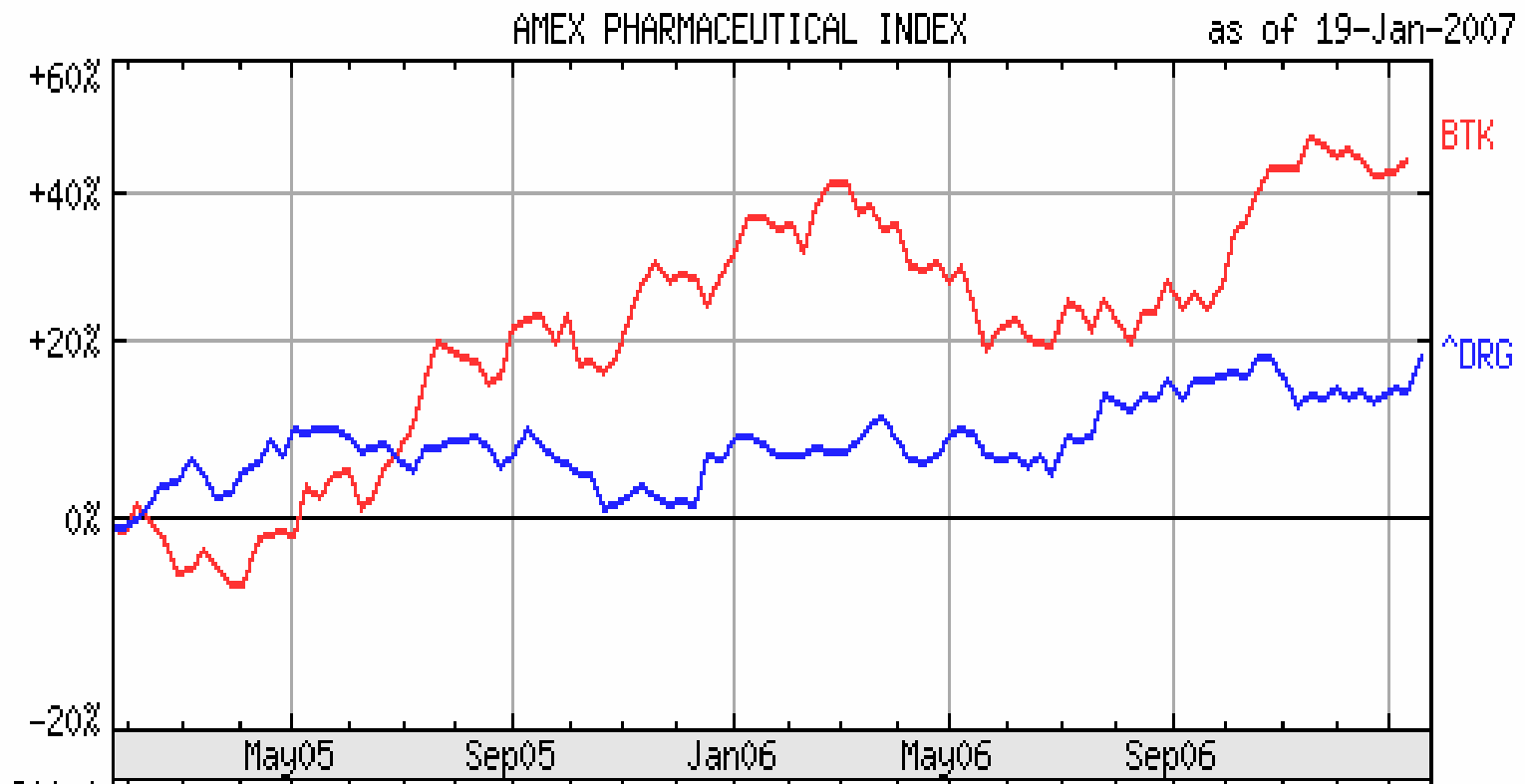


The Rx Dilemma: Searching for the Grail

**June 21st, 2007
EphMRA conference**

The Perceived Value is Real

The Biotech Index has grown at twice the rate of Pharmaceuticals



Biotech 2006

Half a trillion \$ and growing at 19% per year

	<u>US</u>	<u>Europe</u>	<u>Asia</u>	<u>Canada</u>
Sales	\$72B	\$12B	\$3B	\$2B
Number of Companies	1500+	1600	700+	470
Number of Employees	146,100	68,000	12,000	7,740
Number of Public Companies	363	120	140	81
Market Capitalization	\$491B	\$26B	\$15B	\$14B

