

Rising to the Productivity Challenge

A Strategic Framework for Biopharma



The world is entering a new age of anxiety, and so too is the biopharmaceutical industry—not because the future necessarily looks bleak but simply because the future has become so difficult to read. R&D has grown dizzyingly complex as the genomics revolution reconfigures the pipeline, patient groups fragment, and collaborations replace solo corporate efforts, to name just some of the changes. Traditional categories dissolve, and old paradigms turn paradoxical. How are we to make sense of it all?

In the face of such complexity, there are two tempting reactions: one, to utter prophecies of doom; the other, to shrug it all off and continue with business as usual. Neither reaction is appropriate. The better response is to confront reality squarely and respond flexibly to your findings.

This publication is the first in a series of reports dealing with the vexing question of productivity in biopharma R&D. It provides an overview of the drivers of productivity and of the possible remedies for today's productivity

malaise. The organizing framework is a model of the inputs and outputs of R&D. There are five major sites for intervention in this model: front-end innovation, external sources, the R&D engine, the political and regulatory environment, and people, team, and culture. Published simultaneously are the first two follow-up reports, which explore aspects of the sites for intervention in greater depth. These first two reports offer a review of governance techniques and a guide to traversing the licensing landscape.

Upcoming reports will explore other strands of the overall strategy—strands that companies should already be weaving into their planning in order to navigate the future.

*Philippe Guy
Senior Vice President and Director
Worldwide Leader of the Health Care Practice*

Productivity Crisis or Crying Wolf?

Well, Everyone Says There's a Productivity Crisis. Open a business newspaper, glance through the trade rags, eavesdrop on industry pundits—it seems that everyone is saying that biopharma productivity is in decline. The pessimism has sunk so deep, it's starting to sound like the early 1990s again.

Back then the talk was of an industry under threat. If no dramatic increase in productivity was forthcoming (in this case, measured by the number of drug approvals per dollar spent on R&D), the industry was in trouble. Disappointed investors would bail out, and share values would decline precipitously. Some industry executives spoke out boldly about their fears. Jürgen Drews, for example, then head of R&D at Hoffman-La Roche and something of a spokesperson for the R&D community, warned in 1993 that unless R&D productivity improved, money could be more profitably invested elsewhere.¹ To validate his hypothesis, in 1995 and 1996 Drews analyzed productivity at the top 50 pharmaceutical companies, scrutinizing the number of their preclinical compounds and predicting that without a substantial increase in drug output, companies would fall far short of market expectations.² At about the same time, the CEO of SmithKline Beecham, Jan Leschly, joined the fray, exhorting companies—including his own—to double productivity at a minimum.

So what did happen? The quantity of drug approvals did not increase. And it did not increase despite ever increasing investment in R&D.

So how did the industry perform? The answer is spectacularly well. Revenues grew at a rapid clip, and valuations outstripped the major market indexes.

Judging productivity in terms of the number of drugs produced can be substantially inaccurate.

What are we to make of this paradox? And what can the experience tell us about where growth is headed now? Is there a productivity crisis today or is it just a case of crying wolf?

What Has Driven Growth up to Now? In 1628 the king of Sweden, Gustavus Adolphus of the House of Vasa, rejoiced as the finishing touches were placed on the new flagship of his fleet, the *Vasa*. It was perhaps the most magnificent ship in the world, boasting a capacious cabin, 64 guns, and a crew of 150. As it set sail for the first time, a slight breeze sprang up, and the ship heeled to port. Water poured in through the lower gun ports. The ship listed further. It sank before it ever left the harbor. At least 30 men died, and the king was not pleased.³

Had the shipbuilders made a scale model of the vessel, they

would easily have established how unstable the design was: the two heavy gun decks, the masts and riggings, and the large cabin were simply too much for the narrow hull. The *Vasa* disaster had one positive effect. It taught the next generation of shipbuilders the value of modeling their designs.

The lesson of the *Vasa* still holds good, for biopharma analysts as much as for shipbuilders. By modeling industry trends and understanding what drove growth in the past, we can resolve the paradox, gain a deeper understanding of growth and productivity, and keep our predictions on an even keel.

Let's begin by asking what exactly is meant by "R&D productivity." Many people measure productivity in terms of *number* of drugs produced per dollar invested. A more accurate measure would be *value* of drugs per dollar invested. According to this approach, producing two drugs with annual sales of \$500 million each is no better than producing only one drug with annual sales of \$1 billion.⁴ As Exhibit 1 shows, measuring productivity just in terms of the number of drugs produced can be substantially inaccurate.

