



Pharmaceutical Executive

2015 Pharm Science Strategic Outlook An Industry in Flux: 2014-2015 Market Trends



WHERE BUSINESS MEETS POLICY

STILL A 21ST CENTURY GROWTH INDUSTRY...

- Continued progress in the basic science of biology and genomics lead to a cascade of advanced treatments that use the body's own defenses to attack disease. Oncology and auto-immune disorders are poised for the greatest gains, along with better diagnostic tools to make the application of drugs more precise for the patient.
- Industry sales growth to average 5.1 per cent annually to 2020, when worldwide sales will reach the trillion dollar mark.
- Specialty and biologic drugs requiring complex manufacturing protocols will make up more than half of industry sales by 2020, with oncology drugs dominating at a record high growth rate of more than 10 per cent CAGR up to 2020.
- Specialty and biologics is where the industry will continue to make the bulk of its profits; therapeutic vaccines are also a significant new opportunity.
- Novartis [see Pharm Exec's Pharma 50 <http://goo.gl/35ZI1S>] is currently the largest company by sales and is expected to maintain this position to 2020, with more churn in ranking at the middle-level as the industry undergoes another wave of consolidation.
- A restructuring of capabilities is emerging as biotech companies benefit from their increasing status as the new source of innovations, while big Pharma looks more toward its competence in global-scale, late-stage development, distribution and marketing.
- New and emerging threats to global health underscore the industry's continued relevance in tackling disease.

Top 5 Pharma Companies				
Rank	Company headquarters (website)	2013 Rx Sales (USD in min)	2013 R&D spend (USD in min)	2013 Top-selling Drugs (USD in min)
1	Novartis Basel, Switzerland (novartis.com)	\$46,017	\$9,360.3	Gleevec (4,693) Diovan (3,524) Lucentis (2,383)
2	Pfizer New York, New York (pfizer.com)	\$45,011	\$6,254.0	Lyrica (4,595) Pprevnar 13 (3,974) Enbrel (3,774)
3	Roche Basel, Switzerland (roche.com)	\$39,143	\$8,293.5	Rituxan (7,503) Avastin (6,751) Herceptin (6,562)
4	Sanofi Paris, France (sanofi.com)	\$37,701	\$6,117.4	Lantus (7,592) Plavix (2,460) Lovenox (2,262)
5	Merck & Co Whitehouse Station, New Jersey (merck.com)	\$37,519	\$7,123.0	Januvia (4,004) Zetia (2,658) Remicade (2,271)

Note: Annual sales of prescription medicines; 2013

BUT INVESTMENT DYNAMICS NO LONGER FAVOR ORGANIC GROWTH

- Big Pharma is cash rich and asset poor.
- Productivity crisis in in-house R&D: is the model broken?
- High drug candidate failure rate, especially in costly Phase III studies.
- 60 billion+ R&D spend in 2013 for 29 FDA approved drugs, mostly for small-population biologics.
- M&A activity is reaching all-time high, with 2014 deal volume to date at more than \$250 billion.
- Big Pharma's in-house corporate venture funds are back and in a buying mood.
- Smaller biotechs with unique, clinically differentiated assets are driving innovation.
- Big Pharma puts its stable of older off-patent medicines on the block for potential buyers outside the industry.
- Collectively, the changes promise a more diverse industry, particularly with the entry of buyers from adjacent sectors – adding many potential new customers for the BtoB advertising vertical.

RAISING THE BAR ON PERFORMANCE...

- Activist investors use shareholder arbitrage to force companies to “get lean.”
- Partnering and licensing opportunities are increasingly selective, with less margin for error.
- One-time market authorization yields to periodic reevaluation through the product life cycle.
- Relentless compliance scrutiny, expanding globally beyond illegal US off-label marketing toward multi-billion \$ penalties for foreign corrupt practices.
- Pressure on industry to respond to a more diverse customer base, with multiple engagement points beyond the physician.
- Operational challenges in high-potential emerging country markets: how to turn strong revenues into sustainable profits?
- A bump up in patent expirations for big selling drugs in 2015, although the worst of the “patent cliff” is over.
- China growth engine slows – GDP 14.2% in 2007 vs. 7.5% this year – while public debt burden rises amidst more bias toward foreign multinationals.
- Greater pricing pressures in Europe amid generalized budget austerity.
- Pricing's bottom line: future global profits depend on maintaining price freedom in the US.
- Growing complexity in clinical trial requirements, including big Phase IV population studies extending beyond the patent term.
- New competitive threats from generics, CROs and adjacent industries – Google, Nestle – outside health care.
- Crowding in key therapeutic categories - “counter launch” campaigns hype the marketing bill.
- Social media's disruptive effect on the patient/physician relationship and the accuracy of clinical trials – an alternative, open source information stream.
- Formal patient group engagement in drug development, regulatory approval, market access.

