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Keywords: *fully integrated and emerging biotech companies, genomics*

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Marketspace

Key financial trends that shape biotech business growth

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Date received: 29th October, 2004

Abstract

Datamonitor analysis has identified two key company categories currently shaping the biotech industry: the leading biotherapeutics players and the emerging biotherapeutics players. Analysis of financial trends of companies in these categories from 2001–2003 has revealed that, despite strong revenue growth recorded by the leading biotherapeutics players, highly variable cost bases strongly affected net profits. Conversely, the emerging biotherapeutics players saw a decline in revenue growth, due to a reduction in collaboration or licensing revenue. Both leading and emerging biotherapeutics players strongly increased R&D spend over this period. Future growth of the leading and emerging biotherapeutics sectors will be driven primarily by M&A/licensing agreements, and in-house pipeline development driven by continued strong R&D spend.

INTRODUCTION

After nearly three decades of biotechnology funding cycles, the industry is undergoing a fundamental change that will necessitate the creation of radically new business models. Biotechnology's *vertical model* is representative of the business created by the leading or fully integrated biotech players (market cap recorded in October 2004 ranging from US\$3.6 to US\$72bn). It consists of an integrated organisational structure with access to independent development, manufacturing and marketing capabilities.

Datamonitor has also identified a second group of companies led by ten emerging biotherapeutics players (market cap recorded in October 2004 ranging from US\$0.8 to US\$1.7bn) which are attempting to advance their pipelines based on their in-house developed innovative technological platforms (eg antibodies, oligonucleotides or small molecules). However these companies are not able to independently market or fully

develop any of their lead products. Sales and marketing capabilities, together with strong revenue growth is what determines investor confidence and funding, two of the key factors in determining stock performance. (Figure 1).

FINANCIAL TRENDS FROM THE LEADING PLAYERS Income and R&D investment analysis

Total revenues from the top ten biotech companies increased from US\$12.3bn in 2001 to US\$21.4bn in 2003 (Figure 2). The largest revenue increase in terms of absolute sales was generated by the market leader Amgen, driven by its leading recombinant therapeutic proteins Aranesp (darbepoetin alfa), Neulasta (pegfilgrastim) and Enbrel (etanercept). Genentech recorded the second largest 2003 revenues, due to strong oncology franchise growth, driven by its therapeutic antibody Rituxan (rituximab). Amgen recorded the second strongest revenue compound annual growth rate (CAGR) during 2001–2003, behind Gilead.

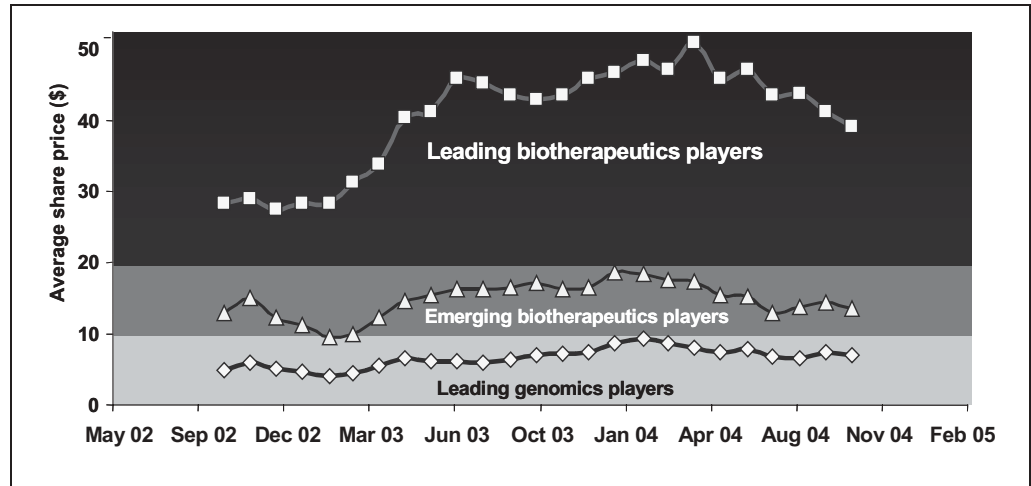


Figure 1: Stock performance of the biotech industry’s three main waves of leading players. Ten leading biotherapeutics players: Amgen, Genentech, Serono, Biogen IDEC, Genzyme, Chiron, Gilead, MedImmune, Millennium and ImClone. Ten leading emerging biotherapeutics: Abgenix, Alexion, Cambridge Antibody Technology (CAT), ICOS, ISIS, Medarex, NPS, Protein Design Labs (PDL), Tanox, Vertex. Ten leading genomics players: CuraGen, Gene Logic, Celera Genomics, deCODE genetics, Exelixis, Incyte, Human Genome Sciences, Nuvelo, Lexicon, Sequenom
 Source: Datamonitor, company reports, Reuters and EDGAR online

