

Marketspace

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The market of therapeutic recombinant proteins to 2010

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Abstract

Datamonitor's recombinant protein analytical framework shows that the sector with 77 marketed and 104 pipeline products will reach maturity undisturbed from potential biogeneric threat. It will see its value growing from US\$35.8bn in 2004 to US\$53bn in 2010 with a compound annual growth rate of no higher than 7 per cent. In terms of protein class focus, erythropoietins will continue to lead sales with 2010 sales of US\$11.4; almost one-fifth of the sector's value. Haematology diabetes/endocrinology and oncology will continue to be the key therapy areas with 2010 sales of US\$13.4bn, US\$9.5bn and US\$8bn, respectively. Amgen's blockbusters Enbrel, Neulasta and Aranesp will be the sector's key leading blockbusters, with combined 2010 sales of more than US\$10.8bn, capturing one-fifth of the sector's value.

INTRODUCTION

The growth and prosperity in the biotechnology sector in the past three decades have been based on the commercialisation of recombinant DNA proteins (rDNA) followed by the creation of a multi-billion dollar therapeutic protein business with hundreds of private, public, horizontal, emerging or fully integrated players. Using its in-house forecasting methodology and information

extracted from key industrial conferences and through a well-established network of key opinion leaders, Datamonitor has constructed a global rDNA proteins analytical framework of more than 100 firms and 180 products.

MARKET SIZE GROWTH TO 2010

As Figure 1 illustrates, the rDNA proteins portfolio (pipeline and marketed products)

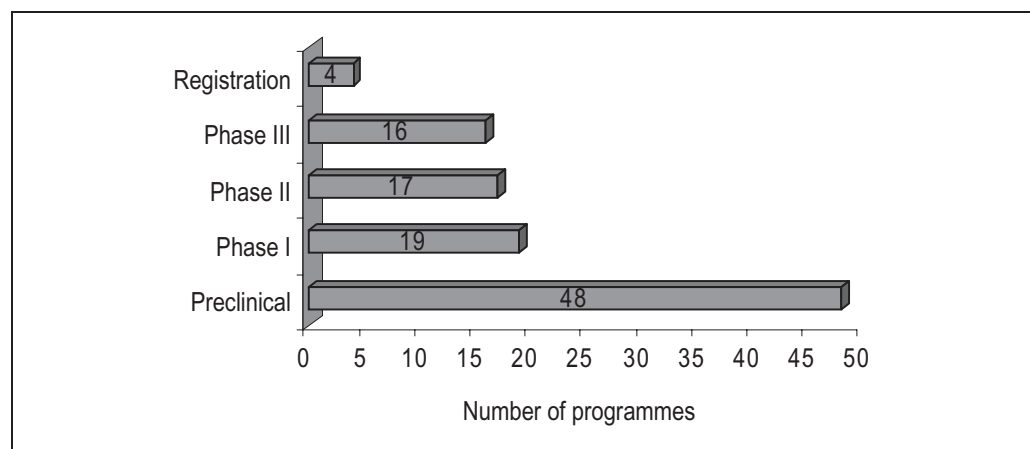


Figure 1: rDNA proteins portfolio distribution according to stage of development, 2004
Source: Datamonitor

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contains approximately 181 products, of which 104 (57.5 per cent of the rDNA portfolio) are in preclinical/clinical development or awaiting approval, and 77 are marketed. More specifically, the rDNA pipeline contains 48 preclinical products, 19 in Phase I, 17 in Phase II, 16 in Phase III and four in registration.

In terms of protein class specification

and product numbers, Figure 2(a) shows that currently the rDNA portfolio is dominated by four types of recombinant proteins: GF (growth factors) with 27 products, followed by IFN (interferons) with 26, HT (hormonal therapies) with 24 and IL (interleukins) with 21.