If you analyze revenue growth over the past decade or so, you find that it is due entirely to blockbusters—drugs with peak sales of at least \$500 million a year. (See Exhibit 2.) Theoretically, this growth could have come from either more blockbusters or more revenue

per blockbuster (through faster launches, higher peak sales, longer patent life, or slower post-patent sales erosion). It turns out that 80 percent of the growth was due to the increase in the number of blockbusters, with 20 percent due to an increase in revenue per blockbuster, principally through faster launches. As for peak sales and patent life, the averages here remained essentially unchanged; and as for post-patent sales, they actually eroded faster rather than slower (though

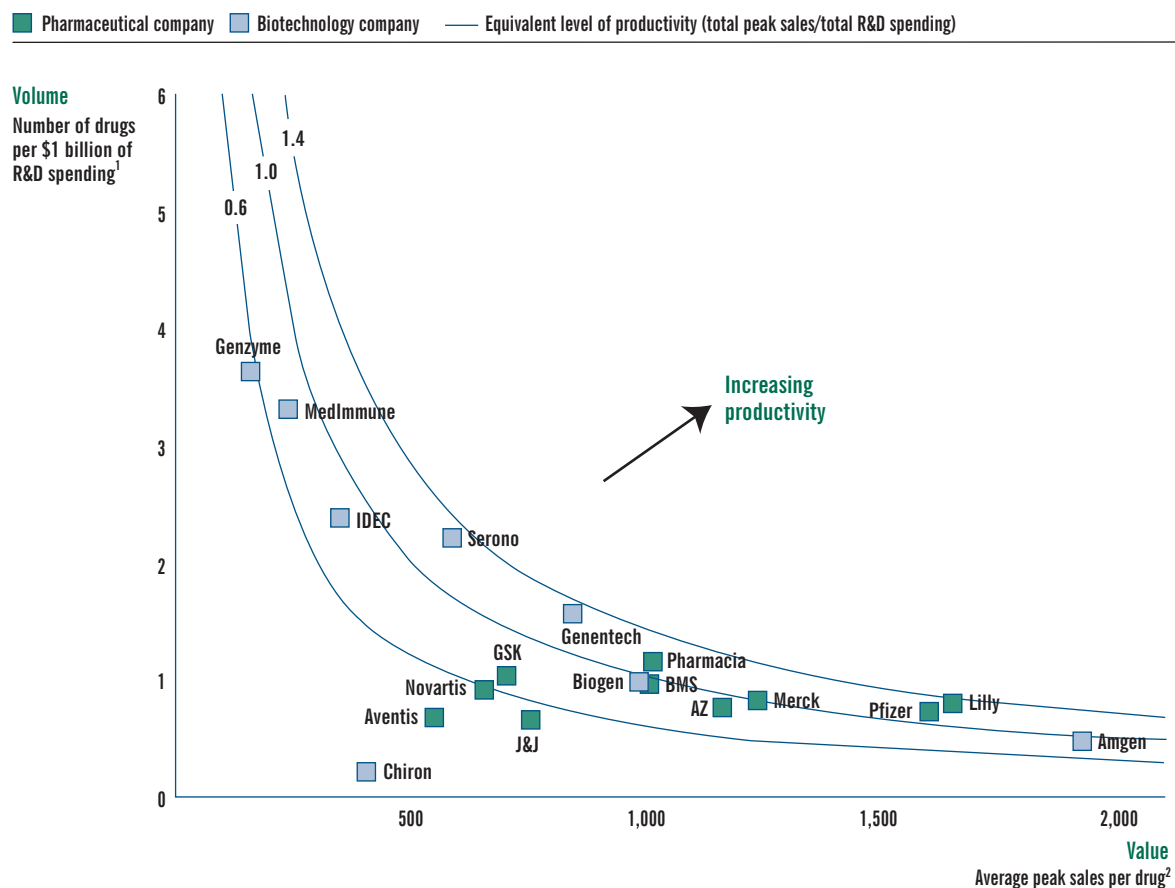
this setback had minimal effect on revenues relative to other factors).

The crucial finding is that most revenue growth came from an increase in the number of blockbusters—and that is the basis for gauging how revenue will grow from now on. The increase in the number of blockbusters for the ten biggest pharmaceutical companies was due to a one-time surge in the rate of blockbuster launches—up from five or fewer

per year in the 1980s to about eight per year in the 1990s. (See Exhibit 3.) The rate of patent expirations, which lag launches by about 12 years on average, did not increase during the 1990s. Hence the stock of blockbusters increased throughout the decade, despite no further increase in the rate of new launches. Only now, in a waltz linked across the span of more than a decade, is the rate of patent expirations catching up, but it is doing so inexorably. For

EXHIBIT 1

PRODUCTIVITY DEPENDS NOT JUST ON THE NUMBER OF DRUGS PRODUCED BUT ALSO ON THEIR VALUE



SOURCES: Annual reports; Lehman Brothers; BCG analysis.