Source: Burrill and Company

The Rx Dilemma

The problem is companies are reaping what they sowed

- Consolidation has created inertia, a climate that doesn't foster innovation and has created impossibly high hurdles
 - Phase III failure rate increased to 50%, compared to 35% a few years ago
 - Approximately \$50B of 2005 revenue must be replaced by 2010
- Integration of medicinal chemists and molecular biologists has been difficult
 - Only 18 NMEs were approved last year
 - A fact that drove the \$20B in partnering deals last year.
- Resource attraction and retention will become increasingly difficult with the flight of capital and the reality of down-sizing
 - As goes Pfizer.....

Looking for the Grail

But what is IT?

- IT is the next great thing
 - The molecule, protein, device, diagnostic, combination or approach that will:
 - Address an unmet need
 - Fill a hole in the pipeline
 - Expand the market
 - Develop a new franchise
 - The next new business model
 - A partnership, a deal or a collaboration that might/could/should/will result in new competitive advantage and value
 - The next untapped geography, population or market

Implications and Ramifications

What does IT mean to the BioPharm industry?

- New R&D facilities in non-US and non-European venues
 - In 1997, Novo led the way into China
 - Roche has built its 5th R&D center in Shanghai
 - In 2004, there were more than 600 and the number is over 750 today
- Global clinical trials with an estimated 25% conducted India and China by 2012
- A “relocated” zenith in stem cell research (China, Singapore and South Korea)
- A new, larger NCE engine (India)

Implications and Ramifications

Most importantly, what does IT mean to us?

- The opportunity is to develop perspective, opinion and expertise to help guide companies and clients through:
 - New regions (e.g. China, India, South America, Eastern Europe, etc.)
 - New technologies (e.g. Cell therapy, iRNA, nanotechnology)
 - New collaborations (e.g. academic agreements on a global scale)
 - New business models (e.g. globalization of R&D)
- The need is to extend our thinking, networks and models to include these new approaches

Degussa's China strategy

“The issue of risk is enormously overestimated”

Utz-hellmuth Felcht, Chairman, Degussa

Looking for the Grail

Where do you find IT?

- First there are the *Usual Suspects*: Buy, Acquire and Merge
 - Scaling -Mid tier consolidation in US, Europe and Japan
 - Bayer/Schering, Merck AG/Schwartz, Merck AG/Serono
 - Astellas, Daiichi/Sumitomo
 - Genzyme/AnorMED
 - Diversification – Big Pharma and Biotech rolling up Little Science
 - Genentech acquiring Tanox (a Mab company), Merck-Sirna (an RNAi company)
 - Gilead acquiring Myogen, a return to its Oncology roots
 - Biogen Idec acquiring Syntonix (hemophilia)
 - GlaxoSmithKline acquiring PRAECIS Pharmaceuticals (cancer treatments)
- However, increasingly, and opportunistically, it will come from new sources
 - Singapore is investing \$7.5B over the next five years in drug discovery, stem cell research, biomarkers, bioimaging and cohort studies
 - According to the OECD, China is now the second highest R&D investor, displacing Japan
 - We all know what India has done, but they also now have innovation squarely in their sights

What if.....

Pharma had large scaled-up R&D organizations in China and India?

- ROI extravaganza
 - Better(?) but definitely faster and cheaper: Cutting development costs by 50-65%
 - A new value proposition
 - What if the facilities were to scale on level of Harlow, Groton and West Point
- Turbocharged pipelines
 - Enhanced risk profile
 - Failing faster
- A research bonanza: what \$20 billion might buy
 - Stem cell therapy
 - Cell therapy
 - Novel science (e.g.Mono)



**Dr Jurgens Drews has predicted pharmaceutical companies will become sales and marketing organizations.
This is the chance to change that.**

Implications and Ramifications

Again, What Does This Mean to Us?