When looking at the degree of therapy area representation (Figure 2b), oncology

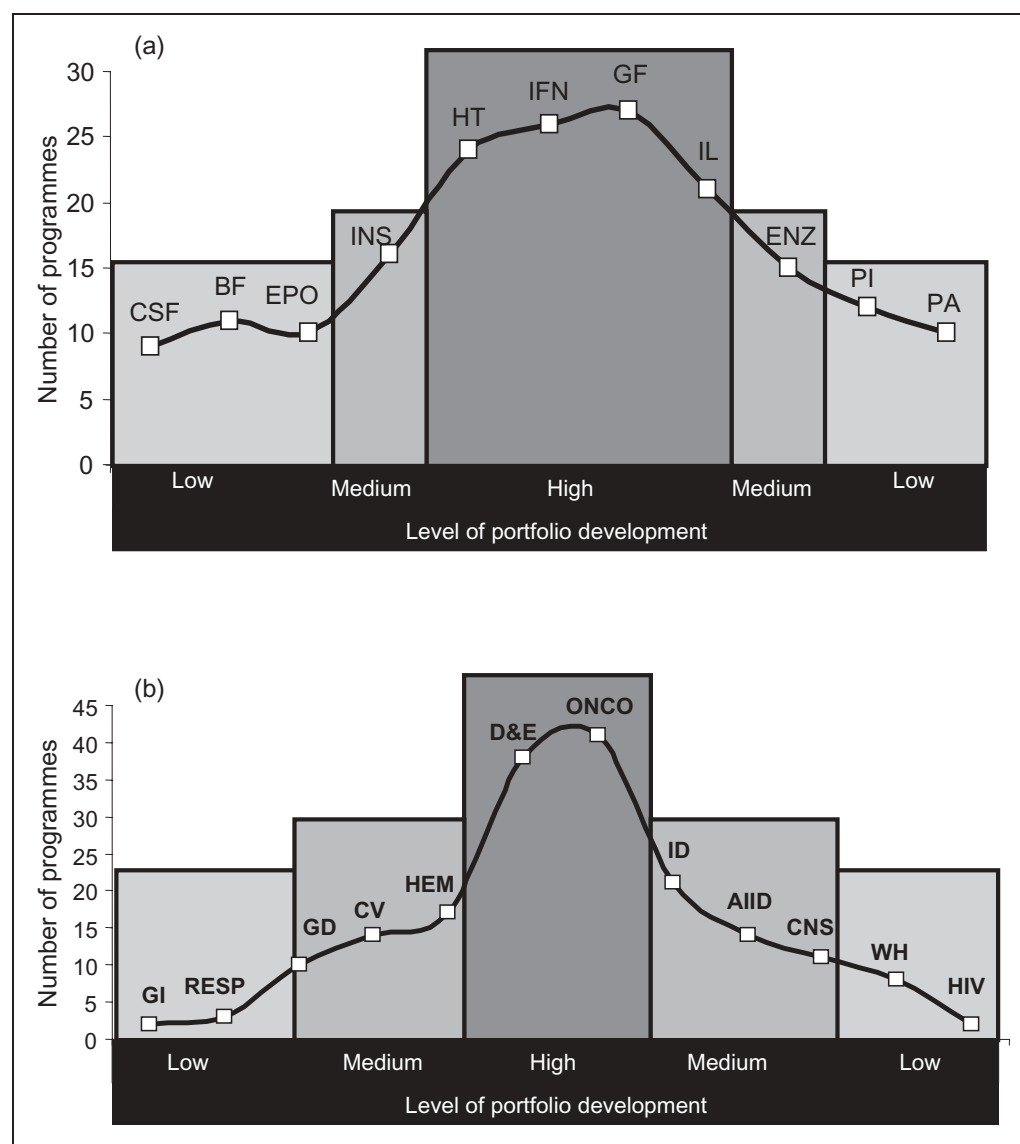


Figure 2: rDNA proteins portfolio distribution. (a) Protein class specification and product numbers (BF, blood factors; CSF, colony-stimulating factors; ENZ, enzymes; EPO, erythropoietin; GF, growth factors; HT, hormonal therapies; IFN, interferons; IL, interleukins; INS, insulins; PA, plasminogen activators; PI, protein inhibitors). (b) Therapy area representation (AIID, arthritis, inflammation and immune; CNS, central nervous system; CV, cardiovascular; D&E, diabetes and endocrinology; GD, genetic disorders; GI, gastrointestinal disorders; HEM, haematology; HIV, human immunodeficiency virus; ID, infectious diseases; ONCO, oncology; RESP, respiratory disorders; WH, women's health)
Source: Datamonitor

(ONCO) with 41 products (23 per cent of rDNA portfolio) and diabetes and endocrinology (D&E) with 38 (21 per cent of the rDNA portfolio) dominate the therapeutic recombinant protein portfolio, followed by infectious diseases (ID) with 21 and haematology (HEM) with 17.

