Making Pharma Sector Investment More Attractive: Why the Business Model Needs to Change

Presentation to ITMAT Symposium
May 5-6th 2006
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Appearances not what they seem

Healthy underlying fundamentals:
- aging population,
- increasing disposable incomes,
- new markets opportunities in the BRICS,
- medical advances
- continued potential of genomics

So why do growing number of institutional investors believe current pharma business model faces inevitable, fundamental change?
Leadership of Big Cap global pharmaceutical companies is under growing pressure:

- Patent expiries
- Low R&D productivity
- Risk averse regulatory environment
- Price pressure
- Lack of trust
Patent Expiries
(US majors hit hardest)

% of 2005E pharma sales at risk of US generic competition between

Sanofi-Aventis receives a profit share on drugs with a US patent expiry betwe
We plot US patent expiry exposure using 2005 US sales of these drugs as a p
of 'developed' pharma sales (ie end-user sales).

---- Error bars show extent of worst case generic threat

Source: Lehman Bros Estimates
Innovation remains illusive

In 2005 of 18 NME approvals < ½ developed by EU or US majors (compared to 31 in 2004)

Source: Lehman Bros Estimates
Increasingly risk averse regulatory environment

Tufts Study Nov/Dec 2005 Findings:

- Trials are longer, larger and more complex – made worse post-Vioxx
- Requirements for PIV monitoring increasing – 3/4s new drug approvals 1998-2004 have mandatory post-marketing studies (25% increase over previous 10 years)
- Northwick Park trial, UK
Continued **downward pressure on health budgets** everywhere

- Europe – expressed as price cuts, reference pricing, generic competition and cost-effectiveness evaluations
- US – Medicare likely to lead to initial volume sales increase, but this could be completely off-set by discounts and rebates by 2008
- Japan – flat sum reimbursement and increase in co-pays flattening market
Continued **downward pressure on health budgets** everywhere

- Emerging Economies – Chronic diseases increasing: diabetes, CVD, asthma, Increase in pressure for “affordable” patented treatments from middle classes. Growth in HIV/AIDS in India and China.

- Developing and LDCs infectious diseases needs remain unmet, chronic diseases also increasing. Political pressure sustained, if not more acute.
Trust Eroded in Sector with Unique Social Contract

New Realities – Among Other Industries Pharma’s Reputation Has Fallen the Most

Percentage of those surveyed who think industry is doing a good job serving their customers

*When it comes to reputation, pharmaceutical companies’ star has fallen*

Source: Harris Interactive Survey from PricewaterhouseCoopers report *Recapturing the Vision: Integrity Driven Performance in the Pharmaceutical Industry*
And eroded trust leads to vicious circle:

Contributes to:

- Greater risk aversion on trials
- Increase in demands for price cut
- Further scrutiny of value for money
- More questions about innovation, etc.
Blockbuster: From source of strength to source of vulnerability?

1. Over-reliance on a small number of drugs + limited prospects of newcomers has led even leaders in the industry to:
   - seek to stave off losses on patent expiry by fierce patent defence
   - sharp price rises
   - aggressive marketing strategies

Net effect = further erosion of trust
Blockbuster: From source of strength to source of vulnerability?

2. Distraction Risk: pressure to maintain margins could detract efforts from where they are needed. Could this pressure be the proverbial fiddle being played while Rome burns?
Will model prove agile enough to adapt to challenges?

- Innovation - Does blockbuster marketing deprive research of funding?
- Personalised medicine – does blockbuster marketing model work for more targeted meds?
- Developments in diagnostics, prevention and monitoring
- What about access needs in poor countries which remain largely unmet?
- What about urgent need for new antibiotic research?
- New players from emerging economies (with views on IP)
- New Disruptors – PPPs
- Newly knowledgeable consumer and payers advocating
  - More and better R&D,
  - More value for money (questioning me-toos)
  - demanding better studies of side effects.
Pharma Futures conclusions:

- Change is inevitable for the industry: Muddling through and fire-fighting is not an option.
- Industry needs to change strategy towards regulators, government, patients and once again become a trusted partner.
- Requires investors and industry to change to achieve a better alignment of health and shareholder needs
So what about the Investors?

Pension funds are part of a system which encourages a short-term focus on EPS with knock-on consequences
Impact of short-termism

“Over time, analysts have become obsessed with the question of whether a company meets its quarterly EPS numbers, and not with whether a company is built to last...The focus on short-term results has, I believe, had a counter-productive influence on companies, on investors and on analysts themselves.”

William Donaldson
Former Chairman, SEC
CFA Institute Annual Conference 2005

Survey of over 1,000 directors (global): More than half admitted to having only a "limited" understanding of where the company's long-term objectives would position it in five to ten years

McKinsey & Co
2005 Special Edition
So what about the Investors?

But …

Pension funds are also institutions with an interest in the long-term well-being of the sector
Long-term interest in the sector: Pharma Futures

Investor-led dialogue. Pension Funds with a long-term interest in the sector which want to:

- Work with industry to identify ways to complement traditional risk management tools (bottom-up stock-picking or underweighting the sector).
- Incorporate long-term and extra-financial considerations into research processes.
- Develop metrics and analytics to support investment and governance/engagement decisions to ensure durable value from pharmaceutical industry.
- Executive decision-making processes to be better aligned with long-term thinking and impact on shareholder value.
E.g. of Pharma Extra-financials

New filters to evaluate investment relevance of issues relating to innovation, including:

- Remuneration system better linked to progress in pipeline value creation
- Regulatory shift from placebo to gold standard
- More sophisticated metrics on R&D capital allocation and marketing v. R&D
- What is not done – antibiotic research
E.g. of Pharma Extra-financials 2

Regulation

New filters to evaluate investment relevance of changes to regulatory environment, e.g.

- Pressure for independent PIV data collection
- Consequences of Cox-2 debate (including greater disclosure of clinical trials & shift to comparison with gold standard)
- Ways of integrating post-marketing studies on drug safety into sales revenues models
Extra-financials – Emerging Markets

New filters to evaluate investment relevance of issues in emerging markets, e.g.

- The fact that 80% of world population still without access to Big Pharma’s products, including assessment of opportunity (foregone) and risk (political backlash)

- Growing v. static markets – Future growth potential lies with new patients with new needs in emerging markets
Conclusions

- A growing number of institutional investors convinced that current pharma business model faces fundamental change
- Pharma execs also beginning to see this
- Short termism in a sector with 12 year R&D lead time is absurd
- Number of projects recognising need to identify and measure extra-financials increasing
- … It has only just begun…