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GENERICS ATTACI

US branded drug sales saw a modest bump in 2009, but maybe hold off on the champagne, because generics are still surging and another wave of big patent expirations is right around the corner, Matthew Arnold reports

ales of branded drugs in the US rose 5.1% to \$300 billion last year, according to IMS Health, as a break in major patent expirations and drug safety scares fueled spending. That's a significant improvement over 2008's record-low 1.8% growth, even if it pales in comparison to the double-digit increases enjoyed through much of the go-go Oughts.

But happy times aren't exactly here again. Next year will bring another round of blowout blockbuster patent expiries accounting for a loss of more than \$30 billion in US sales, including the likes of Lipitor, Plavix, Seroquel, Zyprexa and Actos. Brands worth nearly \$20 billion in US sales lose patent protection in 2012, and after a lull in 2013, another \$20 billion worth will be exposed to generic competition in 2014.

And the inexorable march of genericization continues, with branded drugs now accounting for only a quarter of dispensed scripts in the US. Just six years back, branded drugs made up 46% of prescriptions dispensed.

"We could see that 75% [generic] volume share going up to 80%, maybe even a little higher," says Michael Kleinrock, director, Thought Leadership at IMS Health. "It really depends on the future contribution from the pipeline. Right now, we're seeing a large group of products that contribute a lot to sales go through the end of their protected life cycle."

On the bright side, the market for prescription drugs has proven remarkably robust at a time of tremendous economic distress. Dispensed prescription volume in retail channels grew 2.1%—to 3.9 billion dispensed prescriptions—up from 1% growth in 2008. While the volume of new therapy starts in the 17 major chronic disease areas declined by around 1%, the volume of add-on therapy starts, switches and refills rose nearly 2% in 2009.

IMS credits that growth in part to sustained pricing practices by manufacturers competing on the basis of clinical evidence and value.

"We consider that resilience, based on the treatment of medical need, to be an important factor in why the industry has delivered the 5.1% economic growth we saw in 2009, despite the economic crisis," says IMS's Kleinrock.

Other factors, according to IMS Health, include greater use of specialty pharmaceuticals, which now constitute 21% of the US market and grew 7.5% last year, and include better inventory management practices by retail pharmacies.

Surprisingly, fears that unemployed and underemployed patients would split pills or skip refills have proven largely unfounded.

"What we've seen in our patient level data does not reflect people stopping taking their drugs for six months," says Kleinrock. "It reflects a very, very moderate level of patients slowing down their visits to doctors and usage of drugs, but it's more about switching to lower-cost alternatives—either lower-cost brands or generics. And even that's relatively moderate."

This year, at least, should prove pretty tranquil, says Deutsche Bank managing director Barbara Ryan, but come January, buckle your seatbelts.

"I think 2010 will be like 2009, with not a great deal of new product introductions having much of an impact," says Ryan. "By the same ≥ token, there are not an enormous number of patent expirations, which become much more pronounced in 2011 and 2012. I suspect we aren't going to see anything be better than last year—if anything, $\ddot{\ensuremath{\wp}}$ it will probably be a little weaker."

The essentially flat 1.8% growth of 2008 was the industry's lowest in IMS Health's 55-year history. "Other factors that contributed to that low growth in 2008 were pre-existing factors, prior safety issues and large levels of patent expiries," says Kleinrock. "We don't see those factors continuing as much. We haven't had in the industry a very large product or class of products experience a Vioxx-class safety issue in the past five years, so that lack of a negative issue is essentially a positive for the market. And certainly, we are in a lull period in terms of the impact of patent expiries on the industry between the last big back in '06-'07 and the next big batch in 2011-2012."

Patent protection loss will also have a knock-on effect of forcing companies to slash R&D spend, as Bernstein senior analyst Tim Anderson noted in a December briefing.

"Investors need to understand the degree to which large, highly-profitable products 'fund' other parts of the organization, such as R&D," wrote Anderson. "At present, most companies paint a picture of not cutting R&D, but unless pipelines are able to generate substantial new product flow over the next few years, our models suggest the more desperate 'cliff' companies might be forced to do this."

Merck's Cozaar loses patent protection this year, as do Johnson

"I think that 2010 will be like 2009, with not a great deal of new product introductions having much of an impact"

-Barbara Ryan, Deutsche Bank

& Johnson's Levaquin, AstraZeneca's Arimidex and Eli Lilly's Gemzar. Those are relatively small hits, but there isn't much in the near-term pipeline that looks promising.

"Next year, maybe some factor 10as, but there's really not much on the horizon for the remainder of this year that's likely to be all that spectacular," says Deutsche Bank's Ryan. "Unfortunately."

Given the long lead time on drug development, there's not a whole lot companies can do but ride out the storm.

"At least for the four major drug companies, they've already made their beds," says Ryan. "In the case of Merck and Pfizer, they've done big mergers to dilute their dependence on products that will lose patent protection and to create economic synergies that will, in large measure, replace lost profits once they are genericized. And Lilly and [Bristol-Myers Squibb] have basically bet on their research pipeline. There's much higher risk to their cashflows over the next couple of years, because they face an earnings cliff, but they would hope their pipeline is successful enough that they will have a rapid acceleration in revenue and earnings off that cliff. Whereas Merck and Pfizer have sort of alleviated the cliff, but by the same token, they're that much larger and have diminished the impact of anything that might come out of the pipeline by definition of their size."

That means companies need to look beyond the US for growth. "Sales outside the US, particularly in these emerging markets, are going to become a much more significant part of all these companies' business," says Ryan. "That's going to be where growth is taking place, barring some dramatic epiphany in R&D. And that could happen, but unless somebody comes up with a breakthrough Alzheimer's drug or something that meets a critical unmet need, then the US will continue to decline as a percentage of the industry's overall sales."

