MARKETSPACE

Leading therapeutic recombinant protein sales forecast and analysis to 2010

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Abstract

As part of Datamonitor's biotechnology strategic market analysis, the authors have performed an analysis of the top 20 therapeutic recombinant proteins (defined by 2010 forecast sales), providing a forecast from 2004 to 2010 of product sales by therapeutic and product class. Based on this analysis, which was conducted in June 2005, leading companies operating in this sector are identified. Market analysis indicates that the total compound annual growth rate (CAGR) of these products from 2004 to 2010 is set to be 7.7 per cent, which is lower than other biotech markets such as the monoclonal antibody market. This lower growth rate reflects the mature nature of the therapeutic recombinant protein market. The arthritis, immune and inflammatory disorders franchise is set to record the strongest growth, with a forecast 2004–10 CAGR of 16.8 per cent, while the diabetes and endocrinology franchise is set to record the weakest growth (1.6 per cent). The leading product class in terms of total forecast 2010 sales is the erythropoietin class, which is set to generate approximately one-third of total top 20 product sales. The strongest-growing product classes are set to be fusion protein and colony-stimulating factors, while insulins are forecast to be the weakest-growing sector. Amgen is set to continue to lead the recombinant protein market over the forecast period, with the company's contribution to top 20 recombinant protein market sales set to rise from one-third of total 2004 sales to one-half of total 2010 sales.

Keywords: *therapeutic recombinant protein, biotech market analysis, oncology, erythropoietin, Amgen*

INTRODUCTION

Products launched under the umbrella of the biotechnology market broadly fall into four key categories: therapeutic recombinant proteins (rDNA proteins), monoclonal antibodies (mAbs), therapeutic vaccines and nucleic acid therapeutics (DNA/RNA therapies). Of these categories, rDNA and mAb products are the leading classes in terms of total forecast sales, with products from these classes set to account for at least 90 per cent of total biotechnology market sales by 2010. Blockbuster revenue has played a key role in the establishment of all biotechnology markets and leading companies operating in these markets, and future growth of both the rDNA and mAb sectors is set to continue to rely strongly on blockbusters. Datamonitor's biotechnology analysis team has therefore analysed and constructed sales forecasts for the leading rDNA products, in terms of product class, therapeutic class, together with the leading biotech/pharmaceutical companies operating in this sector.

Total sales generated by the top 20 products in terms of 2010 forecast sales were US$29bn in 2004. Sales are forecast to rise to US$45bn by 2010 – a compound annual growth rate (CAGR) of 7.7 per cent. This is relatively low compared with the explosive 2004–10 CAGR of 19.8 per cent for the mAbs sector, and reflects the fact that the rDNA market is entering a maturation stage. This stage was reached in 2002 and it is the latest part of the market's evolution. It is the third phase of market growth, which kicked off with an innovation and business generation phase (1982–1991), distinguished by the evolution of bacterial to mammalian-based protein production systems and formation of early biotech business models. This phase was followed

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by a business expansion and market capture phase (1992–2001), characterised by manufacturing standardisation and the establishment of a multi-indication and multi-class environment. The mature stage is characterised by low degree of innovation relative to the other two phases, with life-cycle management and strategic marketing dominating expenditure on rDNA products.

SALES BY THERAPY AREA

Sales generated by the group of top 20 rDNA proteins can be split into eight therapy areas from 2004 to 2010, as demonstrated in Figure 1. Biotechnology products are primarily centred on the oncology and AIID (arthritis, immune and inflammatory disorders) franchises, and this trend is mirrored by the group of leading 20 rDNA proteins. Oncology products generated the greatest percentage of sales in 2004 (36 per cent of total sales) and this franchise is set to retain this position in 2010 (35 per cent of total sales). However, it should be noted that since anaemia products are grouped in this franchise (as the majority of product usage

