenture Research May-17 based on Evaluate Pharma, and IMS Health 2016.

If pricing continues to come under sustained downward pressure, then it presents a threat to not only recent and upcoming new product launches achieving their analyst growth targets but also companies overall sustaining profitable growth. Our analysis found that between Jan-16 and Jan-17, \$27B or 5.3% was cut from the 2020 sales forecast for the sixteen pure-play pharmaceutical companies in our peer set (see Figure 8a).<sup>14</sup> Additionally, the number of

significant new launch misses vs. analyst targets (>\$200m below target in first two years post launch) rose from eleven in 2007-11 to fifteen in 2012-16, staying fairly steady at about 9% of total new launches.<sup>13</sup> Furthermore, the collective sales lost from these disappointing new launches rose from \$4.5B in 2007-11 to \$8.9B in 2012-16 (see Figure 8b). Overall, the ratio of products exceeding vs. missing analyst targets (to any degree) in the first two years' post

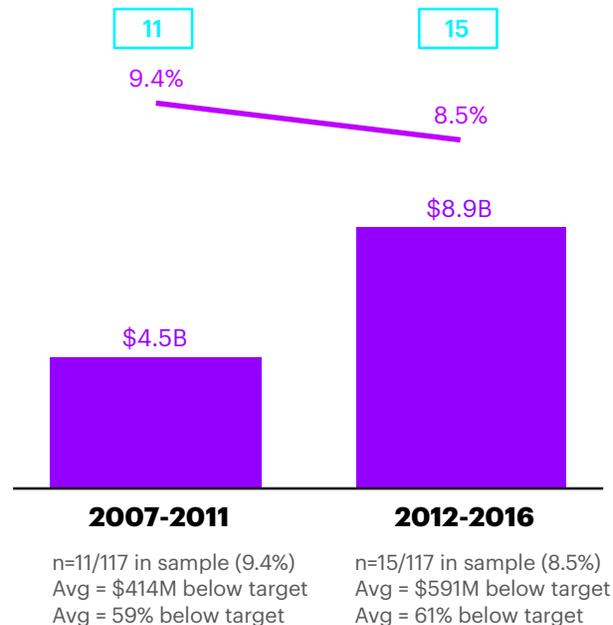
launch has remained fairly stable in recent years at roughly 50:50, highlighting how polarized the commercial environment remains for new launches, and the need for companies to work harder to achieve the commercial potential of their products and achieve a return on spiralling R&D costs.<sup>21</sup> Peer group average R&D spend as a % of revenue has risen from 16.3% in 2011 to 17.7% in 2016, with estimates for the average R&D spend per NME approval rising to between \$2.6B and \$4.0B.<sup>22, 23, 24</sup>

**FIGURES 8A & 8B. REVISIONS IN ANALYSTS' TARGET SALES FORECASTS**

**2020 Sales Forecast, Revision Between Jan-16 and Jan-17**



**NME launches >\$200m below Analyst Target in First 2 Years Post Launch**



■ Sales lost

## KEY FINDING #4

### **HIGH PERFORMERS DEVELOP BREAKTHROUGH SCIENCE, BUT BRING OUTCOMES TO MARKET.**

The five High Performers have greater product strength in their portfolio and pipelines, but are also backed by robust outcomes value data compared to standard of care today. Meanwhile, the rest of the peer group are in different stages on this path. In an increasingly crowded and competitive market where a faster pace of product substitution is squeezing the product life cycle, product alone will often not be enough to differentiate.

### **HIGH PERFORMERS ARE OUTPERFORMING THEIR PEERS IN FOUR KEY AREAS:**

1. BUILDING MARKET DOMINANCE
2. SHIFTING FROM VOLUME TO VALUE
3. BUILDING PATIENT EMPOWERMENT
4. CREATING NEW SIMPLIFIED BUSINESS MODELS