Sustained spending by Pfizer has buoyed industry promotion significantly



Pharma sector spend on promotion held up remarkably well in 2009, despite a grinding recession, a spate of mega-mergers and few new drugs to launch.

"Total industry promotion actually went up about 2% from 2008 to 2009," says Melissa Leonhauser, director at SDI. "That's probably just holding constant, because the cost of some things probably went up, but that's a pretty positive story. You have the suffering economy at the same time you're going through a bunch of mega-mergers, so for promotional spend to actually increase a little bit, that's good.

SDI tracks five types of promotion: detailing; DTC advertising; meetings and events; e-promotion; and journal advertising. Spend in three of those categories was up last year, as detailing spend rose 3%, DTC went up 2% and e-promotion saw a 6.6% gain. Meetings and events spend dipped 1.7% and journal ad spend slumped by a whopping 19% to an all-time low of \$287 million, with around 21,000 ads placed.

"Our guess is that the universe of journals has declined as many have gone out of business, and others are now moving online," says Leonhauser. Advertisers may be shifting their journal ad spend from print to digital ads, though it remains to be seen how much of those advertising dollars they're recouping. Internet rates have been climbing for the past couple years, but it's still a fraction of the cost of print advertising.

The one notable blip in the DTC spend for the year was an astronomical increase in radio advertising—spot radio advertising was up 309% and network radio up 58%. The bump was largely attributable to Pfizer's "Only" campaign for Lipitor, aimed at staunching generic switches. And that's the story of promotional spend in 2009—Pfizer pretty much single-handedly buoying spend while most of the other big players retrenched.

Pfizer's overall promotional spend was up 4.4% for 2009 to \$2.6 billion, according to SDI data. Pfizer's spend on detailing and meetings and events fell by 15%, while the company's journal ad spend fell 16%, but its DTC spend rose 46% and its e-promotion spend rose almost 79%.

"Pfizer, as well as some smaller companies, is really helping keep that spending up," says Leonhauser. AstraZeneca, the fourth-biggest promotional spender in the US, also increased spend, by 22% to \$1.3 billion. Other companies increasing spend included No. 8 Forest (+18%), No. 9 Abbott Labs (+8.3%) and No. 12 Takeda (+10.9%). Those cutting US promotional spend included Merck, GlaxoSmithKline, Lilly, Novartis, Sanofi-Aventis, J&J, Bristol-Myers Squibb and Boehringer Ingelheim.

The year saw a 13% reduction in the number of sales reps for the top 40 pharmas. "There's a trend toward sales forces declining anyway, but on top of it, they had to make cuts as they underwent mergers," says Leonhauser. "But interestingly, the number of details is only down 2%, and detailing spending increased 3% because the cost of the reps in the field increased."



- * Denotes IMS Health data
- ** Denotes SDI Promotional Audits & Kantar Media data

Note: 2008 promotional totals for Pfizer, Merck and Roche include spending for Wyeth, Schering-Plough and Genentech product portfolios, respectively

1. Pfizer

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US Sales* | \$27.8 billion | \$27.7 billion |
| Journal ad spending ** | \$35.0 million | \$41.6 million |
| Promotional spend * * | \$2.6 billion | \$2.5 billion |
| | | |

Top products (global sales): Lipitor (\$11.4b), Lyrica (\$2.8b), Celebrex (\$2.4b), Norvasc (\$2.0b), Viagra (\$1.9b)

Wyeth, which Pfizer purchased last year for \$68 billion, has given Pfizer a biologics platform and a way to supplement growth. In the run-up to Lipitor's 2011 patent expiry, Pfizer has sought to diversify. Pfizer's third big pharma acquisition in 10 years, Wyeth brings legacy products such as Effexor and Prevnar, mitigating Pfizer's patent cliff, somewhat. Pfizer is open to further acquisitions (it bid for generics maker Ratiopharm this year, losing to Teva). Going forward, the combined entity plans to shed about \$2-3 billion in costs and cut nearly 20,000 jobs while decreasing R&D spend by \$3 billion. Turning to the pipeline, Alzheimer's treatment Dimebon failed to show effectiveness in a late-stage study, but an oral JAK-3 inhibitor for RA remains a late-stage standout. And Prevnar-13v, a version of the vaccine for adults, is among the candidates inherited from Wyeth. In March, Pfizer made good on a promise to disclose its compensation for US healthcare professionals, saying it paid out \$35 million to 4,500 HCPs in the second half of 2009.

2. Merck

| 2009 | 2008 |
|----------------|----------------|
| \$19.8 billion | \$20.1 billion |
| \$7.9 million | \$13.6 million |
| \$1.9 billion | \$2.2 billion |
| | \$7.9 million |

Top products (global sales): Singulair (\$4.7 b), Cozaar/Hyzaar (\$3.6b), Januvia (\$1.9b), Fosamax (\$1.1b), Gardasil (\$1.1b)

Merck is engaged in building momentum in its own business while managing the Schering-Plough integration. The firm has targeted \$3.5 billion in savings by 2012 and a 15% reduction in its 100,000-strong workforce. It absorbed sole revenue rights to Vytorin and Zetia, but these are no longer stars in the cardiovascular firmament. The Schering legacy does include several growth drivers: Remicade, Simponi, Nasonex and Clarinex, as well as launch product Saphris. Sales of Gardasil have been flat, while the launch of generic competition to the Cozaar/Hyzaar hypertension franchise is likely to have a negative impact on revenues, as will Singulair's expected patent expiry in 2012. Sales of Singulair, Januvia/Janumet and Isentress are surging. During the year, Merck acquired Avecia Biologics, expanding its existing biologics expertise and manufacturing capacity, and struck 50 other licensing and alliance deals.