Based on the previously described market structure, Datamonitor forecasts that the sector of therapeutic rDNA proteins will grow in value from US\$21.7bn in 2001 to US\$53 billion in 2010 (Figure 3). More specifically, the market saw its sales volumes between 2002 and 2003 increasing by 19.9 per cent (well above the pharma industry average) from US\$26.4bn to US\$31.6bn. In 2004, sales are expected to reach a figure of US\$35.8bn, but with a lower growth rate of 13 per cent over 2003, thereby signalling some early signs of market maturation effects.

LEADING PRODUCTS

As Figure 4 illustrates, there is a group of 10 recombinant proteins that will be able to generate sales over US\$1.5bn by 2010 and are expected to drive the sector's growth by 2010. This include three EPOs – Amgen's Epogen, Aranesp and Johnson & Johnson's Procrit; four IFNs – Biogen-IDEC's Avonex, Serono's Rebif, Roche's Pegasys, Schering Plough's PEG-Intron-A; followed by Aventis's INS Lantus and

Amgen's PI Enbrel and CSF Neulasta. Combined sales of the ten leading brands are forecast to grow from US\$18.4bn in 2004 to US\$27bn in 2010, while their contribution to total market size is expected to range between 51 and 52 per cent. In terms of blockbuster revenue performance, Amgen will lead the pack with three super-blockbusters. These will include the biotechnology industry's leading brand by 2010, Enbrel, with a sales forecast of over US\$4bn, followed by Aranesp and Neulasta, with 2010 sales forecasts of US\$3.4bn and US\$3.2bn, respectively.

KEY CLASSES

The class of EPOs will continue to lead the sector's growth with its sales forecast to increase but almost with a flat pace from US\$10.3bn in 2004 to US\$11.4bn in 2010. Its sales contribution to total rDNA sales is expected to decline from 29 per cent in 2004 to 21 per cent in 2010. IFNs and INS will follow, with their sales forecast to grow from US\$5.9bn and \$5.5bn in 2004 to US\$10bn and \$7.2bn by 2010, respectively.

KEY THERAPY AREAS

The leading therapy are will be haematology (anaemia-related disorders) with sales forecast to grow from US\$9.6bn in 2004 to US\$13.4bn in 2010, while its contribution to total rDNA sales

