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...ronics and Depression's Happy Face

Seven years ago, industry observers believed neurostimulation pioneer Cyberonics was all but dead, with an interesting technology and little else. Now, it's targeting a billion-dollar depression opportunity while trying to fend off would-be acquirers.

Schering-Plough: What Went Wrong, What to Do

CEO Fred Hassan faults decentralization and financial over-management for much of Schering's trouble. Reviving Schering through cost cuts will be impossible, Hassan believes. Instead, he's investing.

Keeping Leadership Real: An Interview with Bill George

The former head of Medtronic, the recipient of the Lifetime Achievement award at this year's Phoenix Medical Device and Diagnostic Conference for CEOs, talks about negotiating with Dennis Kozlowski and other ethical challenges confronting corporate leaders today.

Watson's Strategy for Beating the Big Boys

Watson's launch of incontinence drug *Oxytrol* illustrates the opportunities and challenges specialty pharmas face when they try to move into primary care markets, dominated by Big Pharma.

Why Not Europe?

US biotech firms are increasingly deciding not to market on their own in Europe—figuring risk and cost outweigh potential upside.

Rebuilding Big Pharma's Business Model

The blockbuster business model that underpinned Big Pharma's success is now irreparably broken. The industry needs a new approach: the authors say companies should consider a combination of focus, partnerships, customer-oriented solutions, and a business unit-based organizational model.

FDA & Devices: Who's at Fault? • The Antibody Beat Goes On

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THE BUSINESS & MEDICINE REPORT
10 Hoyt Street, Norwalk, CT 06851
(203) 838-4401
40 High St. Wimbledon, London SW19 5AU, UK
+44 (0)20 8879 4000
windhover.com

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FEATURES

COLUMNS

Pharmaceutical Strategy

Rebuilding Big Pharma's Business Model

The blockbuster business model that underpinned Big Pharma's success is now irreparably broken. The industry needs a new approach.

By Jim Gilbert, Preston Henske and Ashish Singh

- While the business climate for pharma companies has changed dramatically in the past five years, the pharma business model has not kept pace.
- Declining R&D productivity, rising costs of commercialization, increasing payor influence and shorter exclusivity periods have driven up the average cost per successful launch to $1.7 billion and reduced average expected returns on new investment to the unsustainable level of 5%.
- Mergers conceived to build scale will not improve returns. Pharmaceutical companies need new business models to restore healthy financial results.
- Four inter-related building blocks can provide the new foundation: focusing R&D efforts and commercial capabilities; making use of product and capability partnerships; providing customer solutions (not just "therapeutics"), and creating a business unit based organization model instead of a functional one. Companies need to find a combination of these building blocks that makes best use of their strengths, improves returns and manages risk.
- Breaking out of the blockbuster mentality — the quest for larger and larger opportunities in whatever disease areas they may occur—will require planned experimentation, aggressive use of partnerships, and eventually a far-reaching transformation in the way most pharma companies organize to compete.

The pharmaceutical industry is a prisoner of its past successes. While the business environment for pharma companies has changed dramatically in the past five years, the pharma business model that served the industry well over the past decades has not kept pace.

This is hardly news to many pharma executives, a surprising number of whom doubt the viability of the blockbuster model. But they can't force their companies free from the massive investments in science, selling capability, plants, and organization that used to yield the rare lottery-winner drug. Nor can they dissuade drug industry leaders who believe that incremental changes to the blockbuster approach (alone or with an acquisition) will rekindle the old sparks and restore historic returns, at least for a while.

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But these strategies will at best only delay the inevitable. Based on recent investment levels, success rates, and forecasts of commercial performance, we expect the blockbuster drug model to deliver just 5% return on investment — significantly lower than the industry's risk-adjusted cost of capital. Only one out of six new drug prospects will likely deliver returns above their cost of capital, an unattractive prospect for investors.

For all but the three largest firms—**Pfizer Inc.**, **GlaxoSmithKline PLC** and **Merck & Co. Inc.** —the choice is relatively stark: with fewer resources to drive primary care products and to invest in the "arms race" in R&D and sales & marketing, they will likely be driven sooner to replace their blockbuster-based strategies. Market value is shifting already to some smaller players that have adopted new models, as companies like **Novo Nordisk AS**, **Genentech Inc.** and **Forest Laboratories Inc.** have demonstrated.