3. AstraZeneca

| | 2009 | 2008 |
|-----------------------|----------------|----------------|
| US sales* | \$18.3 billion | \$16.1 billion |
| Journal ad spending** | \$5.4 million | \$13.1 million |
| Promotional spend * * | \$1.4 billion | \$1.1 billion |

Top products (global sales): Nexium (\$5.0b), Seroquel (\$4.9b), Crestor (\$4.5 b), Symbicort (\$2.3b), Arimidex (\$1.9b)

AstraZeneca delivered decent financial performance last year, owing largely to a boost from H1N1 vaccine orders and Toprol-XL sales. Excluding those two factors, US market growth was just 2%. Its list of challenges remains long: Seven drugs, including market leaders Seroquel, Symbicort and Arimidex, face generic competition by 2014. The firm said it is cutting 8,000 jobs, or 12% of its workforce. And Crestor and Seroquel, two best-sellers, face a patent dispute and liability claims, respectively. In April, FDA delayed approval of Certriad, a pill combining Crestor with Abbott's fenobric acid. But AstraZeneca has four other products awaiting regulatory approval. It has also added four late-stage development projects through external efforts. In February, AZ began marketing Crestor for a new indication. Whether the new indication may lead to broader use of the drug is uncertain.

4. GlaxoSmithKline

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$15.0 billion | \$16.5 billion |
| Journal ad spending ** | \$3.3 million | \$3.5 million |
| Promotional spend * * | \$1.5 billion | \$1.9 billion |
| | | |

Top products (global sales): Seretide/Advair (\$7.8b), Valtrex (\$2.0b), Avandia (\$1.2 b), Flixotide/Flovent (\$1.2b), Relenza (\$1.1b)

"2009 saw GSK return to sales growth and I am confident of our prospects in 2010," proclaimed CEO Andrew Witty earlier this year. Over the next few years, GSK has fewer patent expiries to contend with than its US and European peers—even with mega blockbuster

Advair set to lose US patent protection in 2013—and is diversified in areas like consumer health. The firm has announced layoffs—3,000, according to the *Financial Times*—and Witty says he is reallocating those resources over to emerging markets to "go for growth." During 2009 GSK enjoyed four FDA approvals: Arzerra, Votrient, Cervarix and Hiberix. The imminent regulatory submission for Benlysta, with partner Human Genome Sciences, represents a bigger opportunity. The drug, possibly the first approved treatment in lupus in 40 years, could reach \$4 billion in global sales.

5. Roche

| | 2009 | 2008 |
|------------------------|--|-----------------|
| US sales* | \$14.3 billion | \$12.6 billion |
| Journal ad spending ** | \$8.7 million | \$5.9 million |
| Promotional spend ** | \$239.6 million | \$209.7 million |
| | and the second s | |

Top products (global sales): Avastin (\$5.8b), MabThera/Rituxan (\$5.7b), Herceptin (\$4.9b), Tamiflu (\$3.0b), Pegasys (\$1.5b)

For Roche, bringing Genentech into the group has been a priority after obtaining full ownership of the biotech for \$47 billion. Roche's heavy presence in oncology continues to be the envy of the industry. Still, Avastin stumbled in a trial exploring wider use, prompting some to doubt the Swiss firm's cancer prowess. Its development pipeline comprises 10 new molecular entities and 30 additional indications for existing products in late-stage development. Over the next year or so, Roche expects to file taspoglutide, as well as for several major line extensions of key cancer medicines, including MabThera/Rituxan and Xeloda. Another recent clinical setback was suspension of ocrelizumab in RA, although the company received approval of another RA drug, Actemra, this past January.

6. Novartis

| | 2009 | 2008 |
|----------------------------|---------------------|-------------------------|
| US sales* | \$13.4 billion | \$12.2 billion |
| Journal ad spending** | \$8.5 million | \$10.4 million |
| Promotional spend * * | \$936.3 million | \$944.2 million |
| Ton products (global sales | s). Diovan (\$6.0h) | Gleevec/Glivec (\$3.9h) |

Top products (global sales): Diovan (\$6.0b), Gleevec/Glivec (\$3.9b), Zometa (\$1.5b), Femara (\$1.3b), Lucentis (\$1.2b)

Novartis' Dr. Daniel Vasella said in January he's ready to hand over his CEO reins to Joe Jimenez. Considering the company's steady positioning, he couldn't have timed it better. Granted, the Swiss firm is losing Femara in 2011 and best-seller Diovan in 2012 to generics. "Novartis has a well-diversified business, with strong consumer and vaccines divisions, a strong pipeline and a wealth of newer products on the market to see it past those losses," MM&M noted in January. Gleevec is likely to keep growing, while the pipeline produced one new biologic and two NMEs last year. Other potential sources of upside include MS drug FTY720, possible approval for Lovenox, and two promising late-stage vaccine candidates.

7. Eli Lilly & Company

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$13.2 billion | \$12.0 billion |
| Journal ad spending ** | \$13.2 million | \$23.9 million |
| Promotional spend * * | \$1.2 billion | \$1.2 billion |