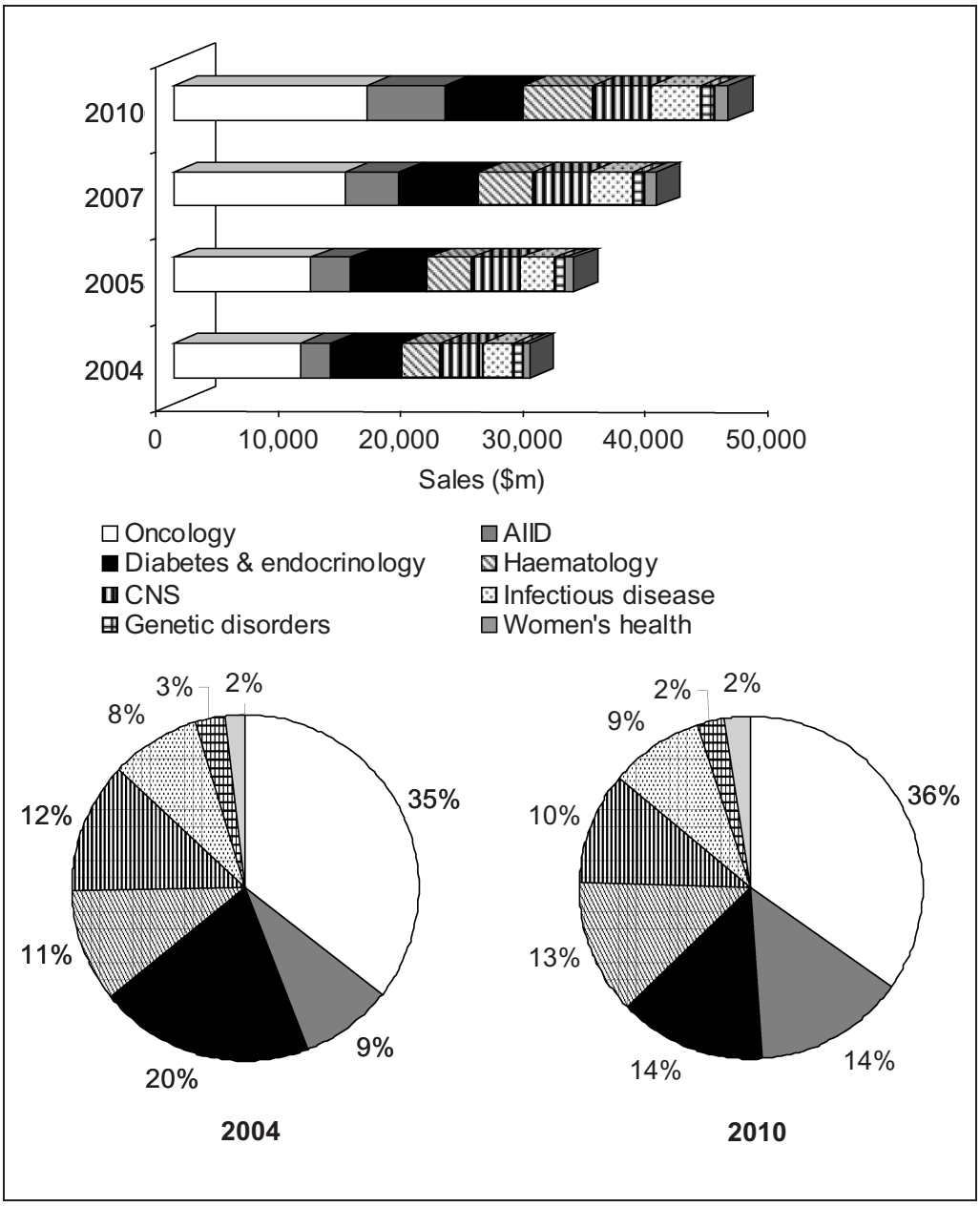

Figure 1: Sales forecasts for top 20 rDNA proteins, split by therapy area (AIID = arthritis, immune and inflammatory disorders; CNS = central nervous system)
Source: Datamonitor, company-reported information

is for chemotherapy-related anaemia), oncology sales are artificially high, since some sales are related to the treatment of dialysis-related anaemia.

Although Amgen's Enbrel (etanercept) is the only AIID product in the top 20 rDNA product class, the product's recent string of approvals and strong uptake across a range of autoimmune disorder indications will power strong franchise growth. Indeed, AIID is set to record the strongest 2004–10 CAGR (16.8 per cent), making it the second-biggest franchise by 2010. Together, oncology and AIID sales are set to account for approximately one-half of total top 20 rDNA product sales by 2010.

