

organization. Therefore, the cost reduction in all aspects of their operation will still be the main theme in 2010 (and even years beyond 2010) throughout the entire pharma industry.

As for the biotech industry, in the near future, there will be much fewer R&D-oriented, small size biotech companies around. New, startup biotech companies will also become rare in the following couple of years. Consequently, there will be much soft outsourcing demands for drug discovery and early stage development service from the small biotech companies. However, the actual situation may be more complicated than that. It might not be that pessimistic. The financial crisis has created a dilemma situation to the small, R&D-oriented biotech companies at least in the next couple of years.

On the one hand, the nature of drug discovery and development requires these R&D-focused biotech companies have an abundant cash reserve all the time during the process of their chase for golden drug products. This was generally easy to realize in the past (just through rounds of fund raising). On the other hand, the financial crisis has directly resulted in the funding shortage in the foreseeable future, in particular in the traditional venture capital investment industry. Many VCs or investment institutions have either lost a big chunk of their investment elsewhere, which made them less flexible for other investments, or become more skittish to invest in R&D-oriented drug discovery companies. As many of them have realized the high risk of drug discovery business, they are now more inclining to invest in those less risky sectors such as the developers of molecular diagnostics and biomarkers as it takes much less time and money to commercialize a product in these areas. They have even become more interested in outsourcing service providers (than before) as these companies generally have a strong revenue performance.

The situation in the venture capital investment industry has strongly reminded those R&D-oriented biotech companies that still remain in the field. From now on, they have to more diligently plan their budgets and use money more wisely. The cash shortage in the near future will become the major threat to their continual operation, not to mention the ambition to expand their programs. Therefore, it can be anticipated that, with such a budget constraint, more small biotech companies will pursue semi-virtual or even completely virtual operation model in order to avoid building the fixed facilities that now have become widely accessible/available in most outsourcing service providers as this will save them a lot cost upfront. As a result, more outsourcing work from these remaining R&D-oriented biotech companies is anticipated in the near future. This will partially offset the declining demands resulting from the reduced total numbers of biotech companies and early stage development programs.

Facing the current tough situation, to all drug companies, either R&D-oriented biotech or major pharma, the key issues are how to speed up their R&D progress while still able to control the overall operation cost. To those pharma companies that have products on market, the extra challenges are how to expand the market territories while still able to

maintain their R&D focuses so as to have a steady growth of revenue performance as the market growth in many developed countries appears to have become stagnant in the following years. However, no matter which type of drug companies, the essential part of these challenges is the work efficiency and productivity.

4.3.2 New operation strategies pharma/biotech industry will likely implement in 2010 and near future

Needless to say, to address these issues, all pharma and biotech companies are going to take a series of actions. To improve the R&D efficiency, on the one hand, they are going to restructure their R&D divisions into smaller organizations. For example, Pfizer is planning to reorganize its R&D divisions into numerous smaller R&D centers, each focusing on only one therapeutic area and containing 100-150 researchers. On the other hand, they are also going to increasingly implement the new R&D model of the “Networked Partnership (NP)” to improve their productivity. For example, Eli Lilly has set up a virtual R&D center at its Indianapolis headquarters (it is called Chorus Operation Group). The new organization is composed of about 30 experts whose responsibilities are to design and implement the R&D plans through managing all collaborations Lilly has with its partners worldwide. Lilly also has a similar operation group in Shanghai though slightly smaller in size than in its US headquarters.