### **THE QUEST FOR MARKET DOMINANCE: M&A ACTIVITY IN LIFE SCIENCES**

The Life Sciences sector is into its 4th year of elevated M&A Activity. 2014 saw a record \$367B in M&A deals, and while 2015 and 2016 saw less deal value (\$272 and \$230B respectively), they are still up from \$147B average for 2007-13.<sup>25</sup> So far in 2017, M&A deal activity stands at \$148B, roughly equal to \$150B in the same period in 2016, showing that M&A remains active in the Life Sciences sector. The elevated M&A deal value in recent years has been driven by scale and consolidation deals (Allergan—Actavis and Forrest deals in 2014, and Teva Allergan Generics deal in 2016), as well as pipeline ‘bolt-on’ deals (Pfizer—Medivation deal in 2016 and Hospira in 2015, and Shire—Baxalta deal in 2016), and portfolio-focusing deals such as the asset swap deals between Novartis, GSK and Lilly in 2014 and Sanofi and Boehringer Ingelheim in 2015. In the quest for a return to sustainable profitable growth, big pharma companies are increasingly looking externally to buy or partner in the best new science. Additionally, as companies continue to refine their portfolio’s focus, they are using M&A and partnering deals to narrow their focus on key therapy areas and business segments where they can maintain dominant positions.

## 1. BUILDING MARKET DOMINANCE

Creating dominant positions in select therapy areas and/or business segments through active deal making and continuous portfolio assessment of the best science.

High Performers excel at building dominant positions in higher growth therapy areas and market segments. They divest non-core businesses and acquire or partner with non-life sciences tech leaders, and looking beyond biotech firms to scout for complementary technologies. Their portfolios are much more concentrated around a smaller number of products, with dominant positioning in their disease areas. High Performers are leaders in both understanding underlying scientific pathways and listening to patient, physician and payer needs. They innovate in their target disease areas, and invest in substituting their own products with new ones before others do. More importantly, especially given tech giants' entries into life sciences space, successful companies need to build a digital strategy with a health-tech focus, and develop new technological capabilities to drive continued dominance. For example:

- **BMS** has been refining its focus on pharma products first and then on select specialty indications. BMS has invested early and built strength in new high growth areas including immuno-oncology through the Medimmune deal, with capital freed up for reallocation from driving operational efficiencies in the business.
- **Eli Lilly** has strengthened its Animal Health business through the Novartis Animal Health acquisition, and diabetes through the Boehringer Ingelheim partnership, and immuno-oncology innovation through its investment in Immunocore and drug combination partnerships with AstraZeneca and others.
- **Amgen** has external innovation partnerships with Boehringer Ingelheim and Advaxis in addition to one with Kite in immuno-oncology in an effort to dominate in new cancer treatments.

## 2. SHIFTING FROM VOLUME TO VALUE

Organizations are shifting from being pure product companies to companies that deliver better value and improved patient outcomes.

High Performers are structuring their entire organization around delivering better patient and economic outcomes. For example, they are breaking down traditional silos in R&D and commercial, using an enterprise-wide approach to data and analytics, developing new digitally enabled commercial models centred on patient outcomes, using services to better support patients and HCPs, and, starting with clinical trials—coming to market with outcomes that are delivered by their breakthrough sciences. High Performers are also committed to investing in real-world evidence to support the differentiation of their products. Comparator trials using a wide range of end points, as well as payer partnerships and outcomes based reimbursement deals. Examples of this include:

- **Amgen** has signed outcomes-based reimbursement deals for Repatha with CVS, Cigna and Harvard Pilgrim.<sup>26</sup>
- **Novo Nordisk** has invested in large RWE studies to generate outcomes data from its diabetes portfolio (e.g., Victoza) including weight loss and CV endpoints, and DAWN2 study into diabetes awareness, self-management and benchmarking.<sup>27</sup>
- **Eli Lilly** has invested heavily in supporting its diabetes portfolio with RWE from PIV trials, including EMPA-Reg which demonstrated improved cardiovascular outcomes of Jardiance, enabling it to differentiate from competing drugs.<sup>28</sup>
- **Roche's** partnerships with Flatiron Health and Foundation Medicine deals, have brought predictive software and analytics to identify best outcomes for cancer patients based on genetic/biomarker profile, part of its 'individualization of treatment' strategy. Roche is also exploring pricing flexibility including novel indication, drug combination and patient specific pricing.<sup>29</sup>

### 3. BUILDING PATIENT EMPOWERMENT

Creating a rich patient interface and understanding of consumerism.