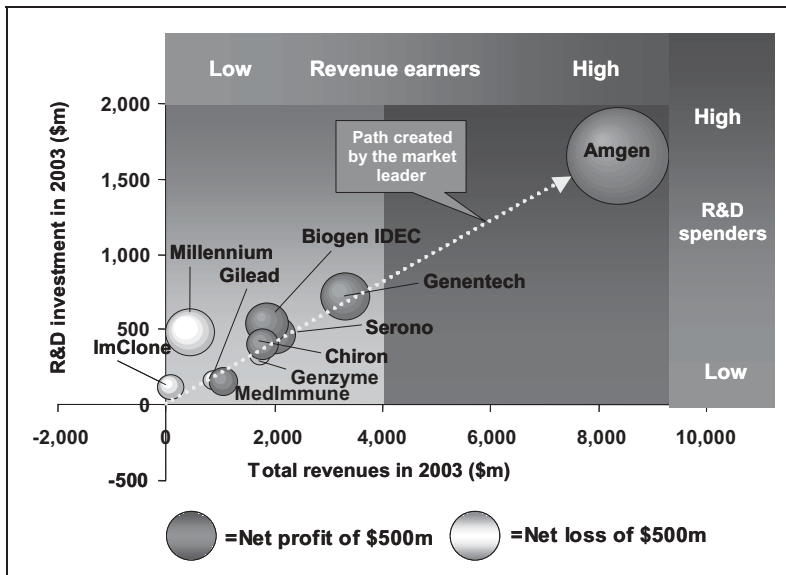


Figure 2: Positioning of the top ten biotech companies in terms of revenues, R&D investment and net profit or loss recorded in fiscal year 2003

Note: Bubble size indicates net profit or loss
 Source: Datamonitor, company reports, Reuters and EDGAR on line

Gilead’s revenues were driven by rapid market uptake of Viread (tenofovir disoproxil fumarate), the company’s leading product. Revenue growth across the top ten biotech companies was driven

by a small number of key growth drivers in each company such as MedImmune’s Synagis and Genentech’s Rituxan, in addition to those already mentioned. Additional growth was driven by increases in royalty revenue.

Owing to highly variable cost bases, net profit recorded by the top ten biotech companies was more unpredictable. For example, Amgen recorded a net profit of US\$1.1bn in 2001, a net loss of US\$1.4bn in 2002 and a net profit of US\$2.3bn in 2003. The company’s net loss in 2002 was primarily related to the US\$3bn write-off related to the acquisition of Immunex. Genentech, which recorded the strongest net income CAGR from 2001 to 2003 also recorded relatively low 2002 net profit, owing to the company recording US\$540m litigation-related special charges, primarily related to the City of Hope litigation judgment over royalties associated with the development of recombinant protein products. Despite the unpredictability in net income, total top ten biotech company net profit rose at a CAGR of 29.3 per cent from US\$2bn in 2001 to US\$3.3bn in 2003.

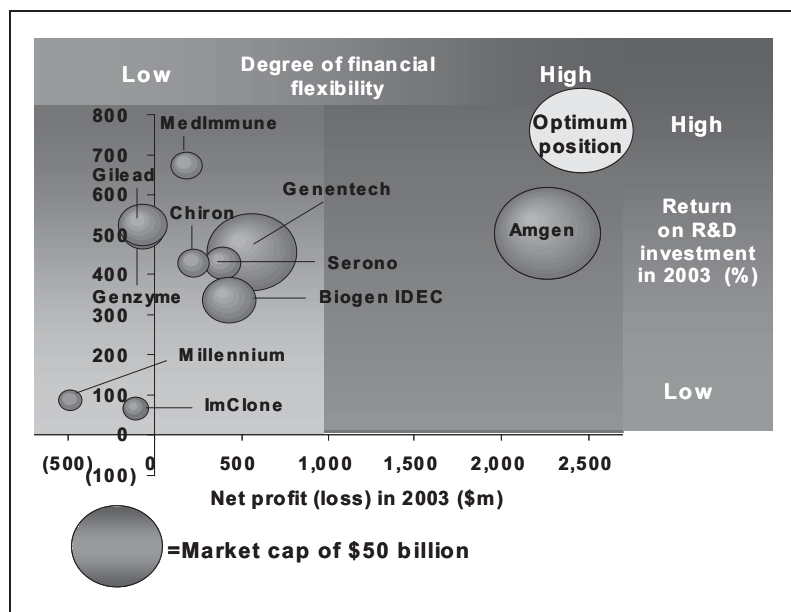


Figure 3: Positioning of the top ten biotech companies in terms of market cap, return on R&D investment and profit or loss recorded in fiscal year 2003. Note: Bubble size indicates market capitalization
Source: Datamonitor, company reports, Reuters and EDGAR online

