

The Future of Pharma: Adjusting the Pharma R&D Model

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The pharmaceutical industry has enjoyed a protracted winning streak in which it has scored a decade of tremendous growth and profits on the back of novel and important medicines. But where will the victories come from in the next ten years? The pharma industry has entered a period of significant uncertainty and transition, characterized so far by higher R&D costs and fewer new drugs against a backdrop of calls for price controls and access restriction as society reaches the limits of willingness and ability to pay for pharmaceutical innovation. Add to the mix the 10-20 year investment horizon for research-based pharmaceuticals and a U.S. presidential election in which the industry is often under attack, and one thing becomes abundantly clear: The traditional pharmaceutical R&D business model will not generate adequate returns on today's expenditures to discover, develop, and bring the next wave of new drugs to market. As a result, the model will need to either: (1) evolve significantly; (2) reduce investment to focus on those areas with sustainable returns; or (3) incorporate a combination of both.

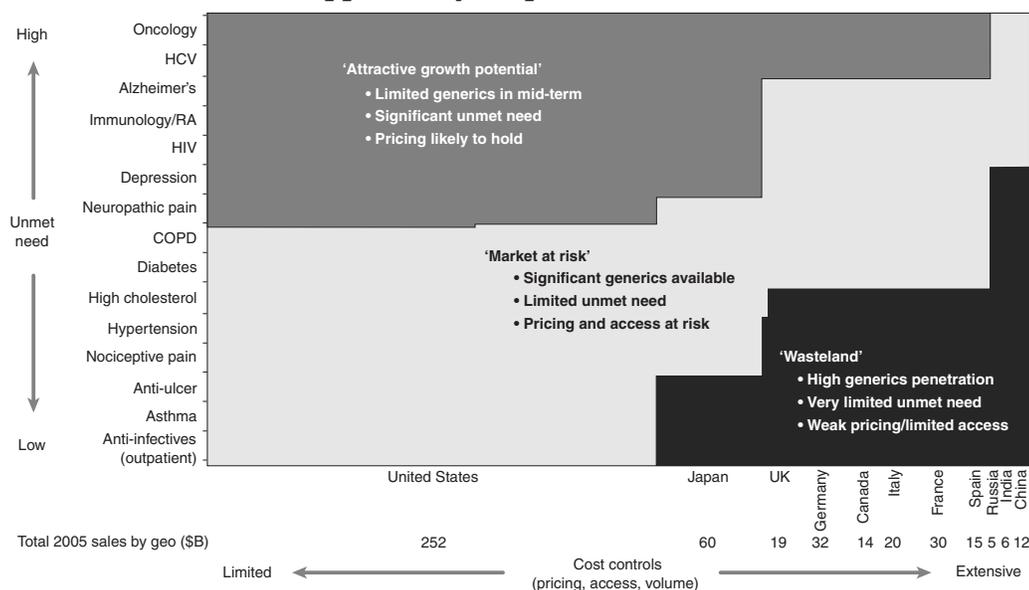
By any historical standard, 1995-2005 was a frothy one as the worldwide pharmaceutical market doubled in size from \$280 billion to \$600 billion. In spite of this, the industry as a whole has created limited shareholder value since 2000, underperforming the S&P 500's own tepid results. Total shareholder return (CAGR) from the beginning of the decade through year-end 2007 was only 2.7% for the pharmaceutical industry versus 3.6% for the S&P as a whole and 5.9% in the relatively low-growth consumer goods sector. The apparent contradiction can be explained by pharmaceutical P/E ratios, which have tumbled by 50% as investors have done their own math on rising R&D and marketing costs and declining productivity in terms of R&D expenditures per NDA. In financial terms, investors have "shorted" the industry—placing their bets that pharma R&D has excess capacity and that today's returns are unlikely to be matched as the traditional research-based pharmaceutical business model grinds out the next decade of new products.

