What a Difference a Year Makes!

The 2008/9 Harten Group Survey

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Keywords: Biotech funding, Emerging markets, Executive confidence, Patent expiry, Stock market performance, Survey

THE PAST 12 months have seen economic turbulence on a scale no-one could have predicted. So how has this impacted on the pharma and biotech sectors? Harten Group's seventh annual industry survey takes a look at the facts behind the headlines.

☐ GIVEN OUR NATURAL tendency to recall recent events more clearly, especially in view of the dramatic nature of the economy in the second half of 2008, one could readily describe it as "a year of two halves". While the first six months of 2008 were reasonably predictable for our industry (economic slowdown, ongoing restructuring, pressure for healthcare cost containment), in the second half and especially the last quarter, the sector felt the consequences of the banking crisis.

"… one could readily describe [2008] as "a year of two halves"."

These unique circumstances raise some new questions for this year's survey:

- How far are the changes taking place in the industry unrelated to the present economic climate?
- To what extent is the sector likely to be affected by the credit crunch?
- What impact has it had on last year's survey predictions?

Survey demographics & methodology

AGAINST THIS UNEXPECTED and unpromising backdrop, Harten Group's seventh annual survey canvasses executives' views of the issues currently facing the industry in 2009. We surveyed over 350 executives in pharma and biotech companies (divided roughly three to one respectively) in December 2008. Respondees fell into four generic job categories:

- Chief Executive Officers, Managing Directors and General Managers (8%)
- Medical: clinical research, regulatory and medical information (65%)
- Commercial: business development, marketing and licensing (16%)
- Others: operations, HR and project directors (12%)

The survey invited participants to identify their top five issues facing the industry in 2009 from a list of 20. They were also asked to list the most important issues in 2008 retrospectively, which provided an opportunity to compare the previous year's prediction with reality. A comparative question was added to the survey to understand how respondees think 2008 compared to 2007 and will compare to 2009.

The response rate is slightly down on last year and the distribution of participants by function has a higher proportion of 'Medical' and rather fewer 'Others'. However, the two year cohorts are deemed to be broadly comparable at the level of analysis used in this article.

In the present circumstances, this year's survey will eschew usual practice of reviewing individual factors to focus purely on the overall year-on-year comparison; how participants felt 2007 compared with 2008 and 2008 in turn, against the forecast for 2009.

2008 compared to expectations

GIVEN THE GENERAL level of alarm about the state of the economy, it is worth reviewing the financial performance of the sector objectively.

"[On the FTSE stock index] biopharma has moved counter to the dramatic falls of 2008."

Figure 1 tracks change in three FTSE indices over three years. The most striking feature is the extent to which the biopharma has moved counter to the dramatic falls of 2008. In the previous two years it had underperformed, but in the downturn it proved its worth as a 'defensive' stock in which revenues are not dependent upon personal discretionary spending. As if to confirm this point, a group of companies (Novartis, AstraZeneca, Bristol-Myers Squibb, Schering-Plough and Gilead) recently all posted strong fourth quarter results.

In terms of retail pharmaceutical sales, the UK experienced a 2% drop to $16.7 billion in the 12 months to September 2008, which compares unfavourably with modest increases of 2%, 3% and 4% increase in US, Europe and Japan respectively. However, the biggest increases, of 13.9%, were seen in what IMS terms the "pharmerging markets" (China, Brazil, Mexico, South Korea, Turkey and India), which heralds an important new direction (more on this later).

So what has not changed despite the turbulent times? Some trends with which we have become familiar continued through 2008, notably corporate re-organizations and acquisitions which inevitably lead to headcount reductions. The ABPI estimates that the industry has lost 8,000 jobs in the past three years. Restructuring and consequent job losses have been announced at three majors during the latter half of the year: AstraZeneca, GSK and Pfizer. The takeover of Wyeth by Pfizer is only the most recent example of an ongoing long-term trend of consolidation within the industry.

Another recurrent theme that appears to have taken on a greater sense of urgency is the 'patent cliff', off which a substantial number of blockbuster medicines will fall in the next few years. Over $70 billion worth of branded medicines will come off patent between 2009 and 2011, and consequently be exposed to generic competition that can erode market share by anything from 30% upwards in the first year alone. While the dates of patent expiries are public knowledge, the anxiety is focussed on the lack of replacement products coming through the development process at a time when the cost of bringing a new drug to market is continuing to rise. It is this so-called 'innovation gap' between the amount spent on R&D (an eye-watering $48.5 billion in 2007) and the outcomes in terms of new approvals (only 19 by FDA in 2007) that is the underlying driver. It now costs considerably more to bring new medicines to market and yet there are fewer coming through to fill the anticipated revenue shortfall.