Top products (global sales): Zyprexa (\$4.9b), Cymbalta (\$3.1b), Humalog (\$2.0b), Alimta (\$1.7b), Cialis (\$1.6b)

| Rank | Company | 2009 Total (Billions) | 2008 Total (Billions) |
|------|------------------------------|--------------------------|--------------------------|
| 1 | Pfizer | \$27.8 | \$27.7 |
| 2 | Merck & Co. | \$19.8 | \$20.1 |
| 3 | AstraZeneca | \$18.3 | \$16.1 |
| 4 | GlaxoSmithKline | \$15.0 | \$16.5 |
| 5 | Roche | \$14.3 | \$12.6 |
| 6 | Novartis | \$13.4 | \$12.2 |
| 7 | Eli Lilly & Co. | \$13.2 | \$12.0 |
| 8 | Johnson & Johnson | \$12.8 | \$15.6 |
| 9 | Amgen Corp. | \$12.5 | \$12.8 |
| 10 | Teva Pharmaceuticals USA | \$12.1 | \$11.2 |
| 11 | Sanofi-Aventis | \$11.1 | \$10.7 |
| 12 | Abbott Laboratories | \$9.5 | \$9.7 |
| 13 | Bristol-Myers Squibb | \$8.9 | \$7.9 |
| 14 | Takeda | \$7.9 | \$7.9 |
| 15 | Boehringer Ingelheim | \$7.6 | \$6.3 |
| 16 | Eisai Corp. | \$4.4 | \$3.9 |
| 17 | Forest Laboratories | \$4.4 | \$4.0 |
| 18 | Mylan Laboratories | \$4.1 | \$3.3 |
| 19 | Otsuka America | \$4.0 | \$3.0 |
| 20 | Gilead Sciences | \$3.9 | \$3.1 |
| | Total others Total market | \$75.3 \$300.3 | \$68.9 \$285.7 |

| Rank | Product | Company | 2009 Total (Billions) | 2008 Total (Billions) |
|------|------------------------------|----------------------|--------------------------|--------------------------|
| 1 | Lipitor | Pfizer | \$7.5 | \$7.8 |
| 2 | Nexium | AstraZeneca | \$6.3 | \$5.9 |
| 3 | Plavix | BMS/Sanofi-Aventis | \$5.6 | \$4.8 |
| 4 | Advair Diskus | GlaxoSmithKline | \$4.7 | \$4.4 |
| 5 | Seroquel | AstraZeneca | \$4.2 | \$3.8 |
| 6 | Abilify | Bristol-Myers Squibb | \$4.0 | \$3.0 |
| 7 | Singulair | Merck | \$3.7 | \$3.5 |
| 8 | Actos | Takeda | \$3.4 | \$3.1 |
| 9 | Enbrel | Amgen/Pfizer | \$3.3 | \$3.1 |
| 10 | Epogen | Amgen | \$3.2 | \$3.0 |
| 11 | Remicade | J&J/Merck | \$3.2 | \$3.0 |
| 12 | Crestor | AstraZeneca | \$3.0 | \$2.1 |
| 13 | Avastin | Genentech | \$3.0 | \$2.5 |
| 14 | Neulasta | Amgen | \$3.0 | \$3.0 |
| 15 | Oxycontin | Purdue | \$2.9 | \$2.3 |
| 16 | Cymbalta | Eli Lilly | \$2.8 | \$2.4 |
| 17 | Effexor XR | Pfizer | \$2.8 | \$3.0 |
| 18 | Lexapro | Forest | \$2.8 | \$2.7 |
| 19 | Lovenox | Sanofi-Aventis | \$2.7 | \$2.6 |
| 20 | Zyprexa | Eli Lilly | \$2.7 | \$2.5 |
| | Total others Total market | | \$225.5 \$300.3 | \$217.2 \$285.7 |

Eli Lilly has eight products each exceeding the \$1 billion mark, but the patent for its top drug, Zyprexa, expires next year in the US. And on a global basis, four of its six biggest sellers are set to lose patent protection by 2013. That means a combined \$11.3 billion, or 52%, of 2009 group revenue will be exposed. As for hope that Effient can help cushion the blow, its sales dropped to \$3.8 million worldwide in Q4 2009. In March, the FDA issued a complete response letter for Byetta LAR which Lilly co-markets with Amylin and Alkermes. Meanwhile, Lilly is trimming ranks by 13%, or 5,000 jobs, while shifting positions to China.

8. Johnson & Johnson

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$12.8 billion | \$15.6 billion |
| Journal ad spending ** | \$13.8 million | \$16.2 million |
| Promotional spend * * | \$687 million | \$767 million |

Top products (global sales): Remicade (\$4.3b), Procrit/Eprex (\$2.2b), Levaquin/Floxin (\$1.6b), Risperdal Consta (\$1.4b), Concerta (\$1.3b)

Generic competition is weighing heavily on Johnson & Johnson's pharmaceutical division, which saw an operational sales decline of 6.1% in 2009. The decline reflects expirations for its top Rx drugs Risperdal and Topamax, which are worth a collective \$3 billion in sales. Pharma sales were up 7% operationally, driven by lead products such as Remicade, whose sales rose nearly 15%. Procrit, Levaquin and Risperdal Consta also saw nice increases. In 2009 it received approval for two biologics, Simponi and Stelara, and its late-stage pipeline includes rivaroxaban being co-developed with Bayer. But challenges remain, says CEO Bill Weldon. In response, J&J is reducing global headcount by up to 8,200.

9. Amgen Corp.

| | 2009 | 2008 |
|-------------------------|----------------|-----------------|
| US sales* | \$12.5 billion | \$12.8 billion |
| Journal ad spending * * | \$3.9 million | \$2.8 million |
| Promotional spend * * | \$74.3 million | \$138.6 million |

Top products (global sales): Neulasta/Neupogen (\$4.7b), Enbrel (\$3.5b), Aranesp (\$2.7b), Epogen (\$2.6b), Sensipar (\$651m)

Amgen recorded a lackluster financial performance in 2009 as it took steps to bring Prolia to market. The biotech giant submitted extra information to the FDA after the agency issued a complete response letter on Prolia, which, if approved, would be the first biologic in the osteoporosis space. Analysts say US sales could reach \$1.8 billion by 2016, just as renal drug Sensipar, whose US sales account for about 3% of company revenue, faces patent expiry. And sales growth has continued to slow for Amgen's anemia drugs, a trend which caused adjusted earnings to come in at the low end of analyst projections last year.

