

► Blockbuster model breaking down

Pharma industry reaches new sales peak, despite rising costs and bigger challenges for drug R&D.

BY ANN M. THAYER

Industry consultants generally are positive about pharmaceutical industry sales growth. However, their optimism is tempered by concerns about the industry's ability to innovate and bring new products to the market. They cite rising R&D costs, thin pipelines, generic competition, and increasing regulatory and pricing pressures among the major challenges drug developers face. As a result, if companies don't soon make changes, growth will continue, but at a much slower rate than in the past decade.

Latin American market turned around after a decline in 2002.

The top 10 therapy classes accounted for a combined 30% of the world market, IMS reports. For the first time in more than 14 years, cholesterol reducers became the biggest category, edging out antiulcerants.

Many shifts in the market are attributable to the loss of patent protection and generics emerging. Still, despite substantial growth, generic products have remained at about 4–5% of total pharmaceutical sales,

Lewis says. And some companies are putting up a good fight. For example, sales of AstraZeneca's antiulcerant Nexium grew a record 62% and attained the number 7 drug spot in 2003, beating out competition from its first-generation product, Prilosec, now available in generic form.

Sales of many other products, including several new ones, grew at substantial double-digit rates despite more intensive competition in their respective classes,

according to IMS Health. "It's also significant that the number of blockbusters continues to grow, with 64 products having over \$1 billion in sales in 2003, and 23 of those over \$2 billion," Lewis says.

But many industry observers are not bullish about larger pharmaceutical and biotech companies relying on blockbusters. Companies following this business model will find it "increasingly difficult to ensure growth in terms of profitability, as there are only a limited number of products in their pipelines," says Ashwin Singhania, an associate with Navigant Consulting (www.navigantconsulting.com).

Although demand is growing, large phar-

maceutical companies are struggling to expand their business, the consulting firm reports, with the leading players posting much slower increases in earnings per share and net income in recent years. The Navigant consultants offer strategies to overcome this growth paradox in the Front Line Strategic Market Report *The Changing Pharmaceutical Market: Strategies for Profitable Growth in a Maturing Market*.

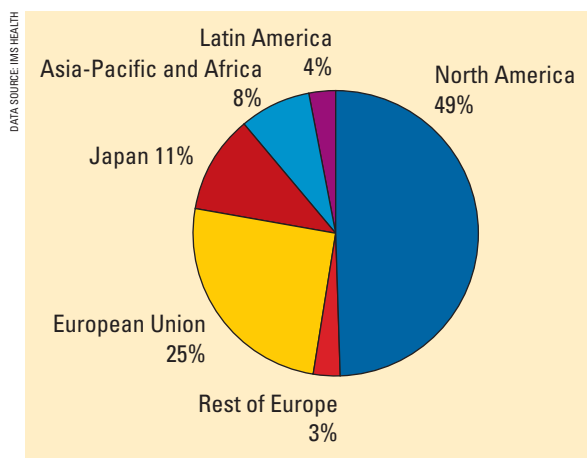
Companies should seek to develop more innovative products, they suggest, even if potential sales are lower than what is customary. The analysts see expansion opportunities in biotech products and targeted therapeutics. However, a better approach will require investing time and money to promote innovation, along with the need to lower costs across all operations and maximize revenues from existing products.

Bain & Company (www.bain.com) is similarly downbeat on the industry's blockbuster attitude in a recent report. The consulting firm anticipates demise from a "heftier-than-thought commercialization price tag" for companies sticking with this path. Factoring in failed drug candidates, it calculates the cost for discovering, developing, and launching a single new drug at nearly \$1.7 billion, a 55% increase over the average cost between 1995 and 2000.

On the basis of recent investment levels, success rates, and forecasts of commercial performance, Bain expects the current blockbuster drug model to deliver just a 5% return on investment. This return is "significantly lower than the industry's risk-adjusted cost of capital," the Bain report says. "This suggests that only one out of six new drug prospects will likely deliver returns above their cost of capital, an unattractive prospect for investors."

However, even with these warning signs and shifting market values, few major pharmaceutical firms are abandoning the blockbuster model. "The pharmaceutical industry is a prisoner of past successes," says Ashish Singh, director of Bain's global health care practice and an author of its study. "Most executives are still in a state of denial."

What the industry needs to replace the



North America is the leading pharmaceutical market. Total global sales for 2003, \$466.3 billion.

IMS Health (www.imshealth.com) reports that the global drug industry posted sales of \$466.3 billion in 2003, up 9% from 2002. The market research firm tracks about 90% of all prescription sales in 80 countries.