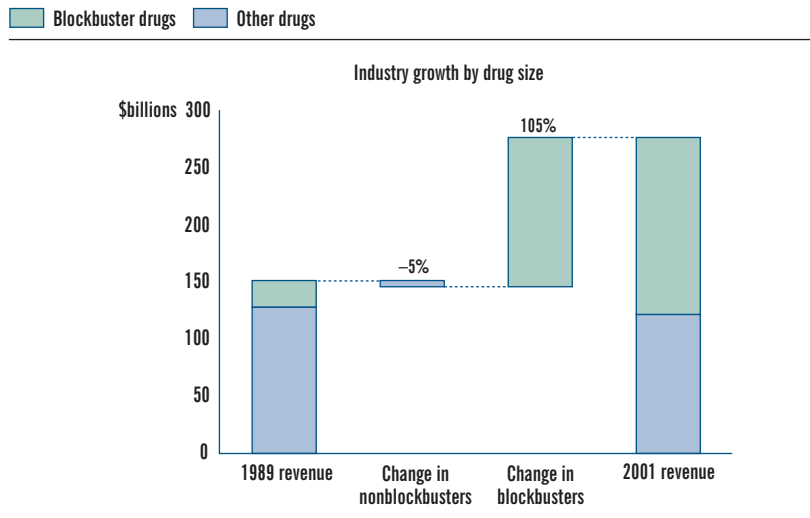
NOTE: Companies are shown as of 2001, prior to subsequent mergers and acquisitions.

¹Output from 1994 to 2004 per \$1 billion (in constant 2001 dollars) spent on R&D from 1991 to 2001; data used for 2002–2004 are risk-adjusted projections.

²Average peak sales of all drugs launched from 1994 to 2004; data used for 2002–2004 are risk-adjusted projections.

EXHIBIT 2

BLOCKBUSTER DRUGS DROVE INDUSTRY GROWTH



SOURCES: Evaluate Pharma; Scrip; IMS Health; BCG analysis.

NOTE: Blockbusters are defined as drugs with peak sales of at least \$500 million in constant 2001 dollars. Figures are adjusted for inflation using U.S. GDP deflators. Only branded products, which accounted for 74 percent of growth, were included in our analysis.

this reason, the increasing stock of blockbusters, which drove growth in the 1990s, is set to level off in the current decade.

The old bathtub analogy provides a handy image here. In 1990 the top ten pharmaceutical companies opened the faucet (launches) somewhat, without correspondingly adjusting the drainage (patent expirations). The water level (the stock of blockbusters—and hence revenues) duly rose. But now the drain is opening wider, and the tub will fill no further. The stock of blockbusters is approaching equilibrium.

Where Is Growth Heading? What does this imply for growth? Well, let’s suppose that no major changes occur in the current key parameters: output of new blockbusters, peak sales per blockbuster, patent life, sales of out-of-

patent drugs, and revenues from smaller drugs.⁵ And let’s also suppose that there are no further improvements in drug launches (and, at about six years to peak, there is limited room to improve). Under these circumstances, revenue growth will tail off sharply in the next few years, to the low single digits.

Perhaps Drews and Leschly were right about the outcome, then, but wrong on their timing. If these unhelpful conditions continue, and no changes happen elsewhere to offset them, growth will inevitably slow.

Of course, changes *are* happening elsewhere. New technologies, notably genomics, are certainly making an impact on Discovery, as confirmed by our conversations with many biopharma CEOs and R&D leaders. Although the press occasionally characterizes

these technologies as failures,⁶ many companies are now dealing with a cornucopia of drug candidates entering preclinical and clinical stages. Companies as diverse as GlaxoSmithKline, Amgen, and Wyeth have discussed these riches openly.⁷ Many others have quietly told us how abundantly their early-stage pipeline is flowing.

Still, genomics on its own is hardly going to resolve the immediate productivity crisis. Bear in mind how long it takes to develop and market a drug. As we noted in our 2001 report, *A Revolution in R&D: How Genomics and Genetics Are Transforming the Biopharmaceutical Industry*, the gains made in Discovery will take years to translate into revenues.⁸ In the meantime, there is a short-term productivity gap to come to terms with.

A further consideration: the bounty in the early-stage pipeline will not automatically translate into value achieved. It will take a very deft balancing act by R&D managers to keep the pipeline regulated and to prevent bottlenecks from jeopardizing the progression of compounds at pre-clinical and other key stages.⁹ And with so many candidates moving through the pipeline, managers will need not only to modulate their quantity but also to monitor their quality. Finally, managers will have to balance the wish to navigate a short-term course of action, while pipelines are thin, with the need to devise a longer-term strategy based on the discoveries coming out of Research.

In an industry where R&D managers typically inherit the course plotted by their predecessors, the current generation is finding the tides unobliging and the old charts somewhat vague. Still, the temptation will be to make only minor adjustments rather than to undertake a thorough remapping and rerouting—to favor short-term fixes over sustained early-stage investment, in other words—and to leave the routes and charts in essentially the same condition for the next generation. Companies that give in to this temptation will in the long run fare less well than their farsighted competitors, but the farsighted will need to keep

their nerve if their short-term performance declines in the meantime.