The diabetes and endocrinology franchise is driven by insulins and growth hormones and is set to be the third largest franchise in 2010, down from its 2004 position as second largest. This decline is because the franchise is heavily dependent on mature, first-generation rDNA products that compete in a relatively saturated market. For this reason, this franchise is set to record the lowest growth with a forecast 2004–10 CAGR of only 1.6 per cent. Forecast sales generated by the remaining therapeutic classes are set to account for approximately one-third of total 2010 sales. With the exception of CNS, which has three products, these franchises are dominated by one or two lead products – for example, the genetic disorders franchise is powered solely by Genzyme's Cerezyme (imiglucerase).

SALES BY PRODUCT CLASS

Despite the low number of product approvals (no more than six between 1982 and 2003), the erythropoietin class is set to be the undisputed leader, in terms of 2010 forecast sales (Figure 2). With 2004 sales of more than US$10bn, this franchise has a high sales base in 2004, therefore the 2004–10 CAGR of 7.3 per cent is slightly below the total top 20 product growth. Forecast growth is powered by very strong sales of Amgen's Aranesp (darbepoetin alfa), based on the product capturing significant US and European market share.

The second-largest sector in 2004 was the interferon market, and this sector is expected to retain its position through to 2010, despite a relatively low 2004–10 CAGR (6.9 per cent). Interferons primarily focus on the treatment of CNS and infectious disease conditions, such as multiple sclerosis and hepatitis C respectively. Both fusion proteins and colony-stimulating factors are expected to experience strong growth (2004–10 CAGRs of 16.8 and 13.5 per cent), based on strong performance of Amgen's products Enbrel and Neulasta (pegfilgrastim). For similar reasons to the sluggish forecast growth of the insulin franchise, the diabetes and endocrinology therapeutic sector is set to record a low 2004–10 CAGR of 1.5 per cent)

LEADING rDNA COMPANIES

Amgen was the undisputed market leader in the rDNA market in 2004 (Figure 3). Four of the top 20 rDNA products were developed and marketed by Amgen and accounted for approximately one-third of 2004 sales. Sales from Amgen's four products are set to consolidate the company's position, by generating approximately one-half of total 2010 sales. Central to Amgen's dominant position over the forecast period is the company's strategy of constructing a series of tailored marketing strategies to ensure maximum penetration of new markets and minimal cannibalisation of its own products.

Following Amgen, the remaining top 5 companies in the rDNA top 20 market are Roche, Serono, Novo Nordisk and Johnson & Johnson. Roche is positioned as the leading global bio-oncology company, although this position is primarily based on its monoclonal antibody and small molecule therapeutics. Its forecast position as the second-strongest rDNA company (based on forecast 2010 sales) is dependent on its hepatitis product Pegasys (PEG-interferon alpha) and, to a lesser extent, its anaemia product

