



The Commercial Value and Importance of Biomarkers

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Proteome Sciences delivers biomarkers, technologies and services to the pharmaceutical, diagnostics and life sciences sectors to improve disease management, treatment and patient outcomes

- Time
 - Typically 12-13 years to bring drug to market
- Cost
 - Average cost of a new drug approval approaching \$2bn
- Risk
 - 92% of drugs fail before launch
 - Less than 1 in 3 pay back R&D cost
 - Most drugs work only for a minority of patients

Challenge – To make safer, more effective drugs quicker and cheaper

So the pharmaceutical industry needs to change?

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Big Pharma's leaky pipeline

Merck, Amgen, Lilly have some of the most significant pipelines in the industry and some of the most significant problems.

By Aaron Smith, CNNMoney.com staff writer
February 1 2008: 2:45 PM EST

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Services

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Successfully developing innovative drugs and enhancing research & development productivity

Deloitte.

Life Sciences & Health Care

The Changing of R&D in the Pharmaceutical Industry

Big Pharma : Dramatic Decline in R&D Productivity

Attrition Remains Very High

10-15 Years

Source: PHARMA, CMR, Gene

Output Not Keeping Up With R&D Expenditures

Global ethical pharmaceutical R&D expenditure, NME output and sales (1994-2003)

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BBC NEWS

You are in: Business

Wednesday, 20 November, 2002, 15:37 GMT

Drug firms 'must change - or die'

See also:

- 22 Oct 02 | Business
- Dr Reddy eyes landmark drug win

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Can pharma innovate fast enough to survive?

Nuala Moran

Biomarkers in Healthcare

- Concerns over drug safety, efficacy and costs are the key drivers for personalised medicine
- Improving predictability of pre-clinical and clinical research will significantly reduce development time and costs
- Selecting the right patient and monitoring their progress based on biomarkers will increase efficacy and safety and be the common feature for all personalised therapies
- Additionally biomarkers will provide a new generation of *in vitro* diagnostics
- Until now discovery and validation of biomarkers was slow and expensive – barrier to adoption by pharma

Biomarkers are crucial to these processes and ProteoSHOP® can now provide fast, flexible and cost effective solutions

Impact of TMT® for biomarkers

- Biomarker discovery and qualification is revolutionised with isobaric Tandem Mass Tags® (TMT®)
- Access to rapid discovery and development of assays for biomarkers reduces the process from years to weeks
- Simultaneous measurement of hundreds of peptide and protein biomarkers
- Single integrated platform technology for biomarker discovery, validation and assay development
- Radically reducing time and cost of biomarker validation

TMT® – Making personalised medicine a reality

Commercial benefits of biomarkers

- Average cost reduction \$420 Million per project from earlier Go/No-Go decisions
- Shorter development times and faster approvals gives longer usable patent life and substantially improved returns on investment
 - For Pfizer's Lipitor an extra year of sales under patent = \$10bn
- Added value through companion diagnostics
- Further enhanced by establishment and adoption of standards based on TMT® reagents and workflows:

“Standards provide the foundation for increased integration and collaboration, and thus play a major role in accelerating development and validation of biomarkers”

- 2007/8 has been transformational for our company
- Leading innovators in biomarker discovery and validation
- Broad high value applications with TMT® accepted by industry – limited global competition
- Granting of key TMT® patents in Europe and US
- Licensing of TMT® to Thermo Scientific will provide long term revenue from catalogue sales – healthcare, life sciences, environmental, food, biotechnology
- Custom applications of TMTcalibrator™ and TMT Reference Materials™ retained ‘in house’
- Mass Spectrometry moving into mainstream clinical diagnostics
- **TMT ® and ProteoSHOP® solutions will have a profound effect across drug development, disease management and advances in personalised medicine generating sustainable revenue**