There is nothing simple about the pharmaceutical industry, and efforts to reduce its essence to a mathematical model will inevitably miss the nuance, brilliance and serendipity that explain many of the industry's stellar successes. Nevertheless, one can aggregate inputs across the industry to assemble an average industry return on investment for a new drug. The results are illuminating. Ten years ago, research costs totaled approximately \$70M per pre-clinical molecule, the probability of success from this stage to launch was about 18 percent, and peak sales per successful drug were roughly \$1.0B. Over a commercial lifespan of ten years post-launch and a net margin of 50 percent, this average successful molecule yielded a 15 percent internal rate of return (IRR)—enough to compensate investors for tying up capital for so long in such a risky gambit.

Today, on the positive side, research costs have been shaved to \$50 million per pre-clinical module as advances in genomics have vastly boosted the number of targets and as robust computing power has given the industry many more "shots on goal." Alas, putting up more shots hasn't raised the score, since the probability of clinical success has plummeted to only 8 percent. Looking forward, assume peak sales advance a bit to \$1.1 billion, but net margins shrink to 40 percent as managed care and government payers flex their purchasing muscle. Under such a scenario, the payback tumbles to an estimated 11 percent IRR. This is not bad in the abstract perhaps, but is a far less favorable return than investors have come to expect for the long and risky wager involved in funding the traditional pharmaceutical model. By contrast, a lower-growth area like consumer goods—insulated by brand power rather than patent power—starts to look like a more attractive bet for investors.

What is pharma's best bet for recouping investment in drug discovery and innovation? By cross-referencing therapeutic areas with high unmet need (as indicated by low generic penetration and strong price levels) against international markets with access and pricing policies more favorable to innovation, an opportunity map for the research-based pharmaceutical business comes into focus.

An Opportunity Map for Pharma R&D



Source: IMS, SG Cowen TA Outlook, Datamonitor, Lehman Pipeline, UK NHS, Japan Ministry of Health, LSE study for EU Commission on Pharma Pricing, BCG analysis

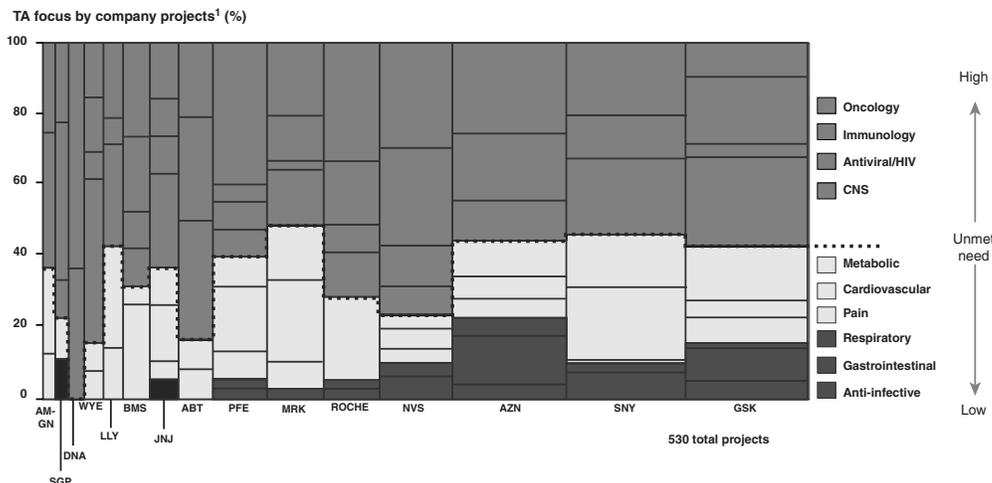
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A strong demographic tailwind featuring an aging population and rising purchasing power in developing economies favors industry growth in therapeutic areas and geographic segments where the unmet medical need is profound and pricing and access controls are less onerous. In these spaces, robust R&D can still provide a reasonable return over a 10-20 year investment horizon.