The Crisis Is Affected, for Better or Worse, by Increasing Complexity in the Industry. While growth is slowing dramatically, the industry is at the same time becoming more complex—compounding the difficulty of decision making but offering new opportunities, too.

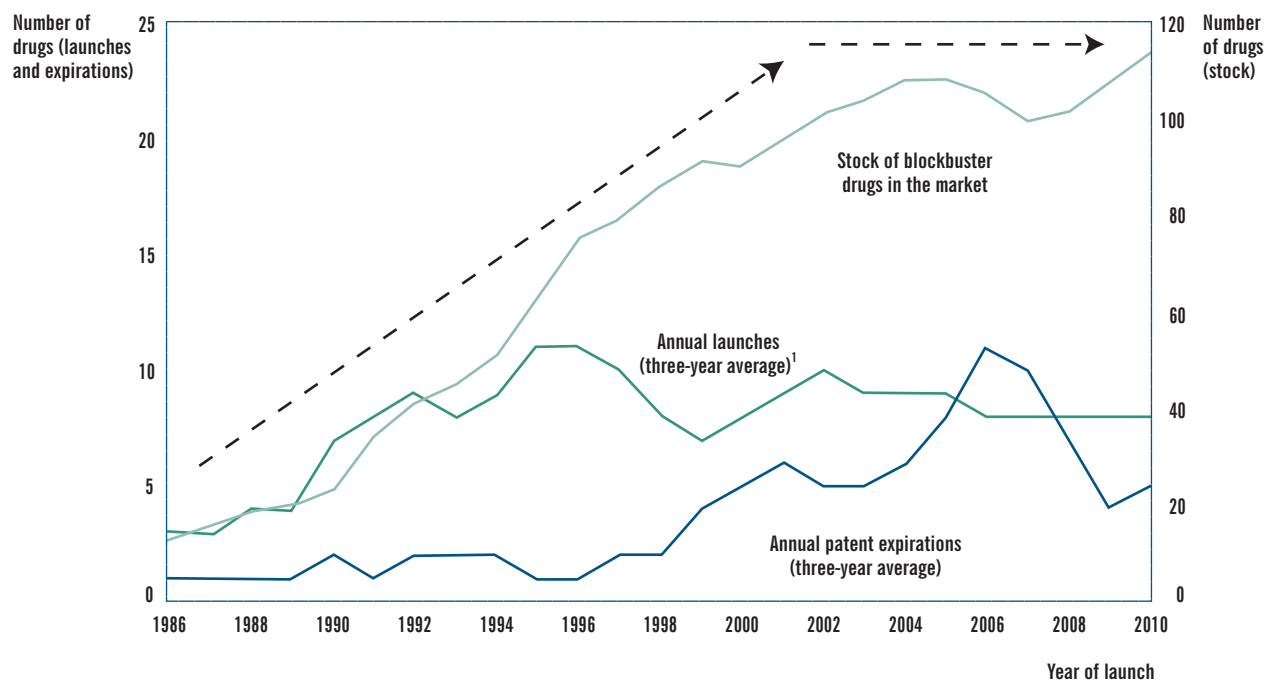
First, big pharma is getting increasingly bigger. The top five R&D budgets now average nearly \$5 billion—a fivefold increase in the past decade. Such scale brings economies, of course, but also complications. Scale makes

portfolio decisions trickier, as R&D managers can no longer command the detailed knowledge they would like to have about all of the company's projects. Scale can make collaboration and governance cumbersome. And scale militates against the intimate kind of dialogue and partnering enjoyed by academia and small biotechs, and thereby hinders parts of the value chain that are highly insight-driven, such as medicinal chemistry in Discovery or protocol design in Development.

Second, the monolithic patient group is disintegrating, as patient stratification becomes increas-

EXHIBIT 3
THE NUMBER OF BLOCKBUSTERS IS APPROACHING EQUILIBRIUM

Stock, Launches, and Expirations of Blockbusters at the Top Ten Pharmaceutical Companies



SOURCES: FDA; Lehman Brothers; Paine Webber; Scrip; BCG analysis.

NOTE: Blockbusters are defined as drugs with peak sales of at least \$500 million in constant 2001 dollars. The top ten pharmaceutical companies are as of 2001, including all former companies, mergers, and acquisitions.

¹Output from 2001 to 2004 is based on risk-adjusted predicted launches; assumed output from 2004 is equal to the 1991–2001 average.

ingly feasible. A case in point is Genentech's Herceptin. It is highly effective for the approximately 20 percent of women with breast cancer in whom the HER2 growth factor receptor is overexpressed, and it enjoys a dominant market share in this niche. Sales, driven in part by the increasingly widespread use of the HER2 diagnostic test, have now topped \$1 billion per year. Another such case is AstraZeneca's Iressa. Only about 10 percent of patients with non-small cell lung cancer respond to Iressa, but they improve dramatically. The low response rate was initially a mystery. But early this year, two groups of independent researchers discovered a common underlying mutation in the tumors of most of the responsive patients. Diagnostic

tests are now being developed, and Iressa is emerging as a key therapy for this subgroup of lung cancer patients.