High Performers are personalizing the impact of their science to patients and/or patient populations, using real-world evidence, patient services and digital engagement across the entire healthcare ecosystem. They are driving better consumer experience for both healthcare professionals and for patients, through partnerships with technology and consumer orientated sectors, as well as investing in real-world evidence and data analytics. For example:

- **Amgen** is conducting population studies at its deCODE unit to identify genetic risk factors for common diseases to drive new drug discovery and identifying responder patients (e.g., discovery of PCSK9 Repatha and ASGR1 gene role in CV risk).<sup>30</sup>
- **Novo Nordisk** has a 'Patient Centred Value' business approach as part of Triple Bottom Line culture.<sup>31</sup> DAWN2 is its long-standing study into diabetes awareness, self-management and benchmarking.<sup>27</sup>
- **Roche** has partnered with PatientsLikeMe in a patient reported study of experiences with cancer medications, and with Qualcomm to harness data from patients with remote anti-coagulation monitors.<sup>32, 33</sup> Roche is also undertaking non-interventional studies with patient reported outcomes to better understand the quality of patients' lives, including in haemophilia patients to inform its clinical development of Emicizumab.<sup>34</sup>

### 4. CREATING NEW SIMPLIFIED BUSINESS MODELS

Transform core operations to build new simplified businesses that meet unmet patient and healthcare system needs.

High Performers continuously work on transforming their organization for operating efficiency and productivity, driving savings for reinvestment into innovative health solutions. They are building innovative new business models that are data-driven and digitally empowered and adapting more readily to rapid changes in customer demands, market climate and shifts in their product portfolio. We also see High Performers leveraging unique cross-industry collaborations and new technologies like artificial intelligence, remote patient monitoring and automation. Examples include:

- **Roche's** data analytics strategy is driving productivity and process efficiency throughout the organization, while its 'individualization of treatment' strategy focuses on linking treatments to patient's genetics and disease biomarkers.<sup>35</sup> The company also acquired mySugr, a digital diabetes management platform maker, to complement its diabetes business.<sup>36</sup>
- **Novo Nordisk** has collaborations with Glooko in developing a diabetes monitoring app and with IBM Watson in gathering data about impact of insulins and patient compliance.<sup>37</sup>
- **BMS** has invested in collaboration with liquid biopsy technology company Grail, helping to detect cancer early from minute genetic fingerprints in blood samples. BMS is using Grail analytics to inform its R&D decisions and development Companion Diagnostics and Care Management solutions.<sup>38</sup>
- **Amgen** has invested in digital health incubator eHealth Ventures consortium along with the Cleveland Clinic, and in video game therapeutics technology company Akili. Amgen also has a partnership with Unilife in wearable injectable Rx delivery devices.<sup>39</sup>

# CONCLUSION

Since our study last year, investor confidence in the pharma sector has taken a step back. Optimism over sales growth from new specialty science persists, but is challenged by growing pressure from payers and governments for curbs in new drug spending and greater scrutiny of pricing. Investors are closely watching the performance of recent launches for signals on the speed of their uptake and the net sales price achieved. Shifting the entire organization to be in the business of selling patient outcomes and building a rich interface with patients are key challenges all companies need to address to unlock the value of their science. The gap between High Performers and the rest of the peer group has narrowed, and peer group performance has become more bunched. All of this has had the effect of accelerating the pharma industry's need to adopt new business models that address the consumerization of healthcare and the drive for delivering outcomes-based value.

There has been a shift to more specialty and bigger specialty products, but the breakthrough science era we're in now is very different to years gone by. When breakthrough science and corporate restructuring is not enough, top performers are focused on delivering superior outcomes for patients, better value for the system and enabling data-driven, digitally-powered enterprises to transform results. Innovative new products alone will not be enough to succeed; High Performers will also need to adapt with new capabilities to realize the commercial potential of great science. They will need to develop advanced outcomes data packages to demonstrate long-term patient value, offer flexible pricing models and patient support services to drive optimal affordability and realization of outcomes at scale.

**THE CHALLENGE AHEAD IS REALIZING VALUE BY COMBINING THE COMMERCIAL PROMISE OF NEW SCIENCE WITH DELIVERING PATIENT SERVICES AND ECONOMIC OUTCOMES IN A RAPIDLY CHANGING HEALTHCARE ECONOMY.**