In some respects, the three industry heavyweights face an even more perilous situation. Highly profitable legacy product portfolios, coupled with inflated expectations about pipelines and future business development, have held back executives from developing new business models. With scale where it matters—in the develop-

CONTINUED ON NEXT PAGE

ment and commercialization of new drugs—they can afford to draw out the transition. As second-tier players restructure away from having large primary care sales forces, for instance, each of the largest pharma companies may position themselves as the primary care commercialization partner of choice, providing reach and frequency to smaller companies.

But it can't last. The prevailing model—a fully integrated pharma company that participates everywhere it gets a chance—won't deliver sustainable growth. And because the long cycles of science tend to hide costs and divorce accountability from action, many pharma executives have been slow to respond. With time to plan, they need to begin revamping their business models now.

We believe that four inter-related building blocks will define the next stage. First, companies must shift drug development strategies and commercial capabilities from being *opportunistic*—pushing a broad array of compounds on the premise that every chance is worth exploring—to being *focused* on the most promising areas of science and most attractive target customers. Second, they will transition from *fully integrated* pharma companies to greater reliance on *partnerships* to manage risk and return, across both product pipelines and functions. Third, they will gradually change their emphasis from science-driven *therapeutics* to *customer solutions* with the drug at the center. And fourth, they will replace *functional* organization models with *business units* that encourage more integrated decision-making, coupled with direct accountability for the consequences of those decisions.

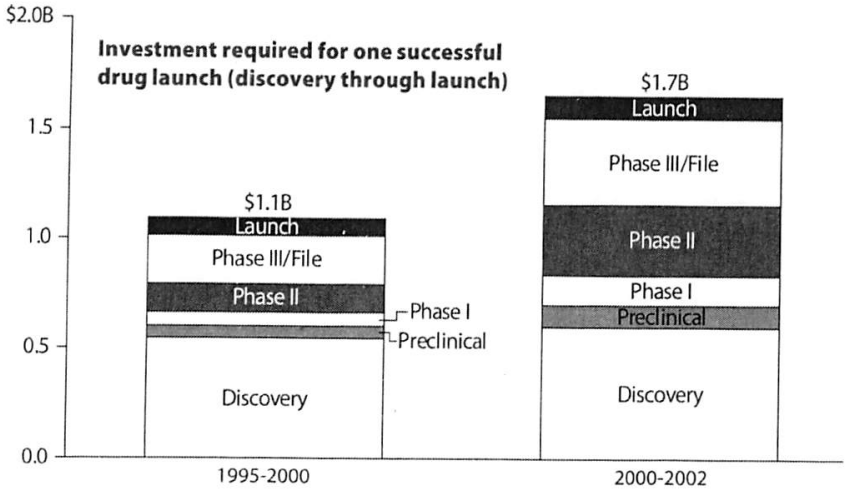
The Blockbuster Model Is Broken

Unlike most industries where a handful of winning strategic models often prevail side by side, the pharmaceutical industry majors have all converged over the last decade on one strategic model. The approach focuses the majority of a company's investment on creating blockbuster product franchises—that is, brands that achieve global sales of more than $1 billion. Over the last decade this model has created more than $1 trillion of shareholder value for Big Pharma.

The factors driving down returns from the blockbuster model to 5% are well known: declining R&D, rising costs of commercialization, increasing payor influence and shorter exclusivity periods. When the costs of failed prospective drugs are factored in, the price tag for discovering, developing and launching a single new drug has risen by 55% over the last five years to nearly $1.7 billion. *(See Exhibit 1.)* This increase results from a drop in cumulative success rates from 14% to 8% and an increase in research, development and launch costs of nearly 50% for each of these steps. *(See sidebar, "The Rising Cost of New Drugs.")*

Investment Escalation per Successful Compound

EXHIBIT 1



Avg ROI %	9%	5%
Probability of reaching 12% ROI	30%	15%

SOURCE: Bain drug economics model, 2003

Blockbusters aren't going away. Big-franchise compounds will continue to be an important source of profits for the industry. But how they are made will change significantly. Primary care blockbusters of me-too compounds will be increasingly difficult to bring to market profitably, as a result of the hard economic logic spelled out above and increasing outcomes-based reimbursement. Currently, almost 50% of blockbusters are next-in-class compounds that don't provide highly differentiated therapeutic value, and the percentage is higher for the largest companies. But a new generation of blockbusters, driven by innovation, is likely to emerge from a more specialized business model, and these billion-dollar drugs will continue to be a driving force for growth.