The principal corporate beneficiaries of patent expiries have been generics manufacturers whose revenues have doubled since 2002 to $72 billion. The major

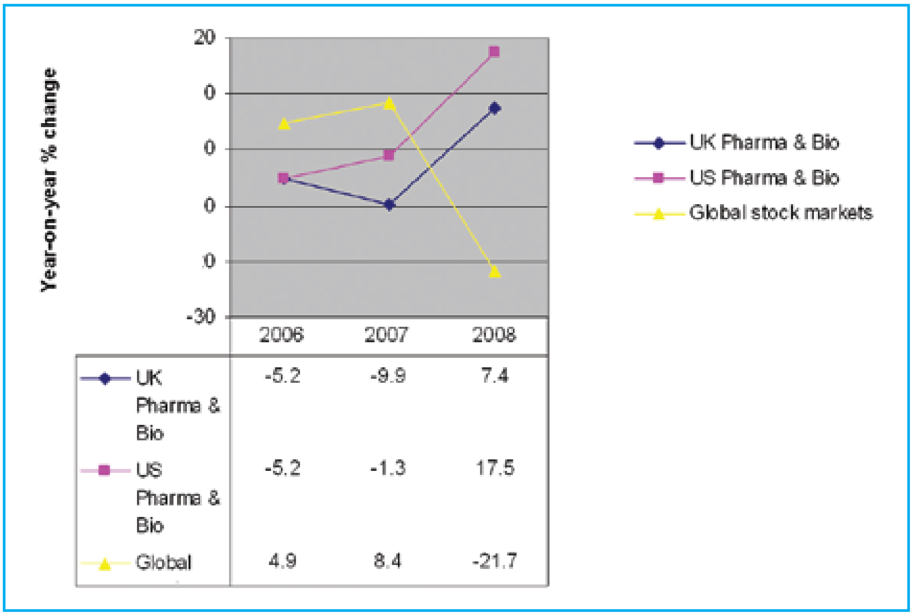

Fig. 1 Comparison of US and UK pharmaceutical and biopharma companies' performance relative to global stock markets, from 2006 to 2008.

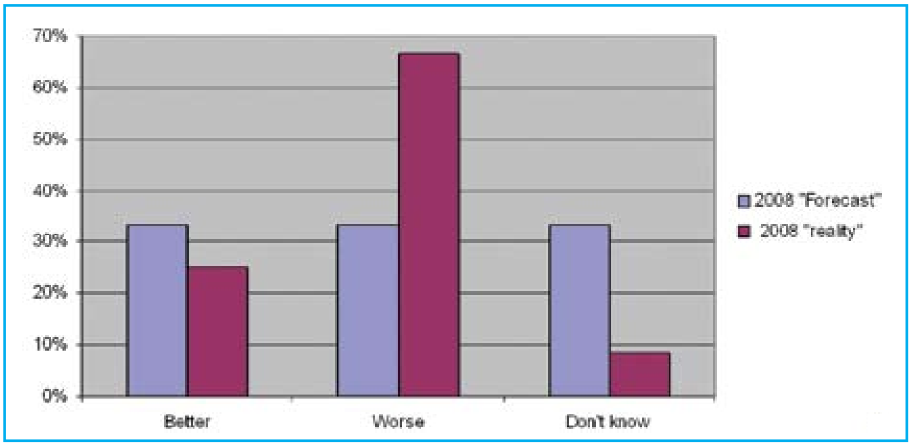

Fig. 2 Actual performance in 2008 compared with predictions.

pharma companies have modified their traditionally hostile stance by entering the market through acquisitions (for example Novartis's recent acquisitions within its Sandoz division and Sanofi-Aventis's purchase of Zentiva) and alliances, such as between GSK and Aspen, of South Africa. The larger independent generics companies, such as Teva and Actavis have been equally acquisitive in their drive to build scale.

In summary, the biopharma sector landscape has not changed substantially despite the turbulence of 2008. Its financial performance has been modest in revenue terms, though its market valuations have proved a welcome counter to the market as a whole. The long-term rationalisation has been ongoing and concern over generics has mounted with the impending end of the period of exclusivity for several blockbusters.

So, against this backdrop, what did our survey participants report?

As figure 2 shows, participants in last year's survey (completed December 2007) were equally divided as to whether 2008 would be a better or worse year than 2007. However, in retrospect two-thirds thought 2008 had been worse than expected, perhaps not surprisingly given the timing of the survey (December 2008). A further quarter took a longer view and concluded that on balance it had been an improvement on 2007.

What will 2009 hold?

☐ TURNING TO 2009, there is no apparent reason to believe that any of the current downward forces on the sector will lessen. If anything, they will only intensify; for example, pressure on healthcare cost containment, increasing regulatory burden and consequent resource cost of bringing new medicines to market. Recent announcements by major players show that the corporate rationalisation is by no means over. This

"… two-thirds thought 2008 had been worse than expected…"

is born out by the increased pessimism shown in figure 3, in which almost 60% of respondents believe 2009 will be a more difficult year than 2008, which itself was perceived as substantially worse than 2007.