# RESEARCH NOTES AND SOURCES

- 1** [Biotech takes a hit after Clinton tweets about EpiPen pricing](#). CNBC, August 2016.
- 2** Accenture Research based on Capital IQ, Index Value Jul 16, 2015 to Sep 22, 2017.
- 3** Financial Times 11 July 2017, '[Global pharma sales forecasts cut amid pricing pressures](#)'. Article quotes recent Research from SSR suggesting US drug List Prices increased 6.5% in Q1-17 down from 10.9% in Q1-16, and US net prices fell negative in Q1-17 to -1.2% compared to 4.1% in Q1-16.
- 4** Accenture Research based on analysis of New Molecular Entity (NME) approvals by the FDA CDER division 2009-2016, with specialty drugs defined as those with high pricing and lower volumes, generally (but not always) biologicals and/or prescribed by specialist physicians. Where an NME is approved in the last four months of the year, the following year is taken as year one of launch. The approvals of Sovaldi, Harvoni and Genvoya by Gilead are excluded from this analysis as they are considered outliers in performance and not representative of the rest of NME approvals.
- 5** Accenture Research based on reported actual sales to 2016, where a drug was approved in the last four months of any year, the following year is considered the first year of launch and sales.
- 6** Accenture Research estimates based on the number of products in late stage development and expected attrition rates.
- 7** The Pipeline Replacement Ratio is calculated as the ratio of Sales Replaced (from patented existing and newly launched drugs) in any year compared to the sales lost to patent expired products in the same year (Products already off patent, or going off patent in the year in question), sourced from Evaluate Pharma.
- 8** Accenture Research analysis of sixteen pure play pharmaceutical companies performance 2009-16, with revenue growth expressed as unweighted average of reported growth rates at constant exchange rates.
- 9** Accenture Research analysis of 16 Pure play pharmaceutical companies performance 2009-16, based on total Core Operating Margin (EBIT/ Group Revenue—excluding exceptional items).
- 10** Enterprise Value (EV) for the total pure play peer group is calculated from the Market Capitalization and net debt positions across all companies. Current Value (CV) is calculated from the total Net Operating Profit less adjusted taxes (NOPLAT) across the peer group, and Future Value (FV) is the difference between EV and CV in any year.
- 11** The Affordability gap is measured as the difference between forecast sales growth 2017-21 of recent (2012-16) and upcoming (2017-21) new launches sourced from Evaluate Pharma, and forecast pharma spending (including savings from generics) growth 2017-21 in developed markets sourced from IMS Health.
- 12** Outlook for Global medicines through 2021, IMS Health, December 2016.
- 13** Accenture Research analysis of New Molecular Entity approvals 2007-16, comparing Equity Analyst consensus Forecast sales for the first two years post launch, to actual sales recorded, raw data sourced from Evaluate Pharma 2017.
- 14** Accenture Research analysis of 16 pure play Pharmaceutical Companies, the \$ growth of the largest product contributor to reported sales growth 2009-16 is compared to total company revenue in 2009, and an average taken across all companies. This is compared to an average across all pure play Pharmaceutical Companies, of \$ growth forecast of largest product contributor to 2016-21 forecast Revenue growth compared to 2016 Total revenue. Raw data is sourced from Evaluate Pharma 2017.
- 15** Accenture Research analysis of FDA (CDER and CBER Divisions) approvals of New Molecular Entities 2005-16.
- 16** Based on FDA CDER division annual reports in each year, and their reporting of Orphan drugs and First in Class designations of New Molecular Entities Approved.
- 17** Accenture Research analysis of product sales facing patent expiry, both historically and forecast, and the sales they are forecast to lose post loss of exclusivity compared to the sales growth of new and existing patented products. Raw data sourced from Evaluate Pharma 2017.
- 18** Accenture Research analysis of 16 pure play pharmaceutical companies, the \$ growth of the largest product contributor to reported sales growth 2009-16 is compared to total company revenue in 2009, and an average taken across all companies. This is compared to an average across all pure play pharmaceutical companies, of \$ growth forecast of largest product contributor to 2016-21 forecast revenue growth compared to 2016 total revenue. Raw data is sourced from Evaluate Pharma 2017.
- 19** Accenture Research analysis of reported gross sales compared to net sales after all discounts, for selected large pharmaceutical companies 2008-16. For some companies global sales data is shown, and for others US only sales data is shown.
- 20** [Credit Suisse Research analysis of US drug pricing](#), May 2016; and [2017 Credit Suisse analysis referenced in Business Insider Article](#), May 2017.
- 21** Accenture Research analysis of 295 NME approvals 2008-16 for which detailed product sales and Equity Analysts forecasts were available, showed over time (with small fluctuations between years) the ratio of products exceeding vs. missing analyst sales targets for the first two years post launch (analyst forecasts taken at the time of approval) was roughly 50:50. Raw data sourced from Evaluate Pharma 2017.
- 22** A simple unweighted average is taken across the pure play peer group of companies, of core R&D expense (excluding exceptional items) compared to Total Revenue, with raw data sourced from Capital IQ.
- 23** [Tufts Center for the Study of Drug Development 2014](#).
- 24** World Preview 2017, Outlook 2022. Evaluate Pharma, June 2017.
- 25** Accenture Research analysis of M&A deals sourced from Capital IQ Jul-17. All deals pertaining to the Life Sciences sector broadly are included, and Total Gross Transaction Value calculated for each. Completed deals are analyzed for 2007-15, and all announced deals (that haven't been cancelled) are considered for 2016 and 2017, recognizing that some more recently announced transactions may have yet to formally close. All M&A transaction types are considered, including partial and full stakes in companies.
- 26** (i) Amgen [23 November 2015](#), (ii) [18 May 2016](#), (iii) [2 May 2017](#).
- 27** (i) [Novo Nordisk Dawn 2 Study](#), (ii) [Novo Nordisk FDA ADCOM Victoza CV risk reduction in Type 2 diabetes patients](#), 20 June 2017.
- 28** Lilly announces Cardiovascular benefits of Jardiance in [EMPA-REG OUTCOME study](#).
- 29** [Roche leads Investment round and signs collaboration with Flat Iron and cloud based oncology software platform](#), 6 January 2016, 12 January 2015 [Roche announces Strategic collaboration and acquisition of majority stake in Foundation Medicine and molecular information on Oncology patients](#).
- 30** [Amgen announces genetics study with deCODE that points to new mechanism affecting cholesterol levels and risk of heart disease](#).
- 31** [Novo Nordisk patient centred business approach](#).
- 32** [Roche and Astrazeneca announces Patients-LikeMe cancer outcomes study](#), 11 March 2016.
- 33** [Roche and Qualcomm Collaborate to Innovate Remote Patient Monitoring](#), January 2015.
- 34** [Outcomes Measures in Haemophilia—Roche's View](#), November 2016.
- 35** (i) [Roche Individualisation of treatment strategy](#); (ii) [JP Morgan Conference](#), January 2017.
- 36** Roche Acquires mySugr to form a Leading Open Platform for Digital Diabetes, June 2017. <https://www.roche.com/media/store/releases/med-cor-2017-06-30.htm>
- 37** [Novo Nordisk teams up with Glookgo to develop diabetes management platform](#), January 2017.
- 38** [Bristol-Myers Squibb equity investment and collaboration with Grail](#), 1 March 2017.
- 39** (i) [Amgen invest in non-pharmaceutical start up Akili](#), July 2016; (ii) [Amgen has invested in digital health incubator eHealth Ventures consortium along with the Cleveland Clinic](#), October 2016; [partnership with Unilife in wearable injectable Rx delivery devices](#), February 2016.