10. Teva Pharmaceuticals

| | 2009 | 2008 | |
|--|-----------------|-----------------|--|
| US sales* | \$12.1 billion | \$11.2 billion | |
| Journal ad spending ** | \$3.6 million | \$5.0 million | |
| Promotional spend * * | \$184.9 million | \$148.3 million | |
| Top products (global sales): Copaxone (\$2.8b), Azilect (\$243m) | | | |

Teva's ability to break into the top 10 this year is a testament to

| Rank | Categories | 2009 Total (Billions) | 2008 Total (Billions) |
|------|--------------------------------------|--------------------------|--------------------------|
| 1 | Antipsychotics | \$14.6 | \$14.2 |
| 2 | Lipid Regulators* | \$14.3 | \$14.5 |
| 3 | Proton Pump Inhibitors | \$13.6 | \$13.8 |
| 4 | Anti-Depressants * * | \$9.9 | \$9.5 |
| 5 | Angiotensin II Antagonists | \$8.4 | \$7.5 |
| 6 | Antineo Monoclonal Antibodies | \$8.0 | \$7.3 |
| 7 | Antiarthritic, Biological Resp Mod | \$6.3 | \$5.6 |
| 8 | Erythropoietins | \$6.3 | \$6.9 |
| 9 | Analogs of Human Insulin | \$6.3 | \$5.0 |
| 10 | Anti-Platelets, Oral | \$6.0 | \$5.2 |
| 11 | Analeptics | \$5.8 | \$4.7 |
| 12 | Steroid, Inhaled Bronch | \$5.5 | \$4.8 |
| 13 | Seizure Disorders | \$5.3 | \$9.6 |
| 14 | GI Anti-Inflammatory | \$4.9 | \$4.3 |
| 15 | Codeine & Comb | \$4.9 | \$4.2 |
| 16 | HIV Antiviral Combination | \$4.7 | \$4.1 |
| 17 | Glitazones | \$4.7 | \$4.5 |
| 18 | Immune System Adjuncts | \$4.0 | \$4.0 |
| 19 | Anticoagulants, Inj. | \$4.0 | \$3.6 |
| 20 | Alzheimer's-Type Dementia | \$4.0 | \$3.4 |
| | | \$158.8 \$300.3 | \$149.1 \$285.7 |

Source: IMS Health, National Sales Perspectives *Includes Merck's Vytorin, Zetia ** Includes SSRI, SNRI products

strong generic—and branded—drug sales. Teva's \$5 billion acquisition of generics firm Ratiopharm Group in March gives it another reason to crow, having catapulted it to the top position in the EU's generic drug market. Ratiopharm, Germany's second largest generics maker, brings a platform for making biosimilars, complementing Teva's acquisition of biogenerics maker CoGenesys in 2008. The purchase, Teva's biggest since acquiring US-based Barr in 2008, also means Teva is now twice as big as its next largest generics competitor, Sandoz. In the US, Teva's sales should benefit from the launch of generic Cozaar and Hyzaar, which have combined branded sales of about \$1.7 billion.

11. Sanofi-Aventis

| | 2009 | 2008 |
|---------------------------|-----------------------|------------------------|
| US sales* | \$11.1 billion | \$10.7 billion |
| Journal ad spending ** | \$4.5 million | \$6.5 million |
| Promotional spend * * | \$916.3 million | \$954.2 million |
| Top products (global cale | o): Lantuc (\$4.2b) I | oveney (\$4.1b) Playiy |

Top products (global sales): Lantus (\$4.2b), Lovenox (\$4.1b), Plavix (\$3.6b), Taxotere (\$3.0b), Aprovel (\$1.7b)

Sanofi-Aventis has been searching for new sources of growth as the firm's thin pipeline offers little hope of offsetting patent expiries for flagship products like cancer drug Taxotere (2010) and blood thinner Plavix (2011). The company made \$9 billion worth of acquisitions last year, including a French nutritional beauty-supplement brand, European generics firm and a US consumer health outfit. The latter, Chattem Inc., gives Sanofi a platform for future Rx-to-

OTC switches, beginning with allergy drug Allegra, whose global sales totaled \$994 million last year even as generic copies arrived in the US. Its vaccines and diabetes businesses are two other future growth platforms. The company has fended off generic competition for cancer drug Eloxatin, striking settlements that essentially give the brand another year and half of exclusivity. Another legal break was a decision by the US Patent and Trademark Office to uphold the Plavix patent until 2012.

12. Abbott Laboratories

| | 2009 | 2008 |
|-----------------------|-----------------|-----------------|
| US sales* | \$9.5 billion | \$9.7 billion |
| Journal ad spending** | \$2.5 million | \$6.1 million |
| Promotional spend * * | \$696.7 million | \$641.7 million |

Top products (global sales): Humira (\$5.5b), TriCor/Trilipix (\$1.3b), Kaletra (\$1.4b), Niaspan (\$855m), Lupron (\$800m)

Abbott Labs has managed to deliver steady earnings growth thanks to a blend of product diversity and fiscal discipline. In Q4, US drug sales fell 8.6% on generic competition to Depakote, and best-selling drug Humira rose just 3.1% in the US. That's a bit scary for Abbott, as it has leaned on Humira for roughly 35% of revenue. Nutritional product sales rose 8.8% to \$1.4 billion while diagnostic product sales rose 8.8% to \$975 million. Vascular product sales rose 9.1% to \$723 million on sales of the company's Xience stent. The company bought a number of small-to-midsize companies last year, including a \$6.6-billion deal for Belgian-based Solvay that is expected to contribute \$3 billion in sales for 2010.