Big Pharma has argued,

if not fully believed, that "bigger is better," and that scale alone would address declining returns from the blockbuster model. The belief stems from sound principles. Scale helps companies to diversify the risk of uncertain investments in discovery and development. In addition, large global commercial operations can boost a company's power to launch new products and expand its in-licensing capacity. Companies also expected that scale would help them exploit next generation technologies such as genomics, spreading their investments in these high-cost operations over a larger set of discovery programs.

Scale will continue to be a source of competitive advantage in development and commercialization for some time to come. But it has not delivered the full range of promised benefits. Size does not correlate with superior performance: Among the top 20 pharma companies, the largest firms perform no better than the smaller companies. Moreover, active acquirers have posted the same performance as non-acquirers, with each group achieving 12% appreciation in market capitalization since 1992.

Consolidation will likely continue, particularly among the largest pharma firms. But the mergers cannot be justified by any real benefits of scale. Rather, they result from the need to bridge near-term profit growth gaps by acquiring another company's product portfolio and wringing out cost synergies. Unfortunately, scale cannot fix the underlying reasons for the breakdown of the blockbuster model.

Behind Pharma's Unwillingness to Change

If the blockbuster model is so thoroughly broken, why are some companies still planning their futures around it? Three factors appear to cloud the industry's picture.

To begin with, the pharmaceutical industry's long investment cycle tends to hide real performance at any point in time. For pharmaceutical companies, current performance depends largely on historic productivity and decision-making, so it takes time to understand and to feel the consequences of strategic actions.

As long investment cycles obscure understanding, so too does the industry's standard practice of expensing rather than capitalizing R&D expenditure. Many companies see expensing R&D as the more conservative, straightforward approach to the P&L; capitalizing R&D would serve to unfairly improve operating profitability. But during periods of rising R&D investment, expensing R&D obscures a more important measure—return on invested capital. If the majors capitalized their R&D expense, their ROI would decline from 25% to 18%. Sometime soon, investors will start demanding a more transparent measure of returns on investment in R&D.

Blockbusters themselves skew the way pharma companies measure their productivity and profitability. While the average drug is expected to deliver only 5% return on investment, a successful blockbuster can yield returns 10-20 times as large. Rather than conclude that the blockbuster model needs fixing, many companies have decided that the only way to cover higher costs and satisfy the imperative to grow is to pursue ever-larger blockbuster drugs.

But companies cannot generate blockbusters fast enough to support sustained growth with healthy returns. Given the current economics of drug development, Big Pharma would need to invest twice as much as it does today to sustain double-digit revenue growth. Instead, Big Pharma is curbing R&D expenditure to cope with near-term performance pressures. In truth, many companies are living on borrowed time until their blockbuster patents run out. In-licensed drugs can buy time, but with the costs of in-licensing rising quickly and the returns from such compounds falling, this approach is unlikely to create much shareholder value.

Finally, experience with PBMs and disease management in the 1990s creates a natural reluctance to lead the creation of a fundamentally new business model. Although these service approaches did not provide the expected benefits, they contain some useful lessons. The investments were more productive, for instance, when companies either took a more focused approach, such as **Schering-Plough Corp.** did with disease management, or made early aggressive moves as Merck did with **Medco Health Solutions**. While **Eli Lilly & Co.** and SmithKline Beecham (since merged into GlaxoSmithKline) experienced large PBM investment losses, Merck preserved the value of Medco, and gained at least some market share for its pharmaceutical business.

Building Blocks

The drug business isn't the first industry to face a radical—and ugly—transition when the old model shows diminishing returns. The shift is usually characterized by prolonged doubt and sharp debate about the next model, along with significant shifts in capital markets investment and stock valuations. The steel industry in the 1970s, retailers in the 1980s and personal computer makers in the 1990s all experienced this form of turbulence.

Big Pharma won't abandon its old model easily. The blockbuster model has served the pharmaceutical industry well, generating over 13% annual growth in market capitalization between 1992 and 2002. What's more, pharmaceutical companies have built a large infrastructure around the blockbuster model, including 80,000 sales representatives in the US alone, trained and paid to focus on the one or two breakout products in a company's portfolio. Organizations of that scale carry considerable inertia, as US Steel, Sears and IBM all discovered.

Despite this inertia, the laws of risk and return still apply. Big Pharma will need to experiment in order to create a new model, managing the inherent risks through a sound strategy and a thoughtful approach to execution.

No one-size-fits-all solution is likely to emerge. Instead, companies will probably craft a tailored model constructed from four inter-related building blocks. Today, niche companies are using each of these blocks to compete successfully among the giants of the industry.

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