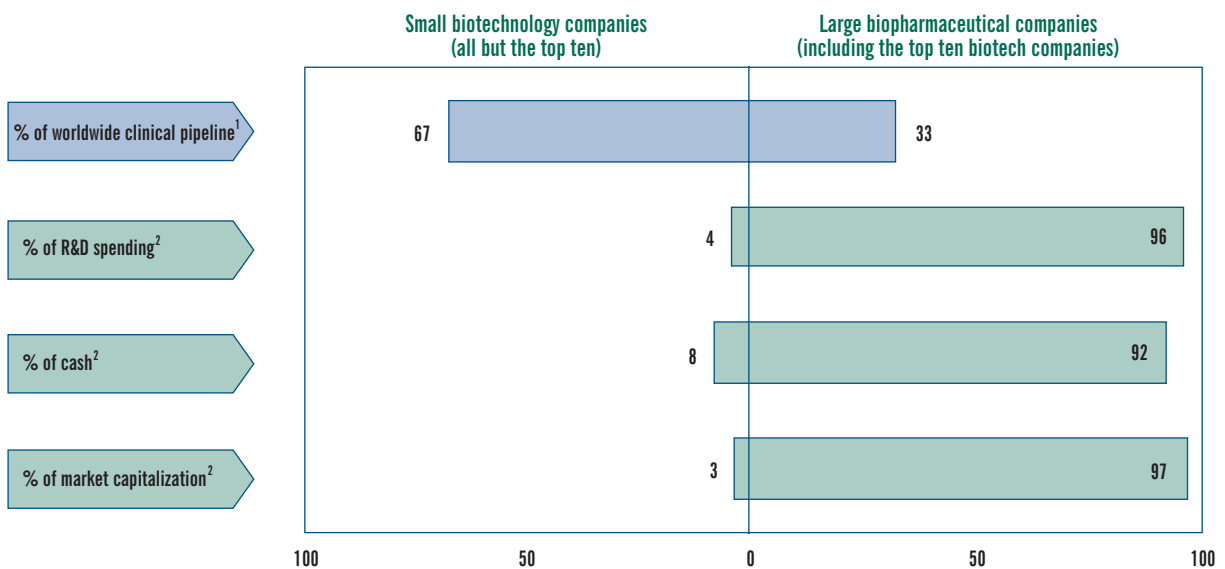
Third, the industry is evolving toward a network model, as definitions of the boundaries of the firm begin to blur. Just consider: small biotech companies (all biotech companies but the top ten) account for less than 10 percent of the industry's cash, market capitalization, and spending on R&D, yet remarkably they hold two-thirds of the industry's clinical pipeline. (See Exhibit 4.) There has to be a strong potential, then, for collaboration between small and large biopharma, with the former providing clinical candidates and the latter providing resources and know-how. And, sure enough,

dealmaking is growing in value at more than 20 percent per year, and penetrating into earlier and earlier stages. Some recent early-stage deals have now reached into the hundreds of millions of dollars. (For example, the Aventis-Regeneron Phase I deal for VEGF Trap has a total potential value of more than \$500 million in milestone payments and upfront fees.) What's more, the migration to earlier stages is making deals more complex—with option payments, contingent milestones, and the like—as collaborating companies seek to find the optimal mix of autonomy and risk sharing.

Fourth, the industry is facing increasing uncertainty regarding drug pricing. The resolution of this uncertainty could have long-

EXHIBIT 4

A MISMATCH BETWEEN PIPELINES AND RESOURCES IS ENCOURAGING A NETWORK MODEL



SOURCES: Lehman Brothers; Pharmaprojects; Value Line; BCG analysis.

¹Using Pharmaprojects February 2003 data.

²Using 2002 end-of-year data for the top 100 biotechnology companies and the top 100 pharmaceutical companies, extrapolated to the full set of biotech and pharma companies using hyperbolic fit to cumulative values. Procter & Gamble, Japan Tobacco, and Johnson & Johnson were excluded from the market capitalization analysis.

term implications for the pace of innovation, and hence for the rate of improvement in the quality of disease care.

The Medicine

Circe, daughter of the Sun, captures Odysseus’s lost crewmen and turns them into swine with her potions. Odysseus knows well the danger of confronting Circe but has the courage to attempt a rescue—alone if necessary. As it happens, he meets Hermes, messenger of the gods, along the way and receives from him a gift of moly, an herb that only gods can safely pluck and a powerful prophylactic against Circe’s spells

and potions. Duly protected by the moly, Odysseus rescues his companions and compels Circe to restore them to their human form—even taller and more handsome than before the ordeal.