Total R&D investment from the top ten biotech companies grew at a CAGR of 21.1 per cent from US\$3.5bn in 2001 to US\$5.1bn in 2003. With the exception of Gilead, all of the top ten biotech companies increased R&D expenditure from 2001 to 2003. Amgen's R&D spend accounted for almost a third of total top ten R&D spend, driven by life-cycle management-related R&D costs and higher licensing costs and milestone fees as part of collaborative R&D deals. Behind Amgen, Genentech and Serono both increased R&D expenditure by US\$160–200m from 2001 to 2003. This was related to similar life-cycle management and collaborative R&D costs, and the clinical development of Raptiva for launch in Europe, respectively. These trends were replicated through the remaining top ten biotech companies, exemplified by deals such as MedImmune's June 2003 payment to Critical Therapeutics for access to new data and technologies. New product development also accounted for significant R&D spend, with the development of new products such as GS-

7340, together with clinical trials and lifecycle management of marketed products, contributing to Gilead's 22.3 per cent increase in R&D spend from 2002 to 2003, as part of the company's strategy to drive up R&D spend following a significant drop from high 2001 spend.

When attempting to map the top ten biotech firms in terms of net profit/loss (fiscal year 2003), return on R&D investment (the ratio of revenues to R&D costs in fiscal year 2003) and market cap (recorded in October 2004), Amgen emerges as the group's leader. Amgen has the strongest combination of profit volume, high degree of return on R&D investment (RoR&D; 505 per cent or revenues more than five times higher than R&D costs) and is positioned closest to the optimum strategic position (highest degree of financial strength and flexibility and the highest level of RoR&D). On the other hand, although there are a number of players such as MedImmune, Genzyme and Gilead with higher RoR&D (compared to Amgen) they either recorded losses (Genzyme and Gilead) or very low profit (MedImmune).

In addition, a number of therapeutic protein or antibody biotech leaders such as Serono, Biogen IDEC, Chiron and Genentech are clustered together reflecting a number of similarities in their business model structure and financial state. However, Genentech, mainly because of its stronger revenue growth and world-leading expertise in innovative anticancer biotherapeutics (Rituxan, Herceptin and Avastin), carries the second largest market cap (US\$51.4bn recorded in October 2004).

FINANCIAL TRENDS FROM THE LEADING EMERGING PLAYERS

Income and R&D investment analysis

During the period 2001/2003, the group of the ten leading emerging biotherapeutics players (in terms of

market cap recorded in October 2004) saw their total revenues (which are mostly derived from R&D collaborations and out-licensing agreements) significantly declining from US\$528m in 2001 to US\$337m in 2003. ICOS was the leading income earner with 2003 revenues of US\$75m followed by Vertex with US\$69m and Protein Design Labs (PDL) with US\$67m (Figure 4).

Similarly with their group's revenue declining revenue trends recorded between 2001 and 2003, the three leading emerging drug developers demonstrated a continuous revenue fall indicative of licensing and collaborative business consolidation. The latter may also signal that potential fully integrated biotech and pharma partners have become increasingly cautious, having faced technological constraints, and/or pipeline failures.

Despite their falling revenues, the ten emerging biotherapeutics developers increased their R&D investment to support pipeline expansion from US\$692m in 2001 to nearly US\$1bn in

2003, almost three times their revenues earned during the same year.

In 2003, Vertex was the leading innovation spender with an R&D investment of almost US\$200m, followed by NPS Pharma with US\$118m and the antisense expert ISIS with US\$117m. Other emerging players with strong R&D investment growth were CAT, which saw its research expenses more than double from US\$32m in 2001 to US\$75m in 2003 (signalling the company's attempt to grow its human antibody pipeline), followed by another antibody developer, PDL, which also saw its R&D spend increasing from US\$52m to US\$83m (Figure 4).

The significant revenue decline is also responsible for the group's inability to record profits in 2003. More specifically, in 2003 the ten players recorded a total loss of approximately US\$1.2bn, almost four times the group's revenue volume. The company with the heaviest losses in 2003 was the small molecule developer Vertex with US\$197m followed by the human antibody expert Abgenix with US\$196m, NPS Pharma with US\$170m, PDL with US\$130m and another human antibody developer, Medarex, with US\$129m.