The modest revenue growth in established markets has led to companies looking to expand into the markets with the perceived greatest potential. Both Pfizer and GSK have

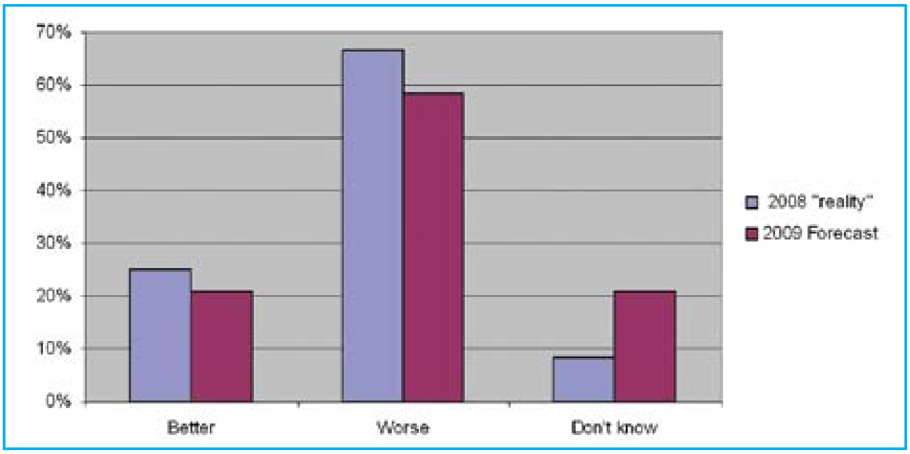

Fig. 3 Predictions for 2009 compared with actual performance from 2008.

"… there is [little] support available for building robust, commercially focussed [biotech] companies capable of generating substantial revenues…"

announced major initiatives to drive growth in the pharmerging markets. The size of the potential emerging markets over the next decade ($300 billions by 2017, equivalent to US plus five largest European markets today) makes the case compelling. Bayer, AstraZeneca and Novartis are also piloting innovative approaches in these markets.

So far, this analysis has not identified any differential impacts between pharmaceutical and biotech companies. But one area where the credit crunch has had a dramatic effect is in biotechs looking for funding, as potential investors take a more cautious approach to risk. The general view is that market funding will be severely limited until next year, at the earliest. With big pharma always on the lookout for potential, there may be some good in-licensing deals to be done. Fortunately, in recent years there has been some evolution of the traditional 'big pharma gobbles little biotech' endgame. 'Externalisation' now includes out-licensing, spinouts and risk-sharing possibilities, plus traditional mergers and acquisitions.

However, a recent report by a combination of biotech and venture capitalists has identified limitations in the role of government funding biotechs. While there is ready funding for start-ups, there is less support available for building robust, commercially focussed companies capable of generating substantial revenues, who would, in their turn, form the next generation of mature companies.

This differential impact on the biotech sector somewhat gives the lie to last year's survey finding that biotechs appeared more positive about the future than pharma companies. Their new-found confidence may prove short-lived if the only growth path available is as part of a major pharma looking to shore-up its product portfolio. Indeed, this year's respondents bear this out. Among pharma respondents, the distribution of "better", "worse" or "don't know" is more-or-less unchanged compared to 2008, whereas biotechs are considerably more pessimistic.

"While the outlook does not generate much short-term optimism, it is considerably better than many other sectors."

Future directions & open questions

IN CONCLUSION, PHARMA appears to have been less immediately affected than other sectors because it has been going through a period of modest growth, accompanied by ongoing rationalisation for some years prior to the events of late 2008. The sector has suffered none of the downside from the 'exuberance' that has affected the financial markets over the past several years. The industry's long planning horizons and cautious approach to risk may have seemed unduly conservative a few years ago; but not now. While the outlook does not generate much short-term optimism, it is considerably better than many other sectors.

In these uncertain times, there are inevitably some questions that will have to remain open until next year's survey, such as what impact will the Obama administration have on our industry? The laudable drive towards widening the availability of medicines through Medicare could boost sales, but probably at the expense of margin. Will Western Europe lose out on R&D investment to newer centres like India? It is still too early to tell what the long-term impact of Satyam's collapse (India's Enron scandal) will have on confidence in corporate governance and its consequences for inward investment. Similarly, was the Mumbai bombing atrocity an isolated incident?

Through 2009, it appears that remorseless forces are gradually reshaping the industry and will continue to tighten their grip. In the meantime, the emerging markets are held out as the likely engines for future growth, which may in time draw R&D expenditure away from Western Europe to be closer to local markets. But, then again, who'd be in the forecasting business right now?

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