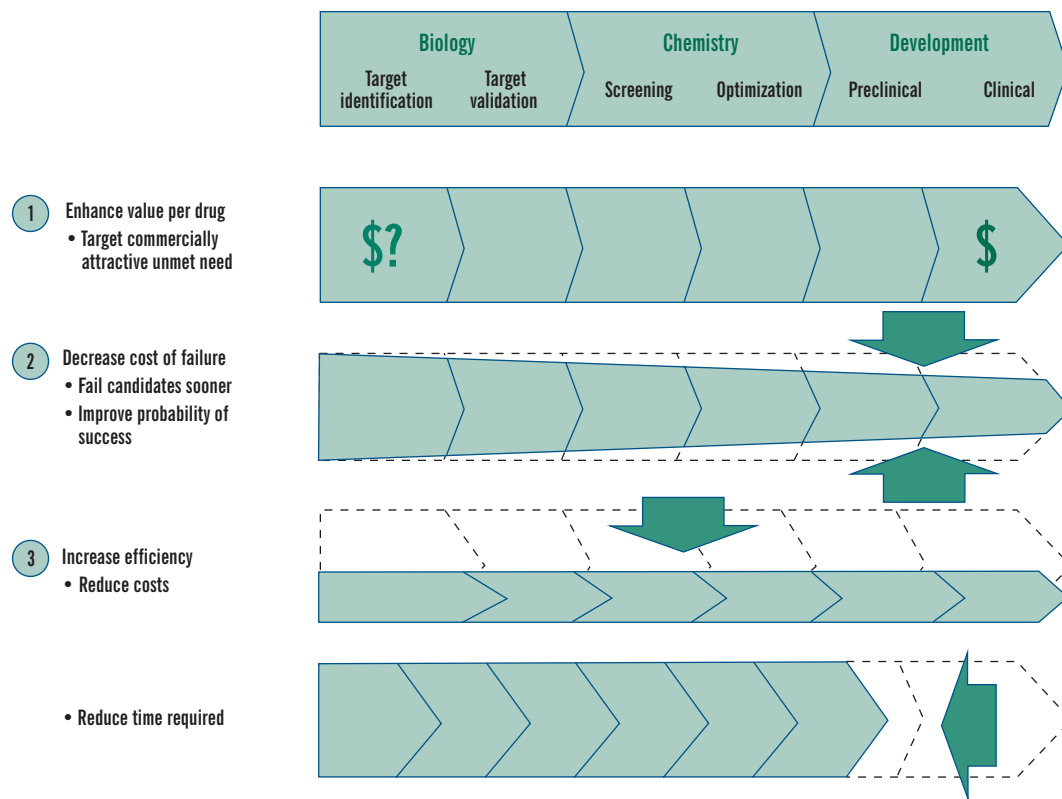
What is the moly for biopharma executives? How can they protect themselves from the “crisis” and rescue their companies—perhaps making them even more valuable and productive than before?

Three Ailments. Ailing productivity will present in any of three ways: poor value per drug, poor efficiency, or high cost of failure. Any strategy to improve productivity must address and treat one

or more of these manifestations. There are three corresponding approaches: enhancing value per drug (for example, by identifying a commercially attractive unmet need); increasing efficiency (by reducing cost or time); and reducing the cost of failure (by failing candidates sooner or by improving the overall probability of success). (See Exhibit 5.)

Of these approaches, the most powerful is the last—reducing the cost of failure. After all, 75 percent of all costs are attributable to failures, concentrated in the earlier stages.¹⁰ Moreover, the cost of failure certainly seems to be a manageable ailment, re-

EXHIBIT 5
THERE ARE ONLY THREE WAYS TO IMPROVE PRODUCTIVITY



SOURCE: BCG analysis.

sponding to appropriate intervention: witness the sixfold variation in success rates across top biopharma companies, as evidenced in research by Joseph DiMasi of the Tufts Center for the Study of Drug Development¹¹ and in private data that we have seen across a range of companies. The cost of failure is a function both of failure rates *and* of the point where failures occur along the value chain. It is far better to fail in the early stages of the value chain than in the later stages, where the costs are enormous. Even worse are products that actually reach the market but fall flat. So for underproductive companies, one good step on the road to recovery would be to sharpen their willingness, and ability, to fail *fast*.

Five Sites for Applying Remedies. Such broad approaches to rein-

vigorating productivity are helpful from a diagnostic point of view, but for more effective treatment regimes you have to look deeper into the causes of the malaise. We propose an organizing framework for thinking about the strategies to pursue. Each strategy affects the three ailments in different proportions: some approaches concentrate on raising the value per drug, some on improving efficiency, and some on reducing the cost of failure. There is no one-size-fits-all cure; rather, R&D executives should contemplate all of the strategies and apply them—all of them, probably—with greater or lesser intensity, in the combination best suited to their company’s specific symptoms.