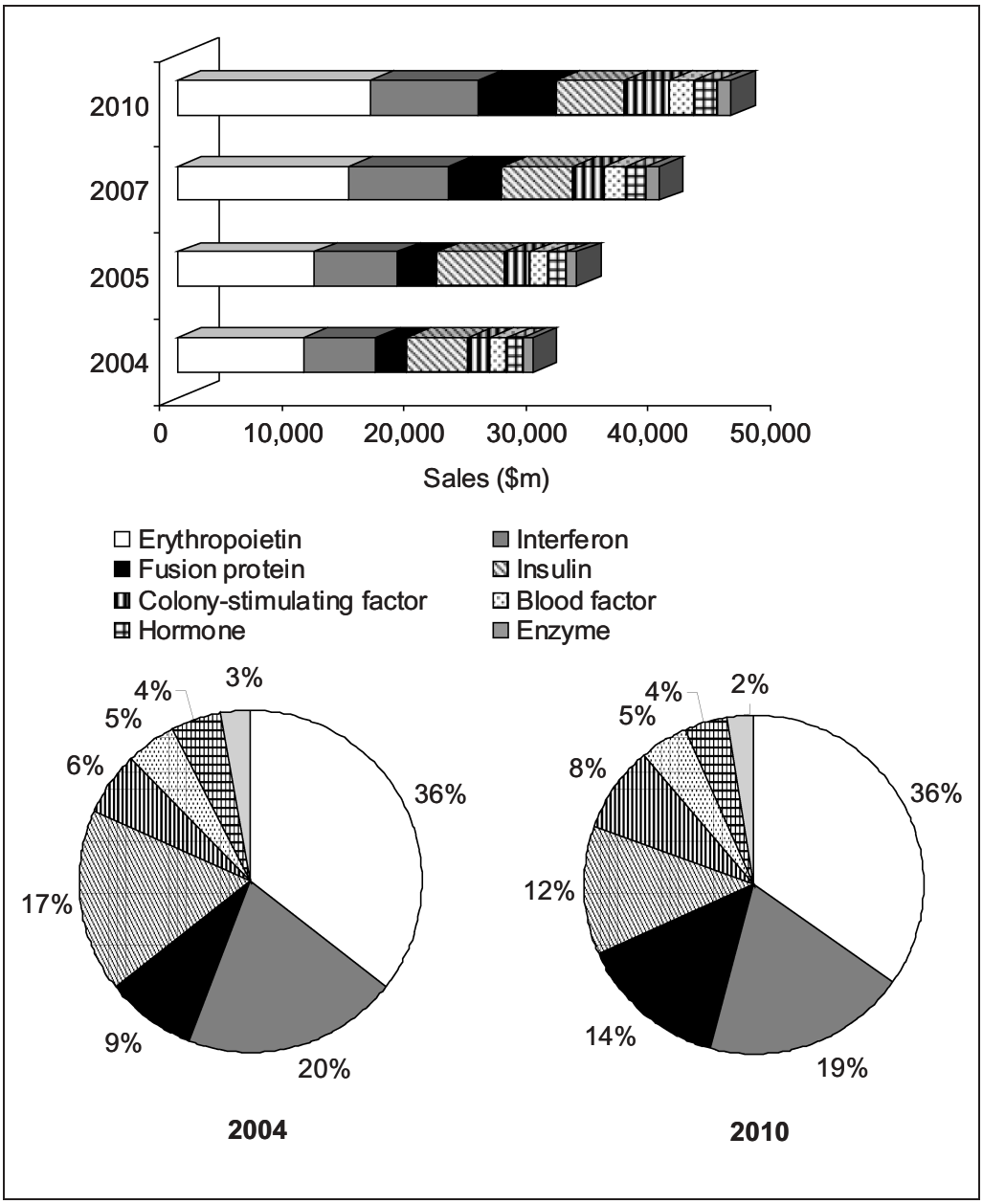

Figure 2: Sales forecasts for top 20 rDNA proteins, split by product class
Source: Datamonitor, company-reported information

NeoRecormon/Epogin (epoetin beta). Serono's position is based on its multiple sclerosis product Rebif (interferon beta), which has driven company growth as a result of its efficacy and safety. Novo Nordisk is heavily dependent on insulin sales, which may limit its degree of growth in the rDNA market over the forecast period, if it relies heavily on sales from currently marketed products.

DISCUSSION

The evolution of the rDNA market from developing products as protein replacement therapies, towards targeting the stimulation or inhibition of targets, has renewed growth prospects for the sector. A number of the top 20 rDNA products are recombinant versions of well-studied proteins, such as insulins, growth hormones and blood factors, and these products contributed approximately 30 per cent of the 2004 top 20 rDNA market. However, these products are now mature and are operating in largely saturated markets. For these reasons, their forecast 2004–10 CAGR is 3.6 per cent. Conversely, rDNA products designed as