13. Bristol-Myers Squibb

| | 2009 | 2008 |
|-------------------------|------------------|-----------------|
| US sales* | \$8.9 billion | \$7.9 billion |
| Journal ad spending * * | \$3.0 million | \$4.3 million |
| Promotional spend * * | \$657.3 million | \$780.2 million |
| | . DI : (AC 11) D | . (64 41) 4 (|

Top products (global sales): Plavix (\$6.1b), Reyataz (\$1.4b), Avapro/Avalide (\$1.3b), Sustiva (\$1.3b), Baraclude (\$734m)

Bristol-Myers Squibb says its "BioPharma" transformation is complete, thanks to the 2009 acquisition of Medarex, which strengthened BMS's biologics capabilities, and shedding its holdings in baby formula unit Mead Johnson Nutritionals. Among marketed products, Onglyza, approved last summer, is off to a slow start, having posted \$4 million for the 4th quarter, while Abilify is on a tear. Sales are also up for Plavix, Reyataz, Sustiva and Sprycel. The company's pipeline includes five key experimental candidates: apixaban, belatacept, brivanib, dapaglifozin and ipilimumab. Several revenue streams will need to be replaced—through 2015, BMS stands to lose Plavix, Avapro, Abilify and Sustiva to generic competition.

14. Takeda Pharmaceuticals

| | 2009 | 2008 |
|-----------------------|-----------------|-----------------|
| US sales* | \$7.9 billion | \$7.9 billion |
| Journal ad spending** | \$9.7 million | \$9.0 million |
| Promotional spend * * | \$559.6 million | \$504.5 million |
| | | |

Top products (global sales): N/A

Takeda says it's focusing on its oncology business for future growth, seeking to leverage its acquisition of Millennium Pharmaceuticals in

| | | Total Prom | | | TC | | motional |
|------|---------------------------|--------------------|---------------------|--------------------|---------------------|--------------------|---------------------|
| Rank | Company | 2009 (Millions) | % change vs 2008 | 2009 (Millions) | % change vs 2008 | 2009 (Millions) | % change vs 2008 |
| L | Pfizer | \$2,612.61 | 4.4% | \$1,088.67 | 46.3% | \$57.72 | 78.9% |
| 2 | Merck & Co. | \$1,914.86 | -12.7% | \$458.01 | -11.3% | \$82.81 | -13.3% |
| 3 | GlaxoSmithKline | \$1,507.86 | -21.7% | \$309.95 | -46.5% | \$17.54 | -33.7% |
| 4 | AstraZeneca | \$1,389.70 | 22.0% | \$442.72 | 57.1% | \$19.73 | 65.9% |
| 5 | Eli Lilly | \$1,162.36 | -2.1% | \$370.37 | -13.7% | \$12.70 | -10.1% |
| 6 | Novartis | \$936.25 | -0.9% | \$119.55 | -17.9% | \$28.24 | 120.6% |
| 7 | Sanofi-Aventis | \$916.30 | -4.0% | \$178.03 | -15.7% | \$19.62 | 69.8% |
| 3 | Forest | \$762.73 | 18.3% | \$6.98 | 147.5% | \$7.18 | 47.8% |
| 9 | Abbott Labs | \$696.65 | 8.3% | \$149.40 | 23.2% | \$7.32 | 16.9% |
| LO | Johnson & Johnson | \$687.81 | -10.5% | \$88.86 | -19.0% | \$39.63 | -1.6% |
| l1 | Bristol-Myers Squibb | \$657.28 | -15.8% | \$276.42 | -36.1% | \$6.23 | 96.7% |
| 12 | Takeda | \$559.60 | 10.9% | \$2.86 | -83.8% | \$8.14 | -41.1% |
| 13 | Boehringer Ingelheim | \$534.41 | -16.4% | \$193.78 | -15.9% | \$7.86 | -69.3% |
| L4 | Nestle SA | \$371.16 | 37.3% | \$78.92 | 239.6% | \$10.23 | 7.2% |
| 15 | Shire | \$326.70 | 14.4% | \$85.10 | 16.7% | \$25.33 | 7.6% |
| 16 | Daiichi-Sankyo | \$300.75 | 8.2% | \$254.00 | N/A | \$2.67 | 70.0% |
| 17 | Bayer | \$294.80 | -4.1% | \$127.01 | -8.6% | \$4.29 | -44.2% |
| 18 | Allergan | \$291.66 | 22.4% | \$137.01 | 55.5% | \$2.56 | -9.6% |
| 19 | Dainippon Sumitomo Pharma | \$243.35 | -18.5% | \$55.15 | -51.1% | \$2.25 | -27.7% |
| 20 | Roche | \$239.61 | 14.2% | \$11.54 | -40.7% | \$7.56 | 26.8% |