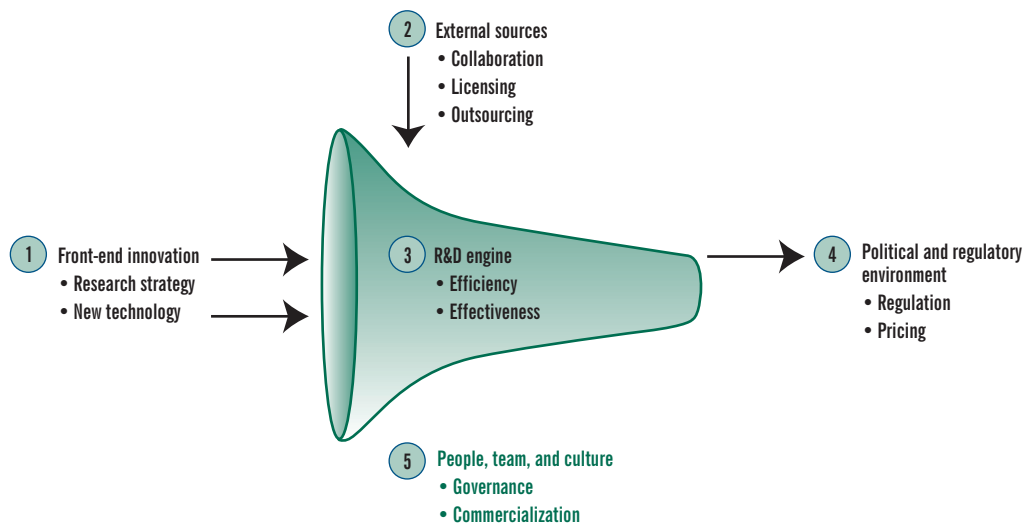
The organizing framework is a model of the inputs and outputs of R&D. (See Exhibit 6.) There

are five major features to consider—five sites for intervention: front-end innovation; external sources; the R&D engine; the political and regulatory environment; and people, team, and culture.

Front-End Innovation. Various strategies need to be in place here—from a research strategy for rationalizing the biologies that Discovery works on, to technology strategies for platform investments in areas such as informatics. If the company fails to design these strategies well and pursue them conscientiously, its long-term productivity will suffer. An ad hoc accumulation of investments may look healthy, and may optimize individual functions or departments, but it will not be of lasting benefit to the corporation as a whole. What’s needed is a cohesive

EXHIBIT 6

AN ORGANIZING FRAMEWORK PRESENTS FIVE AREAS FOR ACTION



SOURCE: BCG analysis.

vision that considers the end-to-end economics. This vision requires the careful integration of several factors: What is the minimum critical scale of efforts in one pathway, and how do we manage at scales well beyond the minimum? How big is the market (in terms of the level of unmet need rather than of current sales)? How strong is our science versus the competitors? And how well can our downstream resources support the indications emerging from our Discovery efforts? After all, decisions in Discovery will in due course have an impact not only across R&D but on the Manufacturing and Commercial functions as well. Choosing a front-end innovation strategy implies focusing, but Discovery by its very nature involves some element of serendipity. To retain this openness and to remain focused at the same time—that is the difficult balance that the strategy has to strike.

External Sources. Companies need to have strategies in place for interacting with outside partners—from in-licensing (where paying the most is neither the only nor the best way to win the game), to structuring collaborations, to calculating when they should outsource activities and when they should keep capabilities in-house. By taking a measured and rational approach to the use of external innovation, a company can benefit handsomely and in some cases almost immediately. (See our follow-up report, *The Gentle Art of Licensing: Rising to the Productivity Challenge in Biopharma R&D.*)

The R&D Engine. Despite years of process reengineering and endless benchmarking, true efficiency and productivity in R&D have proven elusive. Moving forward, leading companies must not only make improvements in such routine and rudimentary procedures as site selection and patient enrollment but also continue honing processes for new

*Those who rise best
to the challenge will
be those who think
most strategically
and act
most proactively.*

approaches such as translational medicine and pharmacogenomics. Additionally, new models are emerging with the continuing rise of contract research organizations and the appearance of outsourcers in countries like India and China, which offer lower cost structures. To approach these resources in the optimal way requires treading a fine line—on the one hand, maintaining necessary capabilities in-house; on the other, taking advantage of these lower cost structures.

The Political and Regulatory Environment. What is the optimal approach to pricing? How can companies best conduct dialogue with regulatory agencies like the FDA and with legislators? Such questions need careful study, in relation to both individual products and overall portfolios, and at both the individual company level and the industrywide level.