- The challenge for MR is that:
 - The usual data sources are either incomplete or MIA
 - Companies must invest to develop their own MI and CI either at a significant resource commitment or at a significant cost
 - As BioPharm takes a page from other industries, and becomes nimble and lean, they will depend, or demand, that agencies fill the gap
- Consider China
 - 1.3 billion people, 33 provinces, 5 regions, tiered hospitals, centralized systems and a drive to join the elite research ranks as a source of novel science
 - The questions we then have to wrestle with include:
 - Where are they spending and what are the key investment priorities?
 - What are the top trends, policies and mandates in delivery and reimbursement
 - How do you reach the “right” people (e.g. physicians, decision makers, influencers)?
 - How do we conduct interviews, focus groups and other primary research techniques, and what does statistically significant mean?

Looking for the Grail

Should you build It?

- The question of the ages.
- As we all know innovation takes longer, costs more and is less predictable in its uptake than ever before
 - Tufts says it takes, on average, 8 years of development and \$1.2 billions to develop the typical new biotech product
 - 66% of new products didn't break any new ground, rather they were "better sameness" and only 15% offer significant improvement
- However, Unmet Need remains high and opportunity, for the right "product", is there for the taking
 - The Unmet Need Score in Sepsis is still in the top 10, it has an underlying treatable patient pool in the millions and less than 20 products under development*
 - Where-as Hypertension has a much lower Unmet Need Score and over 60 compounds under development*

* Source: Decision Resources DecisionBase









The New Mantra

“Choosing Wisely” Has Never Been More Important

- As organizations realize they can't be all things to all people there is a shift (or a return) to a strategy of focus
 - Bayer sells diagnostics division to Siemens
 - Pfizer sells consumer healthcare division to J&J
 - Novo decides to end small molecule development
 - Novartis sells medical nutrition business to Nestle
 - BMS chooses select areas for strategic focus
- We believe the question about “Fit with Strategy” has never held more importance than when choosing, prioritizing or killing NCEs
- Every company says it wants to “develop medicines that address significant unmet need” but at the same time there is a shift towards rational portfolios
- For example our research shows that the top 10 oncology companies have shifted 50-80 % of their pipelines to targeted therapeutics

One Example

US Oncology Leaders 2000 and 2005

Company	2000 Rank	2005 Rank	Trend	Change
Roche/Genentech	4th	1st		+3
Amgen	3rd	2nd		+1
Novartis	6th	3rd		+3
GlaxoSmithKline	5th	4th		+1
AstraZeneca	2nd	5th		-3
Eli Lilly & Co.	7th	6th		+1
Bristol-Myers Squibb	1st	7th		-6
Abbott Laboratories	8th	8th		0

- Key attributes of the leaders:
 - Portfolio of several blockbuster or high-growth products.
 - Approximately 5 marketed products with at least 2 oncology blockbuster (>\$500 MM).
 - Significant R&D spend, usually well ahead of average.
 - Deep pipelines with more than 20 programs
 - Between 40% and 60% of pipeline is externally sourced

Implications and Ramifications

The Challenge to MR is Clear: New Skills and New Capabilities

- Tomorrow's requirements
 - More science: scinets vs docnets
 - Stronger ties to academic institutions globally
 - More geographies and languages: local recruitment and partners
 - More complexity, new models
 - More understanding of politics (geopolitics) and internationalism
- Implications for Market Research
 - More people and partners to cross the geographical and language barriers
 - More PhDs and/or scientific expertise to dig deep, quickly
 - More quants and modelers to understand and represent current and future dynamics
 - More management insight to deal with the inherent challenges, hurdles, questions and decisions that this type of demand will create or require

Looking for the Grail

Will they pay for It?

- This is the new billion dollar question or is it?
- The power has shifted and each of us must clearly understand the value proposition of our products to our payers
 - But first we need to know, and understand, who the payers are
 - And, with new demographics and rules, the old models wouldn't work
- Although purely novel products that fill a significant or long standing need (e.g. Rituxan, Avastin and Gleevec) can command high prices and immediate use today the question is about sustainability
 - With 450 oncology compounds in Phase I, a product with a \$40,000 annual price point will be a dinosaur
- If the cost structures and talents of China and India can drive the pipelines at 1/3-1/2 the cost, a new economic model emerges and a new value proposition must be accepted

Implications and Ramifications

Market Research's New Charter

Develop global perspective and reach,
Predict the future,
Identify products that will fill a known need,
Steer them to rapid approval and
Outline the path to payment.

What could be easier?