| | | | no Spend | | ailing | Meet | | Jou | |
|------|----------------------------------|--------------------|---------------------|--------------------|---------------------|--------------------|---------------------|--------------------|---------------------|
| Rank | Company | 2009 (Millions) | % change vs 2008 |
| 1 | Pfizer | \$2,612.61 | 4.4% | \$1,222.91 | -15.0% | \$208.36 | -14.9% | \$34.95 | -16.0% |
| 2 | Merck & Co. | \$1,914.86 | -12.7% | \$1,138.57 | -12.9% | \$227.59 | -12.7% | \$7.88 | -42.0% |
| 3 | GlaxoSmithKline | \$1,507.86 | -21.7% | \$990.19 | -11.9% | \$186.91 | -2.7% | \$3.28 | -39.3% |
| 4 | AstraZeneca | \$1,389.70 | 22.0% | \$744.67 | 9.2% | \$177.15 | 17.4% | \$5.43 | -58.4% |
| 5 | Eli Lilly | \$1,162.36 | -2.1% | \$630.13 | 9.7% | \$135.98 | -6.9% | \$13.19 | -44.8% |
| 6 | Novartis | \$936.25 | -0.9% | \$624.05 | 8.8% | \$155.87 | -23.0% | \$8.54 | -18.0% |
| 7 | Sanofi-Aventis | \$916.30 | -4.0% | \$603.07 | 1.1% | \$111.05 | -13.6% | \$4.53 | -30.2% |
| 8 | Forest | \$762.73 | 18.3% | \$567.77 | 21.7% | \$153.71 | 7.7% | \$27.09 | -3.1% |
| 9 | Abbott Labs | \$696.65 | 8.3% | \$445.41 | 10.1% | \$92.00 | -12.5% | \$2.53 | -58.8% |
| 10 | Johnson & Johnson | \$687.81 | -10.5% | \$442.55 | -9.4% | \$102.95 | -9.5% | \$13.82 | -14.7% |
| 11 | Bristol-Myers Squibb | \$657.28 | -15.8% | \$314.31 | 11.4% | \$57.31 | -1.8% | \$3.00 | -30.3% |
| 12 | Takeda | \$559.60 | 10.9% | \$451.48 | 17.6% | \$87.47 | 9.0% | \$9.66 | 7.5% |
| 13 | Boehringer Ingelheim | \$534.41 | -16.4% | \$296.47 | -10.2% | \$34.83 | -27.6% | \$1.47 | -71.4% |
| 14 | Nestle SA | \$371.16 | 37.3% | \$231.28 | 15.3% | \$45.65 | 52.8% | \$5.07 | -27.9% |
| 15 | Shire | \$326.70 | 14.4% | \$151.73 | 11.6% | \$59.52 | 23.8% | \$5.02 | -2.2% |
| 16 | Daiichi-Sankyo | \$300.75 | 8.2% | \$217.43 | 17.2% | \$78.56 | -8.0% | \$1.84 | -67.0% |
| 17 | Bayer | \$294.80 | -4.1% | \$139.52 | 0.8% | \$20.63 | 8.2% | \$3.36 | 0.9% |
| 18 | Allergan | \$291.66 | 22.4% | \$118.43 | 2.1% | \$30.63 | 4.8% | \$3.03 | 43.0% |
| 19 | Dainippon Sumitomo Pharma | \$243.35 | -18.5% | \$160.97 | 13.0% | \$24.84 | -33.3% | \$0.14 | -95.2% |
| 20 | Roche | \$239.61 | 14.2% | \$167.22 | 22.1% | \$44.60 | 7.3% | \$8.69 | 48.1% |

2008. Generic exposure has weighed on profit. For the year ended March 31, net income decreased about 34%, despite an increase in sales for Actos and Velcade. The FDA also delayed experimental compound SYR-322. On the bright side, Takeda gained marketing approval for Kapidex and Uloric.

15. Boehringer Ingelheim

| 2009 | 2008 |
|-----------------|--------------------------------|
| \$7.6 billion | \$6.3 billion |
| \$1.5 million | \$5.1 million |
| \$534.4 million | \$639.5 million |
| | \$7.6 billion \$1.5 million |

Top products (global sales): N/A

Boehringer-Ingelheim is coming off a transition year. It cut about 800 sales jobs as part of a reorganization. Its biggest-selling product, lung drug Spiriva, which garners annual revenue of about \$3 billion, underwent an FDA safety review. The agency concluded that Spiriva wasn't associated with any problems. The FDA also approved expanded labeling for Spiriva in COPD treatment. Meanwhile, Flomax, a \$2 billion-a-year product, has begun to see generic competition in the US. Pradaxa could drive future growth.

16. Eisai Corp.

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$4.4 billion | \$3.9 billion |
| Journal ad spending ** | \$1.2 million | \$1.0 million |
| Promotional spend * * | \$62.7 million | \$59.5 million |

Top (global sales) products: N/A

With costs associated with Eisai Corp.'s 2008 takeover of MGI Pharma finally behind it, the No. 4 Japanese drugmaker by sales was targeting \$676 million in net profit and \$8.8 billion in sales for full year 2009. The Tokyo-based company is known for its Alzheimer's disease drug Aricept and heartburn drug Aciphex, co-marketed by Pfizer and Johnson & Johnson, respectively. Eisai kept its earnings projections unchanged for the full year. The next few years could be a choppy, though, with Aricept due to face generic competition in the US in November and elsewhere in 2013. Eisai has boosted total promotional spend ahead of this period.

17. Forest Labs

| | 2009 | 2008 |
|------------------------|-----------------|-----------------|
| US sales* | \$4.4 billion | \$4.0 billion |
| Journal ad spending ** | \$27.1 million | \$28.0 million |
| Promotional spend * * | \$762.3 million | \$644.7 million |

Top (global sales) products: Lexapro, Namenda, Bystolic, Savella (full-year 2009 sales figures unavailable at press time)

An FDA advisory committee voted against approving Forest Labs' Daxas (roflumilast) for the treatment of COPD. The committee members voted in favor of the drug's safety and efficacy, though. So Daxas may still be approved this year, perhaps as soon as this month, with use restricted to moderate-to-severe COPD patients. Analysts are keeping estimates conservative, with peak sales of \$100 million projected for the drug. Forest is also expecting a ramp up in sales for Savella (fibromyalgia) and Bystolic (hypertension), Phase III data for linaclotide (IBS-C) and approval for ceftaroline (infections) by year's end.