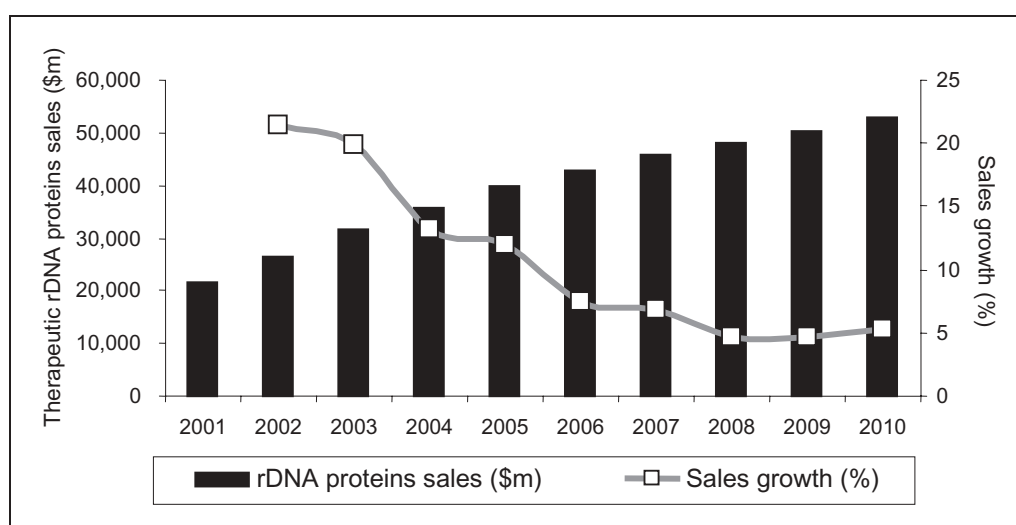


Figure 3: Market size growth to 2010
Source: Datamonitor

Figure 4: Leading therapeutic rDNA proteins, 2003–2010
Source: Datamonitor

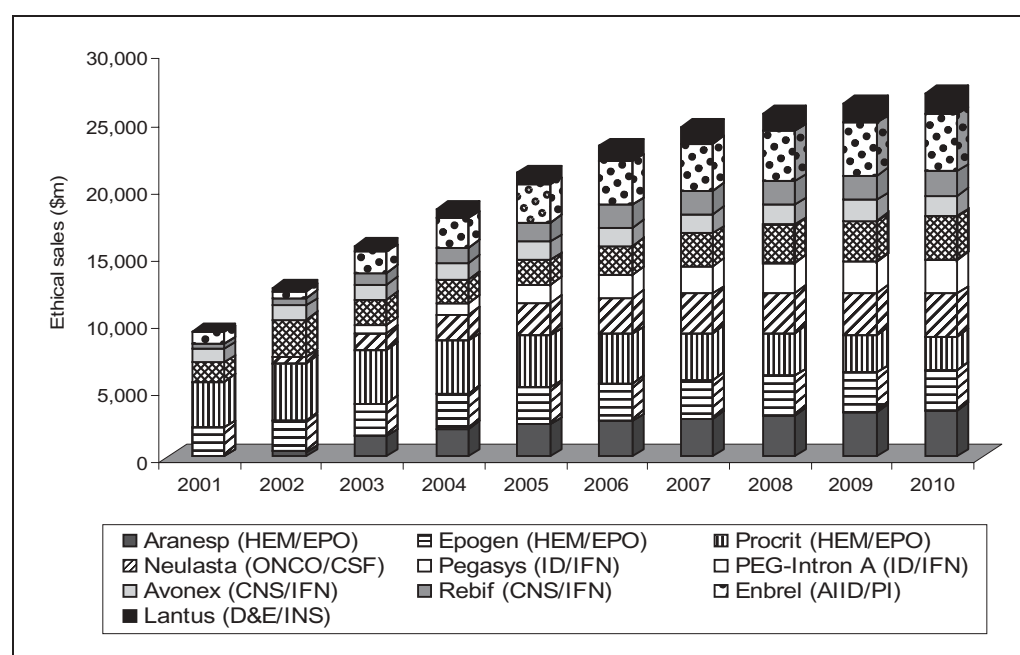
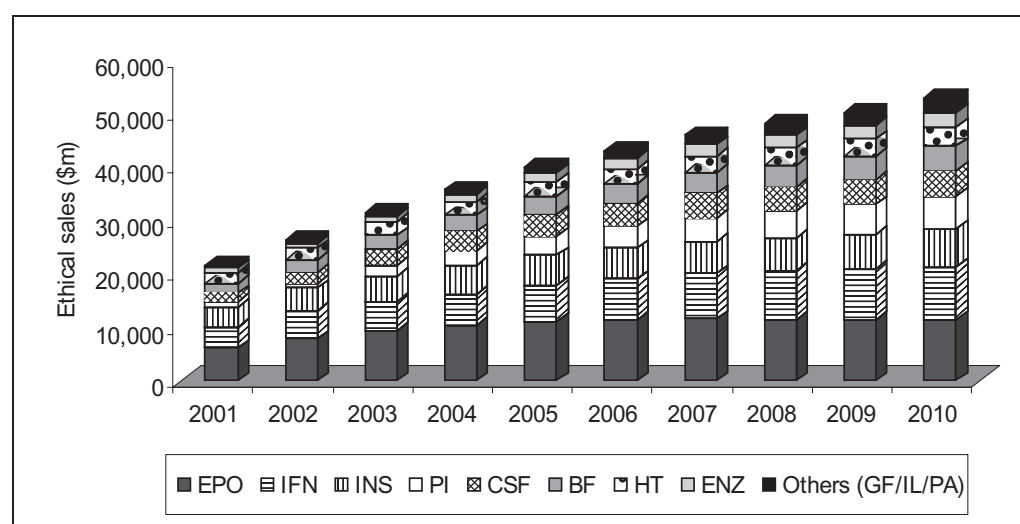