"The global pharmaceutical industry continued to grow at a solid pace in 2003, despite difficult economic conditions and continued pressure on the sector from regulators, the media, and payors," says Graham Lewis, IMS vice president for strategic consulting. European countries outside the EU saw the highest growth rate, at 14%, followed by Africa and the Asia-Pacific region (excluding Japan) at 12%. The North American market grew 11%, while the

old strategy, the Bain report suggests, “is a new, integrated model that effectively brings together planned experimentation, aggressive use of partnerships, and eventually, a far-reaching transformation in the way most pharmaceutical companies organize to compete.” This model might help overcome several factors: rising commercialization costs, declining R&D productivity, increasing payor influence, and shorter periods for exclusive sales because of me-too and generic products.

Bain offer four building blocks that companies can tailor and experiment with to construct competitive new businesses. These elements include focusing on prior experience rather than lucky breaks, using partnerships to balance risk and return, developing a customer-driven approach, and creating integrated operations rather than those along functional lines.

Meanwhile, IBM’s business consultants (www.ibm.com/services) see scientific and technological advances as a way out of the doldrums. They, too, point to existing problems of falling R&D productivity and intense competition. In the three years to 2001, at least 28 products with combined potential peak sales of more than \$20 billion were halted in late-stage development, they report. And they see only 14 potential billion-dollar blockbusters in the pipeline between 2003 and 2008.

But the IBM consultants anticipate com-

panies will have learned by 2010 how to make “targeted treatment solutions,” combining diagnostic tests, drugs, and monitoring devices, as well as patient support services. These solutions, IBM says in its *Pharma 2010: The Threshold of Innovation* report, “will deliver bigger shareholder returns than ever before.”

“Even if the market for targeted treatment solutions is slow to get started, companies that learn how to make such medicines could triple their shareholder value by 2010,” the consultants predict. “If the market for such medicines takes off more rapidly, they could enjoy almost double the growth the industry enjoyed in its heyday.”

But companies will need to transform the way in which they discover, develop, market, and manufacture new drugs, IBM adds, by focusing on the molecular level. Collective changes in the understanding of disease, medicines based on biology rather than chemistry, better drug modeling, and improvements in clinical trials will “blur the boundaries between discovery, development, and the marketplace—creating a fully integrated model,” the consultants explain.

These changes will “massively reduce the time and cost of making new drugs,” they believe. “In 2010, the discovery and development process will take half as long as it does now, and costs per drug will fall to a quarter of the current average.” This means

Pfizer’s Lipitor is the leading drug product

Product	Company	2003 sales (\$ billion)	% growth from 2002
Lipitor	Pfizer	10.3	14
Zocor	Merck	6.1	-4
Zyprexa	Eli Lilly	4.8	13
Norvasc	Pfizer	4.5	7
Epex/Procrit	Johnson & Johnson	4.0	13
Ogastro/Prevacid	Abbott Laboratories	4.0	0
Nexium	AstraZeneca	3.8	62
Plavix	Bristol-Myers Squibb/ Sanofi-Synthelabo	3.7	40
Seretide/Advair	GlaxoSmithKline	3.7	40
Zoloft	Pfizer	3.4	11
Total worldwide sales, 2003		48.3	14

Source: IMS Health.

being able to move from target identification to drug launch in about 3–5 years, increasing success rates from first human dose to market by a factor of 4, and slashing the average cost per drug to as little as \$200 million.

But industry is not yet on this new course, the IBM and other consultants agree. A dramatic gap between spending on technology and its return in the form of new drug entities still exists. Researchers are not yet seeing advances in science and technology translate into a better, and fully integrated, understanding of the body and disease, and, in turn, reduced R&D costs.

Many companies may find it hard to make the necessary transition. “Companies that fail to respond to the market conditions which are now emerging—and those that are currently most successful may well be those that most resist making the necessary changes—will see their value continue to plummet,” the IBM consultants say. “But even those that are most effective in maximizing revenues from traditional products will not be able to generate sufficient growth.”

“It is only by entering totally new terrain that pharma companies can hope to produce the truly innovative medicines for which people will readily pay,” they conclude. Regardless of what happens over the next several years before reaching 2010, they stress that “pharma cannot stand still.” ■

Cholesterol reducers are the leading drug class

Drug category	2003 sales (\$ billion)	% growth from 2002
Cholesterol/triglyceride reducers	26.1	14
Antiulcerants	24.3	9
Antidepressants	19.5	10
Anti-inflammatories (nonsteroidals)	12.4	6
Antipsychotics	12.2	20
Calcium antagonists	10.8	2
Erythropoietins	10.1	16
Antiepileptics	9.4	22
Oral antidiabetics	9.0	10
Cephalosporins	8.3	3
Total worldwide sales, 2003	142.1	11

Source: IMS Health.