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Accenture embarked on its High Performance Business Program in 2003. We have studied thousands of companies across multiple industries and industry segments and 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 bell curve. In our 2010 research, we added a forward-looking dimension to our research methodology that analyzed a company's revenue growth forecast 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.

## ABOUT ACCENTURE'S HIGH PERFORMANCE BUSINESS RESEARCH FOR THE BIO-PHARMACEUTICAL INDUSTRY

Accenture's study of the Biopharmaceutical industry is in its 12<sup>th</sup> 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 2017 update is based on trailing 12-month Q4 2016 financials and analyzes 16 of the largest pure-play pharmaceutical companies in the world over an 8-year period along with June 2016 industry-wide data. Collectively, the pure-play companies studied had \$428 billion in aggregate global revenue, representing nearly half the global pharmaceutical market by net sales. The results have been compared with our 2016 and 2015 studies to identify relative movements in the performance rankings. The analysis pro forma adjusts for the impact of major M&A deals (but not smaller bolt-on deals) and removes the impact of exceptional costs to reveal a normalized picture of ongoing core business operations. A detailed analysis of historic financial performance averaged over one-, three-, five- and seven-year time-frames is combined with consensus analyst forecasts to gain a forward-looking global picture of forecasted revenue growth from portfolio and new product launches as well as to gauge the impact of patent expirations and mature products.

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