When attempting to position the emerging biotherapeutics players in terms of net loss, proportion of revenues to R&D investment achieved in 2003 and market cap recorded in October 2004 (Figure 5), it appears that there are three groups of business models. The first group includes three firms PDL, ICOS (which carry the largest market caps within the group) and Tanox, which have recorded the highest revenue to R&D costs ratios, followed by ISIS and Vertex and a third group with similar market caps but different levels of 2003 losses (varying from US\$70 to US\$200m), which includes five antibody developers CAT, Alexion, Medarex, Abgenix and NPS Pharma.

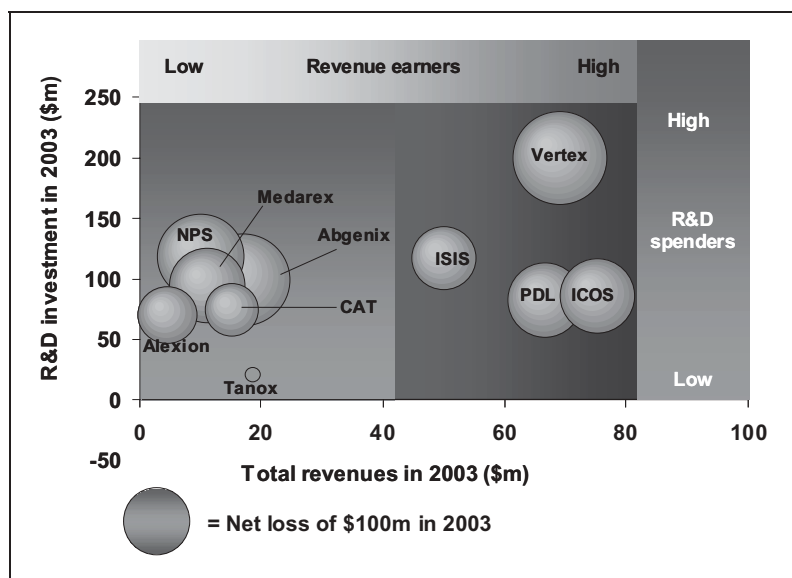


Figure 4: Positioning of the leading emerging biotherapeutics companies in terms of revenues, R&D investment and net profit or loss recorded in fiscal year 2003

Note: Bubble size indicates net profit or loss

Source: Datamonitor

CONCLUSION

The success of mergers and acquisitions/ licensing agreements and current in-house

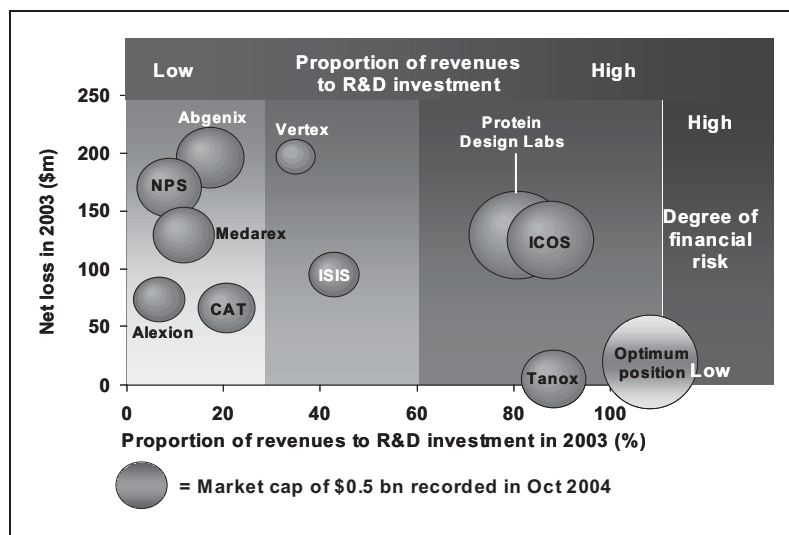


Figure 5: Positioning of the leading emerging biopharmaceutical companies in terms of revenues, R&D investment, market cap and loss recorded in fiscal year 2003

Note: Bubble size indicates market cap

Source: Datamonitor

pipeline development initiatives will decide the degree of evolution for both the leading and emerging biopharmaceuticals business models. Despite the goal of moving closer to sustainable profitability in the long term, the emerging sector is likely to face significant challenges related to manufacturing or regulatory complexities. Consolidation activity is expected to move the emerging companies closer to full integration and potentially to sustainable profitability.

It is Datamonitor's view that intrabiotech or bio-to-pharma deals and commercially attractive technology acquisition activity should help to win the race of innovation and sustainable growth. Clearly, this is and will always mean the survival of the fittest.