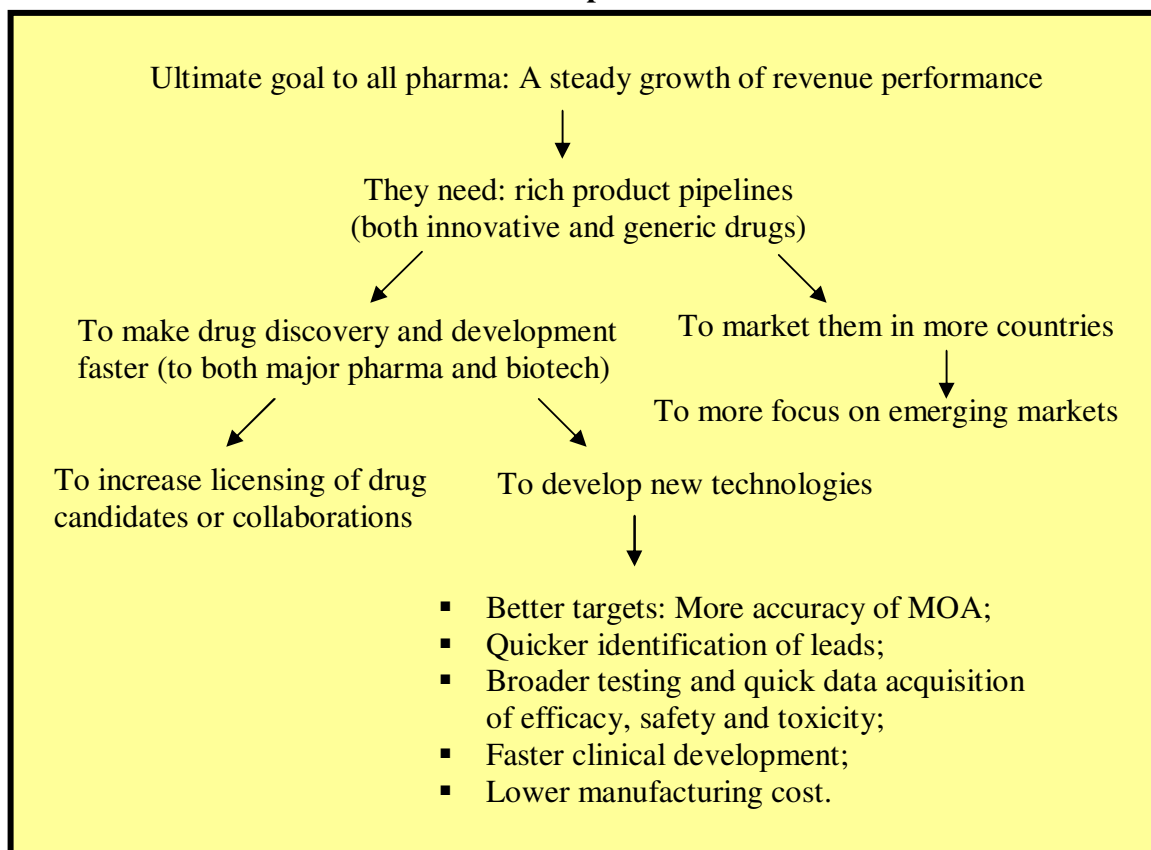
To speed up their R&D progress, pharma will also increase licensing of drug candidates from any drug companies around the world while reducing its own efforts in the early phase R&D. For example, Sanofi-Aventis is planning to reduce its efforts and R&D spending in early stage research and only focus on late stage development and registration.

To expand their market territories, these major pharma companies are going to more focus on those emerging markets. For example, recently several major pharma companies including Pfizer and Novartis licensed sales rights to numerous generic drugs from the generic drug makers (including Indian generic drug companies) and will market them in Asia, Middle East, East Europe and Africa.

4.3.3 How will global pharma outsourcing industry be likely affected?

In the value chain of the series of changes, outsourcing service sector is, unfortunately, in the downstream. How the future global pharma outsourcing industry will likely develop is entirely dependent upon the actions taken by both pharma and biotech industries to address the existing issues within their own area. Figure 13 depicted a strategy tree that outlines all possible strategies that will be likely taken by both pharma and biotech industries in the very near future.

Figure 13
Strategies likely to be implemented by both major pharma
and small biotech companies in near future



To major pharma companies, their ultimate goal is to have a stable revenue growth every year. To achieve that, they need a steady flow of drug products in their product pipelines and gradual expansion of their market space. On the other hand, to have a product pipelines filled with innovative drugs, both major pharma and small biotech companies need to focus on improving productivity so as to make drug discovery and development faster. To speed up that progress, they all have to enhance collaborations with as many companies/organizations and on as many aspects of a drug R&D program as possible. Meanwhile, they will have to look around for appropriate drug candidates so that they can license in.

Meanwhile, they will have to focus on the development of new technologies so as to make the drug discovery faster and the development more quickly. To realize these specific goals, they need to have more accurate therapeutic targets and to know better about the mechanism of action (MOA) of a drug compound. They also need to quickly identify lead compounds and get them optimized more rapidly. In addition, they also need quick results of efficacy, safety and toxicity testing in both preclinical and clinical development stages. All these operations must be organized in an efficient way.

Besides, they also need to address the manufacturing cost for both developmental drugs and approved drugs including generics.

To realize their goals, all drug companies are going to conduct broader and more extensive research on genomics and proteomics including development of special animal disease models, more effective diagnostic tools and better biomarkers and imaging tools. They will also need large size, readily available compound libraries that possess special structural features so that they can screen them right away against their selected targets. Besides, they will also rely on faster, more accurate high-throughput screening systems to screen those compound libraries. Most part of such heavy research work will be outsourced in the manner of collaborations with either academic research institutions (for such tasks as target identification/validation and elucidation of action mechanism) or professional service providers (for discovery, development and manufacturing work). However, they very likely will want to have more control on the late stage development as well as drug registration.

Based on these analyses, we reached following conclusions of how the outsourcing demands by both pharma and biotech industries will likely change in 2010 and even the near future.

1. Outsourcing demands by major pharma companies will likely still remain strong in following areas

a. Research in genomics and proteomics

Major pharma companies are in desperate need to develop better drugs with high success rates. To that end, they need to have more accurate therapeutic targets, become better understanding on MOA and the causes of side effects. To achieve these, they need to increasingly focus on the basic type of research in genomics and proteomics.

b. Compound libraries with special structural features

To improve their efficiency, pharma/biotech companies need a variety of large size compound libraries that are readily available for screening. Ideally, these compound libraries are designed and constructed according to the structural information of the active sites of the well validated targets. So outsourcing of large, structurally diverse, more natural product-like compound libraries will still remain strong; and the wider (than before) R&D collaborations between drug companies and those technically capable professional CROs are expected to take place.

c. Preclinical research