There are two looming threats to bear in mind, however. First, the “attractive” portion of the market has receded in the past 10 years as generics have made inroads and struggling health care systems have imposed greater controls. At the same time, competition in this space has intensified. Of the 530 products in the visible pipeline of the top 10 global pharmaceutical companies, nearly two-thirds are directed to this space. This intensifying competition will increase the overall levels of risk and price pressure on the participating players.

Large Rx Players Competing for the Same Real Estate



¹Limited to compounds classified as preclinical, Phase I, IIa, II, IIb only

Source: Lehman pipeline; BCG analysis

In the “at risk” segments, generics can be expected to make further inroads, and national payers will undoubtedly use their purchasing power to force greater international pricing conformity. Meanwhile, the dark area on the map is a metaphorical “wasteland” for pharma’s R&D interests. These are markets and segments in which discovering, developing, and commercializing a new product with an old business model looks like a poor bet due to low price levels, access restrictions, and availability of generics (both legal and illegal).

Some observers will point out that rising economies can pick up the slack even as Western countries attempt to throttle back pharmaceutical industry growth. It is true that companies will make substantial returns on existing molecules in these rapidly growing markets. However, the opportunity map described above represents a forward look at market segments where the intersection of unmet medical need, strong prices and open access will make the traditional discovery research model viable. With 2005 pharmaceutical expenditures in Russia, India, and China totaling only \$21B versus \$250B in the US alone, the pharma world will indeed catch a cold when the US sneezes—or even snuffles a bit.

As the opportunity map comes into sharper focus, the traditional pharmaceutical R&D business model will adjust to the realities of the future marketplace. Players who want to compete broadly will need to concentrate their R&D investments on the therapeutic areas and technologies of greatest opportunity and develop new capabilities and evolve their business models in new ways, such as:

- Risk management—moving away from an era of high, fixed costs in a fully-integrated system to a more variable cost structure and a well-conceived system for sharing investment and risk across multiple parties by involving stakeholders and partners at different stages of bringing drugs to market.
- Functional specialization—contract research organizations (CROs), contract manufacturing organizations (CMOs), and contract sales organizations (CSOs) all represent opportunities to innovate the current R&D model by identifying and capitalizing on functional areas of expertise, participating in specific aspects of a given function (e.g., biologics manufacturing only), or acting as a “service provider.”
- Business model innovation—changing the paradigm of how R&D functions in the health care environment and re-orchestrating R&D activities, overall pharma assets and capabilities to deliver radically new value propositions to customers. Strategic initiatives may include selling outcomes versus drugs and establishing outcomes-dependent risk-sharing agreements with payers, engaging payers and providers to provide integrated treatment, defining dramatically different sales and marketing models (e.g., no geographically based sales reps, no mirroring, etc), and configuring an R&D and commercial model that can deliver high returns in much smaller market segments with high unmet need.
- Market diversification—redefining market scope and participation to capture the full value of capabilities, expertise, and assets (e.g., expanding into other pharmaceutical markets (including generics), diagnostics, drug/device combinations, even OTC consumer products).

The key uncertainty of this market evolution is one of pace, not direction. But in an industry that features a 10-20 year lag between discovery and the market, the future is now. Innovation that delivers against unmet medical need will always be rewarded, but pressures on the current business model will continue to force strategic changes. Nearly every major company has begun to take the obvious steps to reduce high fixed costs and to defer uncertain research investments. However, the more strategic thinkers are also placing bets in the “attractive zone,” adapting their R&D models to new opportunities in risk management, specialization, experimenting with more radical models, and redefining the market. None of these new gambles represents a payoff as lucrative and certain as the past decade of pharmaceutical success. Still, the market is a self-regulating mechanism, and disease and old age are here to stay. As the pharmaceutical industry sloughs off unproductive capacity and reconstitutes itself under a new pharmaceutical value equation, the future of pharma will no doubt be a bright one for those who place their bets most intelligently.