People, Team, and Culture. They are the bedrock of all the other strategies. Employees can be developed and motivated through both hard and soft incentives. Cultures can be shaped through active management. And cross-functional teaming—in the right amount and at the right level—can be a mainstay of a company's regimen. A governance structure that drives toward the right decisions for the company as a whole is an enormously powerful lever for improving productivity, but one that is hard to get right. (See our follow-up report, *Good Governance Gives Good Value: Rising to the Productivity Challenge in Biopharma R&D.*)

What Chance of a Cure? There is no simple high-level remedy, no panacea, that can be applied at all five of these sites for intervention. Each site must be analyzed on its own terms by R&D managers and receive customized treatment in keeping with the company's specific situation and needs. Each site has unique complexities, which we plan to explore in detail in our continuing series of publications.

These are trying times for R&D managers. The consolation is that trying times are also interesting times. The productivity challenge provides an environment where creativity and courage are at a premium, and diagnostic and prescriptive skills are put rigorously to the test. Those who rise best to the challenge will be those who think most strategically and act most proactively, and they will reap the rewards.

Notes

1. “Pharmaceuticals Group Warned on R&D Spending,” *Financial Times*, 29 September 1993, World Trade News, p. 8.
2. Drews, J., and Ryser, S. (1996), “Innovation deficit in the pharmaceutical industry,” *Drug Information Journal* 30: 97–107.
3. Schneider, Stephen H. (1997), *Laboratory Earth*, New York: Basic Books, p. 68; and the Vasa Museum, www.vasamuseet.se.
4. Disregarding economies of scale in sales force and other infrastructure.
5. Current values for the top ten pharmaceutical companies have been stable for a decade: eight blockbusters per year, \$1.75 billion in peak sales per blockbuster, 12-year patent life, 2-year half-life for off-patent drugs, and \$37 billion in revenues from smaller drugs.
6. For example, Glassman, R.H., and Sun, A.T. (2004), “Biotechnology: Identifying advances from the hype,” *Nature Reviews: Drug Discovery* 3 (February 2004): 177–83.
7. Tadataka Yamada, chairman of R&D for GlaxoSmithKline, noted how research productivity, measured in number of candidates entering clinical trials, has more than doubled in recent years: the *Wall Street Journal*, 3 December 2003, p. D9. Roger Perlmutter, executive vice president of R&D for Amgen, provided data at the March 23, 2004, R&D Day to show that the rate of PST (product strategy team) formation has more than tripled from a few years ago. Robert Essner, chairman and chief executive of Wyeth, stated that the rate of projects entering development has quadrupled: the *Wall Street Journal*, 3 June 2004, p. D4.
8. “It will take a few years, and many deft decisions, for the savings to be realized. The early years of implementation may in fact involve an increase in costs. [But in the longer term, drug development costs] could be reduced by as much as \$300 million.” *A Revolution in R&D: How Genomics and Genetics Are Transforming the Biopharmaceutical Industry* (2001), BCG report, p. 12.
9. The FDA is building a National Critical Path Opportunities List to identify the main bottlenecks in R&D and the actions that can be taken to ease them. *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* (March 2004), FDA.
10. *A Revolution in R&D: How Genomics and Genetics Are Transforming the Biopharmaceutical Industry* (2001), BCG report.
11. DiMasi, J.A. (2000), “New drug innovation and pharmaceutical industry structure: Trends in the output of pharmaceutical firms,” *Drug Information Journal* 34 (4): 1169–94.

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About the Authors

Peter Tollman, Ph.D., is a vice president and director in the Boston office of The Boston Consulting Group and coleader of the firm's biopharmaceutical R&D business. You may contact him by e-mail at tollman.peter@bcg.com.

Simon Goodall is a vice president and director in BCG's Los Angeles office and coleader of the firm's biopharmaceutical R&D business. You may contact him by e-mail at goodall.simon@bcg.com.

Michael Ringel, Ph.D., is a manager in BCG's Boston office and a key contributor to the firm's biopharmaceutical R&D business. You may contact him by e-mail at ringel.michael@bcg.com.

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For Further Contact

BCG's Health Care practice advises leading pharmaceutical and biotechnology companies on many topics, including the strategies described in this report. For inquiries about this report or the Health Care practice, please contact the authors or the following officers:

Steffen Elbert, Ph.D., Vice President and Director, Hamburg
E-mail: elbert.steffen@bcg.com

Philippe Guy, Senior Vice President and Director, Paris
E-mail: guy.philippe@bcg.com

Stuart King, Vice President and Director, London
E-mail: king.stuart@bcg.com

Mark Lubkeman, Vice President and Director, Los Angeles
E-mail: lubkeman.mark@bcg.com

Ulrik Schulze, Ph.D., Vice President and Director, Zürich
E-mail: schulze.ulrik@bcg.com

Marty Silverstein, M.D., Senior Vice President and Director, Boston
E-mail: silverstein.martin@bcg.com

Kim Wagner, Ph.D., Vice President and Director, New York
E-mail: wagner.kim@bcg.com

Hiroataka Yabuki, Vice President and Director, Tokyo
E-mail: yabuki.hiroataka@bcg.com

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