18. Mylan

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$4.1 billion | \$3.3 billion |
| Journal ad spending ** | \$3.4 million | \$1.0 million |
| Promotional spend * * | \$29.3 million | \$23.4 million |

Top (global sales) products: Fentanyl, EpiPen Auto-injector (full-year 2009 sales figures unavailable at press time)

Analysts believe Mylan is one of the most attractive names in generics, but whether it can successfully integrate the acquisition of Merck KGaA's generics business Dey Pharma and achieve 2010 sales and earnings targets are the big questions. The firm, which broke into the top-20 last year, derives earnings from a highly diversified base and has no notable, expected product-specific catalysts. Underappreciated, analysts say, are EpiPen market-expansion possibilities in the US and abroad. Dey markets EpiPen through its US sales force.

19. Otsuka

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$4.0 billion | \$3.0 billion |
| Journal ad spending ** | \$2.0 million | \$34,000 |
| Promotional spend * * | \$18.0 million | \$10.0 million |

Top products (global sales): Abilify (\$4.0b)

| Brand | Company | Indication | Expiry |
|--------------------|---------------|-------------------|--------|
| Merck & Co. | Cozaar/Hyzaar | hypertension | 2010 |
| Sanofi-Aventis | Taxotere | cancer | 2010 |
| Esai/Pfizer | Aricept | neurological | 2010 |
| Eli Lilly & Co. | Gemzar | cancer | 2010 |
| Pfizer | Lipitor | cholesterol | 2011 |
| Sanofi-Aventis/BMS | Plavix | anti-platelet | 2011 |
| AstraZeneca | Seroquel | bipolar | 2011 |
| Eli Lilly & Co. | Zyprexa | antipsychotic | 2011 |
| Takeda | Actos | diabetes | 2011 |
| Purdue | Oxycontin | pain | 2011 |
| Johnson & Johnson | Levaquin | infection | 2011 |
| Pfizer | Xalatan | glaucoma | 2011 |
| Novartis | Femara | cancer | 2011 |
| Eli Lilly & Co. | Alimta | cancer | 2011 |
| Merck & Co. | Singulair | asthma | 2012 |
| Amgen | Lunesta | sleep | 2012 |
| Forest Labs | Lexapro | depression | 2012 |
| Novartis | Zometa | cancer | 2012 |
| Novartis | Diovan | hypertension | 2012 |
| Pfizer | Viagra | erectile dysfctn. | 2012 |
| Wyeth | Premarin | menopause | 2012 |
| Warner Chilcott | Actonel | bone | 2013 |
| GlaxoSmithKline | Avandia | diabetes | 2013 |
| Genentech/GSK | Boniva | bone | 2013 |
| Eli Lilly & Co. | Evista | bone/cancer | 2013 |

Strong sales of schizophrenia drug Abilify, which Otsuka co-markets with Bristol-Myers Squibb in the US and some other markets, helped Otsuka land a spot in this year's top 20. Next up for is an IPO by its Japanese holding company, expected in the second half of the year and valued at about \$11 billion. That would put it roughly on par with Eisai and behind Takeda, Astellas and Daiichi Sankyo. Global sales were roughly \$10.6 billion in the past financial year.

20. Gilead Sciences

| | 2009 | 2008 |
|------------------------|----------------|----------------|
| US sales* | \$3.9 billion | \$3.1 billion |
| Journal ad spending ** | \$3.6 million | \$1.9 million |
| Promotional spend * * | \$64.0 million | \$40.8 million |
| | | |

Top products (global sales): Atripla (\$2.4b), Truvada (\$2.5b), Viread (\$668m), Hespera (\$272m), Emtriva (\$28m)

Sales in Gilead Sciences' antiviral franchise rose 25% last year. The revenue boost was accompanied by a hefty 57% hike in promotional spend. Marketing included DTC work for the Truvada HIV combo pill, as well as a disease awareness campaign around hepatitis B. (The firm markets Viread, as well as Hespera.) The HBV educational campaign included YouTube and Facebook components, as well as live events and media outreach. Among pipeline candidates is a Phase III "Quad" pill combining four drugs to treat HIV/AIDS, while in-line drug Letairis is in Phase III for IPF.

| Brand | Company | Indication | Approval |
|-----------|----------------------------|-----------------------|----------|
| Simponi | Centocor Ortho Biotech | rheumatology | April 24 |
| Dysport | lpsen | neurology | April 29 |
| llaris | Novartis | CAPS | June 17 |
| Stelara | Centocor Ortho Biotech | rheumatology | Sept. 25 |
| Arzerra | GlaxoSmithKline | cancer | Oct. 26 |
| Kalbitor | Dyax | hereditary angioedema | Nov. 27 |
| Savella | Cypress Bioscience | neurology | Jan. 14 |
| Uloric | Takeda | gout | Feb. 13 |
| Afinitor | Novartis | cancer | March 30 |
| Coartem | Novartis | malaria | April 7 |
| Ulsefia | Sciele Pharma | head lice | April 9 |
| Fanapt | Vanda Pharmaceuticals | antipsychotic | May 6 |
| Samsoa | Otsuka | hyponatremia | May 19 |
| Besivance | Bausch and Lomb | antibiotic | May 28 |
| Multaq | Sanofi-Aventis | antiarrhythmic | July 1 |
| Effient | Eli Lilly/Sankyo | anti-platelet | July 10 |
| Onglyza | Bristol-Myers Squibb | diabetes | July 31 |
| Livalo | Kowa | cholesterol | Aug. 3 |
| Saphris | Organon BioSciences | antipsychotic | Aug. 13 |
| Sabril | Lundbeck | anti-seizure | Aug. 21 |
| Bepreve | ISTA Pharmaceuticals | antiallergic | Sept. 4 |
| Vibativ | Theravance | cSSSI | Sept. 11 |
| Folotyn | Allos Therapeutics | cancer | Sept. 24 |
| Votrient | GlaxoSmithKline | cancer | Oct. 19 |
| Istodax | Gloucester Pharmaceuticals | cancer | Nov. 5 |