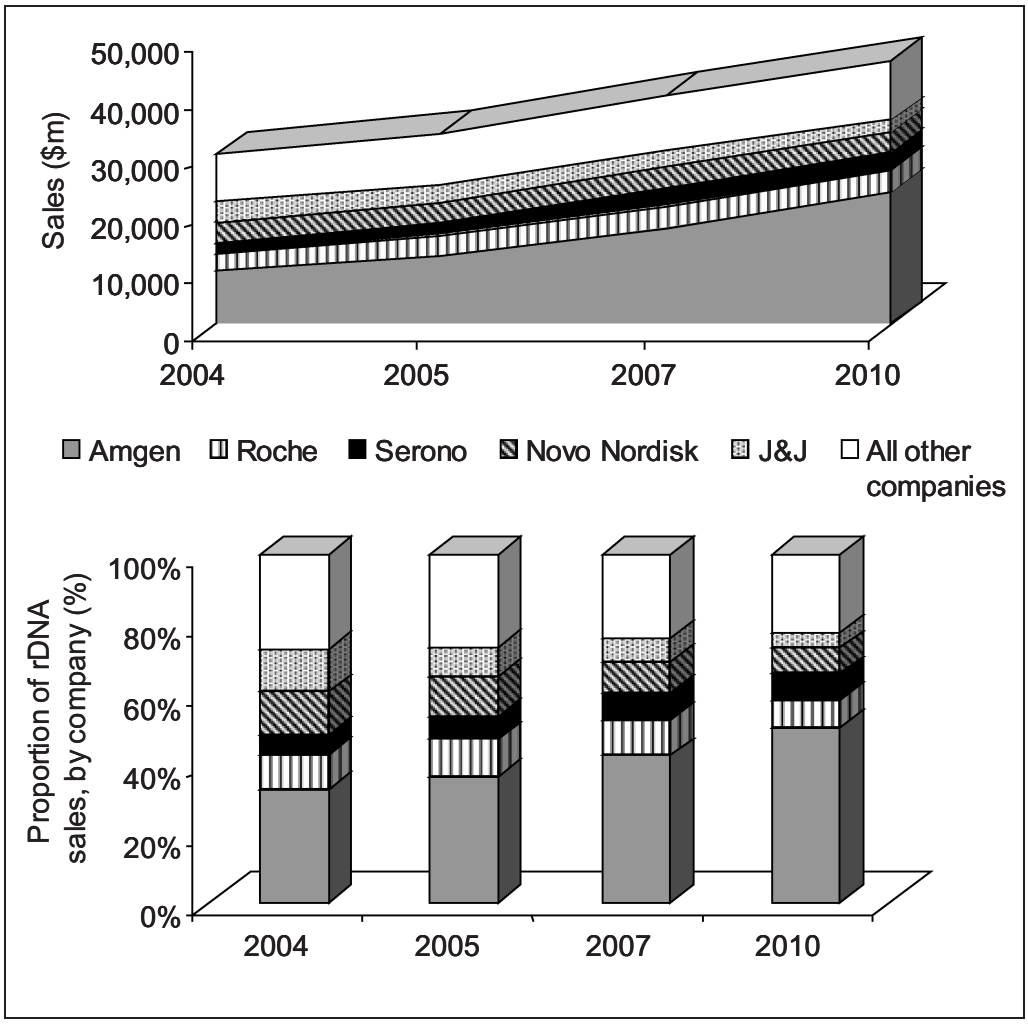

Figure 3: Sales forecasts for top 20 rDNA proteins, split by therapy area (J&J = Johnson & Johnson) Source: Datamonitor, company-reported information

target protein stimulators (e.g. Amgen's Aranesp) and target protein inhibitors (e.g. Amgen's Enbrel) represent the growth drivers of the top 20 rDNA product class, with a forecast 2004–10 CAGR of 9.2 per cent. This class of target protein stimulators and inhibitors is set to account for more than 75 per cent of total rDNA top 20 product sales by 2010. Central to this evolution and growth of this sub-sector is the employment of market and/or indication expansion strategies. In contrast, replacement therapies have been designed to replace specific proteins, and this limits their market and/or indication expansion capability. For example, insulins can currently be used only in diabetes management, and growth hormones can currently be used only for growth hormone deficiency. For these reasons, oncology and AIID are forecast to be the leading therapy areas and erythropoietins are set to be the leading product class by 2010, with fusion proteins and colony-stimulating factors set to record the strongest 2004–10 growth. Conversely, diabetes and endocrinology is set to be slowest-growing franchise from 2004 to 2010.