Figure 5: Leading rDNA protein classes, 2001–2010
Source: Datamonitor



will slightly decline from 26 to 25 per cent. Oncology will be the second most important area with sales forecast to grow from US\$7.9bn in 2004 to US\$9bn by 2010. However, its sales growth will be slow and its contribution to total rDNA sales is expected to decline from 22 to 17 per cent. Similar to oncology, diabetes and endocrinology sales will grow from US\$7.4bn in 2004 to US\$9.5bn in 2010, but with a declining contribution to total rDNA sales from 21 to 18 per cent. In contrast, the areas ID and AIID will

demonstrate strong growth and ascending contributions over the next six years. More specifically, ID sales will more than double from US\$3bn in 2004 to US\$6.4bn in 2010, while its market share is forecast to grow from 8.3 per cent in 2004 12.2 per cent in 2010.

In addition, Enbrel's strong performance and the recent launch of Biogen's Amevive will drive growth within the area of AIID, with sales forecast to grow from US\$2.5bn in 2004 to US\$5.2bn in 2010, while the area's

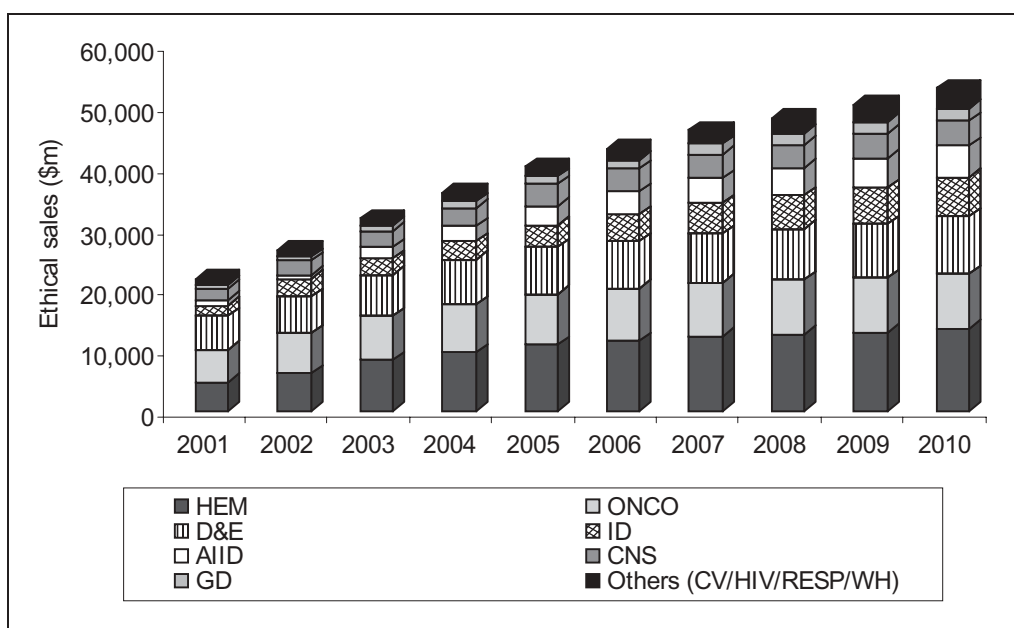


Figure 6: Key therapy areas, 2001–2010
Source: Datamonitor

contribution to total rDNA sales is expected to grow from 7 per cent in 2004 to 10 per cent in 2010.

CONCLUSIONS

The biogenerics sector lacks visibility, owing to the lack of a regulatory path coupled with potential manufacturing limitations or pricing related pressures.

This will enable the therapeutic rDNA proteins sector to reach maturity without significant threats and to recognize a stable although slow six-year (2004–2010) compound annual growth rate of 6.8 per cent. This will be caused by the pipeline's inability to generate new blockbusters and the maturation of some of the sector's current growth drivers.