LEADS TO A NEW VALUE EQUATION

- The Affordable Care Act [ACA] and other health reform measures consolidate payer power in pricing and market access.
- Payers are self-defining value as a measurable outcome that either cures or manages the condition directly or reduces the cost of other covered interventions – this latter is hard to do within a siloed system of care.
- Inconsistencies and absence of a universal consensus on methodological standards of evidence weaken industry ability to make its case on value.
- Therapeutic competition and pending patent cliff for high priced biologics are fueling the payer backlash, including activist-like tactics to mobilize KOL's and public opinion – pricing is no longer an “insider” game.
- The “brick wall” between market authorization and a price/reimbursement decision has been breached in Europe and may emerge in the US as the ACA expands drug coverage for lower income patients.
- Formal HTA programs as a supplement or a condition for P&R continue to spread across geographies.
- Payers press companies to make costly co-investments in diagnostics to ensure precision medicine – targeting only those patients most likely to benefit from treatment.

HEIGHTENED REPUTATION RISKS

- Despite industry claims that it is increasingly a “price taker,” consumers and government payers don’t see it that way – drug makers are aggressively raising margins on existing products, a process largely confined to the US market. Elsewhere, drugs are seen as a “public good.”
- US financial sanctions for deceptive marketing practices, including penalties for violations of an ambiguously defined federal ban on off-label marketing, surpass the \$25 billion mark, as measured over the past five years.
- Vulnerability to biased regulatory enforcement in emerging market countries with weak governance standards.
- With more than 80 per cent of API manufacturing now taking place outside the US, industry could be harmed by adulterated or unsafe medicines imported from other countries, especially as FDA oversight in this area is constrained by a lack of resources.
- Industry information assets vulnerable to transparency/disclosure privacy pressures.

WHAT’S HOT

- Biotech IPOs and out-licensing to big Pharma: The volume of deals is higher this year and involve asset swaps and commercialization rights in multiple markets – slowly, biotech is going global.
- Immunology treatments for cancer that rely on the body’s own immune system rather than invasive chemotherapies to attack tumor growth. Immunologic drugs amount to a potential \$36 billion market for pharma in 2015, according to investment analysts.
- New drug combinations are another hot area in oncology.
- Understanding how the bureaucratic complexities of the US Affordable Care Act will shape future drug utilization patterns, including the effectiveness of the billions of dollars industry spends on patient coupons/rebates designed to block PBM’s growing use of formulary access controls to manage drug benefit costs.
- Using new IT technologies to create more patient-friendly approaches to medicines adherence.
- The “virtual” sales pitch – detailing without a human face.
- Finding efficient and cost effective ways to manage the new reporting requirements on medicines promotion.
- Pressure on the “c suite:” Boardroom issues, politics and competence to address tighter governance oversight.

WHAT’S NOT

- Follow-on medicines in primary care – the investment return is low due to requirements to conduct large-scale clinical/observational trials and the role that cheap generics now play in setting the standard of care.
- The blitzkrieg approach to deploying the field force — it’s no longer a numbers game.
- Funding for basic, pre-competitive research – public budgets like NIH continue to fall.
- Backlash against broad-scope patent protections that can be enforced across geographies.
- Big data without the applied analytics that can furnish useful insights on commercial strategy.

- [William Looney](#), Editorial Director, *PharmExec*, print and online
wlooney@advanstar.com, 212-951-6743, [Twitter@BillPharmExec](#)

Pharmaceutical Executive, 641 Lexington Ave 8th Fl, New York, NY 10022

For brand information and related media opportunities contact:

Group Publisher
[Russ Pratt](#)
rpratt@advanstar.com

Sales Director
[Bill Campbell](#)
bcampbell@advanstar.com
847-283-0129

East Coast Sales Director
[Michael Moore](#)
mmoore@advanstar.com
732-395-1996

N, Carolina Sales Manager
[Laurie Marinone](#)
lmrinone@advanstar.com
508-808-4723

Sales Director
[Wayne K Blow](#)
wblow@advanstar.com
+44 (0) 12244 626 304