

- effectively manage them as they are now impossible to travel to there for on-site visits.
- For those still negotiating with their Indian counterparts, they will definitely cancel their plans.
- For those previously favor outsourcing to India, they may now change their mind.

In the short term such as six to twelve months, India's pharma outsourcing will definitely go down significantly. Its growth could even become negative as compared to the last period. Although it will slowly recover after that, it may take a few years for the industry to reach the same level as it was.

Many outsourcing companies, in particular those originally chose or favored India as their primary choice of destination for outsourcing, will now change their mind. One of the alternative choices to them is to go to China to fulfill their tasks which must be done anywhere anyway.

Therefore, the otherwise negative effects by the current financial crisis on China pharma outsourcing industry in near term might be slightly offset by the switching of outsourcing destination by these companies due to the incident. It is almost certain that in 2009 or even the first half of 2010 many outsourcing companies that originally planned to outsource to India will change their mind. Figure 13 (please see next page) illustrated the impact of the financial crisis as well as the terror attack in India on China's pharma outsourcing industry.

1.1 Qualitative analysis of the impact

On the surface of the impact of the current financial crisis on China pharma outsourcing industry, a significant slowdown of this used-to-be fast growing industry might be inevitable in the next one to two years. However, the degree to which each sector of the outsourcing industry is affected may differ and is also complicated to calculate as several factors, both positive and negative, are knitted together. These factors include changes of outsourcing by major companies, changes of outsourcing by small biotech companies and changes of outsourcing by generic drug makers as well as switching of outsourcing providers by those drug companies that originally outsourced or planned to outsource to India, etc. In this section our detailed analysis about each sector will be presented.

Figure 13
How outsourcing to China will be affected by financial crisis

Impact of Financial Crisis on China Pharma Outsourcing Industry

What big pharma company will do:

- Scale back R&D budget on early stage drug discovery and development;
- Focus on late stage development;
- Still focus on cost reduction both in R&D and manufacturing;
- Will put more efforts on development of novel and generic biologics.

What small biotech company will do:

- Completely cut drug discovery programs;
- Focus on middle to late stage development programs;
- Seriously consider cheaper and more efficient way to conduct drug R&D;
- Wait for more funding, leaving operation temporarily idle.

Terror attack in Mumbai of India:

- Big pharma will reprioritize their development focus in emerging markets;
- Small biotech will choose alternate outsourcing destinations;
- Sourcing stability of pharma raw materials will be reconsidered.
- More Indian CROs/CMOs will establish overseas operation facilities/offices.

How outsourcing to China affected:

- Significant decrease in outsourcing projects of custom synthesis, lead discovery/optimization, and other medicinal chemistry research;
- Significant decrease in outsourcing of ADME/Tox and other preclinical research;
- Decrease in outsourcing of early stage (phase I) clinical research;
- Almost no impact on outsourcing of late stage clinical research;
- Increase in contract manufacturing of APIs and intermediates;
- Start to see increase in outsourcing of contract manufacturing of biologics.
- Major pharma companies will consider their China development programs as high priority;
- More small biotech companies will select China for outsourcing;
- More raw material sourcing will go to China;
- Chinese CROs/CMOs will face more competition at overseas markets.

1.1.1 How major pharma and biotech companies will change their outsourcing behavior

As mentioned earlier, so far outsourcing by those major pharma or biotech companies has been the main stream of the outsourcing activities in China. Although almost none of these cash-rich big companies have been negatively affected by the financial crisis, their outsourcing activities in China could still gradually decrease. The reason is that many companies' wholly owned R&D

facilities in China are now ready to conduct full scale research on their own, resulting in fewer projects to be outsourced.

On the other hand, as the current financial crisis provides rare opportunities to these cash-rich major companies to acquire more drug candidates from small biotech companies, in the next one to two years, the pipeline of drug candidates in many of these major pharma companies will be greatly enriched. As demonstrated by a series of actions Eli Lilly has been taking in recent couple of years, more outsourcing tasks would come from these major pharma companies as they now prefer a new operation model – networked partnership. Under this new business operation frame, these major ones will be increasingly downsizing their fixed facilities that are not utilized every day and outsourcing more and more work, even including core business such as R&D. Although it is not realistic to expect that all these outsourcing projects will go to China, some of them such as those late stage clinical trials and APIs manufacturing of these drug candidates might be moved to China.

On the other hand, due to more drug candidates in hand, these major pharma companies very likely will reduce their expense on drug discovery and early stage preclinical research as these activities have posed to be unnecessary or at least not that urgent any more at this moment. Therefore, outsourcing from these major pharma companies in both drug discovery research such as construction of focused compound libraries as well as custom synthesis of lead analogs/derivatives and early stage preclinical research such as ADME/Tox study as well as animal testing, would likely be reduced drastically.

1.1.2 How small biotech companies will change their outsourcing behavior

As mentioned earlier, to small biotech companies, outsourcing to China just became acceptable only very recently and has still not become popular yet. The current financial crisis will exert both positive and negative effects on the China outsourcing by this group of drug companies:

❑ Negative effects:

For those that currently have been in China for outsourcing or in plan to outsource to China but have extreme stress in cash flow, their outsourcing plans may be cut or postponed until they gain more financial support.

❑ Positive effects:

Those biotech companies that originally did not consider outsourcing to China may now seriously consider this option as the current cash reserves in many of these companies will run shorter and shorter whereas they are still not sure when they would be able to raise additional funding. These companies must use cash

wisely from now on and outsourcing to China to stretch the dollar value of their present cash reserves could become the ideal choice to them.

So combined together, these effects may exert only a slight change or even no changes at all on China's pharma outsourcing industry by these small biotech companies. Rather, it might be a positive impact because, as the numbers in Figures 11 and 12 indicated, it is a large number of biotech companies that got affected by the financial crisis.

1. Financially troubled small biotech companies can stretch the dollar value of their current cash reserves by outsourcing to China

In fact, to these small biotech companies, outsourcing to China not only provide them a number of benefits but also could make them successfully go through the financial crisis and become lucky survivors.

Outsourcing to China can provide following benefits to these biotech companies, in particular under the current financial crisis:

A. A substantial cost saving:

As stated earlier, at present outsourcing to China can achieve a cost saving of at least 60-70%. In terms of the cost saving, service quality and abundant choices of service providers, China by far is the best choice in the world for pharma outsourcing. In the past India sometimes comes on the top of choice list to many biotech companies as these two countries provide similar advantages and as there are other various concerns to many biotech companies when they think of outsourcing to China. But the latest terror attack incident happened in Mumbai will cause some biotech companies to rethink their original choice of outsourcing destination (see more discussions below).

B. Stretching to an extreme extent of the dollar value of their current cash reserves

At this moment the most prominent feature of outsourcing to China is to make these biotech companies able to survive the financial crisis. To these companies, under the current financial situation, the significant cost reduction by outsourcing to China could mean a lot. Even with their current limited cash reserves, they may be able to extend the operation of their current program(s) for an additional number of years (rather than only 12 months if they decided to stay in the West to continue their research).

C. Flexibility: