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**Keywords:** monoclonal antibodies, therapeutic proteins

# Marketspace

## Biotech blockbuster forecasts to 2008

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Date received: 2nd June, 2004

### Abstract

Datamonitor analysis recognises 18 biological brands that are expected to drive sales within the biopharma sector. The group includes 12 recombinant DNA proteins and six antibodies which are forecast to generate sales of US\$29.0bn and US\$13.2bn by 2008, respectively. Haematology, oncology and AIID (arthritis, inflammation and immune disorders) will drive blockbuster sales, reaching US\$11.2bn, US\$9.7bn and US\$8.3bn by 2008, respectively.

### INTRODUCTION

It is not surprising that the market of therapeutic biologicals is reliant on a small number of recombinant protein (rDNA) and monoclonal antibody (mAb) blockbusters. As the industry's leaders and emerging players work to expand their fully integrated models, creating portfolios that are oriented towards high profit margins (which can maintain a business model of high return on investment (ROI) or high return on capital invested) is a critical success factor.

Without a doubt, the future performance of the industry's leading products will affect the future development of the sector and influence investor behaviour. Therefore, Datamonitor's biotechnology analysis presents sales forecasts for the industry's current or future blockbusters in terms of technological or therapeutic focus. This analysis was performed in May 2004.

### BIOTECHNOLOGY BLOCKBUSTERS IN 2003

In 2003, biotechnology's 17 leading brands generated sales of US\$25.3bn. Table 1 includes all products with blockbuster status in 2003 and those with blockbuster potential over the next four years. More specifically, antibody

blockbusters reached US\$5.9bn in 2003 while rDNA protein blockbusters generated sales of US\$19.4bn.

### Sales by therapy area

Figure 1 highlights the therapy areas that the therapeutic proteins and monoclonal antibodies belong to, over the forecast period. The leading blockbuster-generating therapy area in both 2003 and 2008 will be haematology, although its dominance will proportionally decrease over the forecast period, as blockbusters within the oncology, arthritis, inflammation and immune disorders (AIID), and to a lesser extent infectious disease and diabetes franchises, experience stronger growth. In 2003, blockbusters in the haematology therapy area contributed 37 per cent of the total blockbuster revenue, bringing in US\$9,492m. Oncology held second position, generating sales of US\$4,235m in 2003. Following haematology and oncology, AIID and infectious disease blockbusters contributed US\$3,309m and US\$3,481m. By 2008, the haematology franchise is set to contribute proportionally less, as key haematology products such as Amgen's Epogen transition into mature products and follow a lower growth rate trajectory.

With a compound annual growth rate

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**Table 1:** Biotechnology's leading brands

Brand	Marketer	Technology	Therapy area	Sales 2003 (US\$m)
<b>Antibodies</b>				
Rituxan/Mabthera	Roche, Genentech, Biogen-IDEC	chmAb	Oncology	2,094
Remicade	Johnson & Johnson, Centocor, Schering Plough	chmAb	AIID	1,729
Synagis	MedImmune, Abbott	hmAb	ID	931*
Herceptin	Roche, Genentech	hmAb	Oncology	886
Humira	Abbott	FhmAb	AIID	280
Avastin	Roche, Genentech	hmAb	Oncology	0
			<b>Antibody sales</b>	<b>5,920</b>
<b>rDNA proteins</b>				
Procrit	Johnson & Johnson	Erythropoietin	Haematology	3,984
Epogen	Amgen	Erythropoietin	Haematology	2,435
Aranesp	Amgen	Erythropoietin	Haematology	1,544
NeoRecormon/Epogin	Roche	Erythropoietin	Haematology	1,528
Neulasta	Amgen	Colony-stimulating factor	Oncology	1,255
Novolin	Novo Nordisk	Insulin	Diabetes	2,235
Lantus	Aventis	Insulin	Diabetes	550
Pegasys	Roche	Interferon	ID	700
Avonex	Biogen-IDEC	Interferon	CNS	1,170
Rebif	Serono, Pfizer	Interferon	CNS	819
PEG-Intron A franchise	Schering Plough	Interferon	ID	1,850
Enbrel	Amgen	Fusion protein	AIID	1,300
			<b>rDNA proteins</b>	<b>19,370</b>
			<b>Blockbuster sales</b>	<b>25,290</b>

AIID = arthritis, inflammation and immune disorders, ID = infectious disease, ch = chimeric, h = humanised, Fh = fully humanised, mAb = monoclonal antibody.

\* = estimate derived from MedImmune and Abbott 2003 recorded sales

Source: Datamonitor; company-reported information.

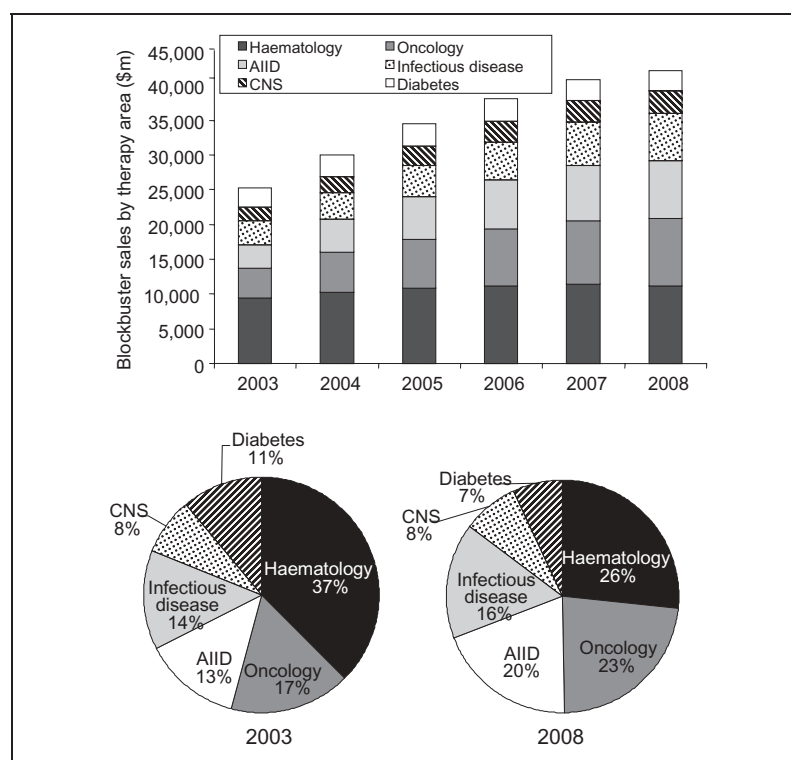
(CAGR) of 3.3 per cent from 2003 to 2008, haematology is set to remain the leading blockbuster therapy area. However, with stronger growth at CAGRs of 18.1 and 20.1 per cent respectively, both oncology and AIID are set to increase dominance and drive the therapeutic protein and monoclonal antibody markets over the forecast period. The infectious disease (ID) franchise is also forecast to record strong growth, with a CAGR of 14.3 per cent from 2003 to 2008. However, diabetes and endocrinology blockbusters are increasingly mature, low-growth recombinant therapeutic protein products, which are set to record a low CAGR of 0.9 per cent between 2003 and 2008.

### Sales by therapeutic class

Historic growth of the biotechnology industry over the past 20 years has been

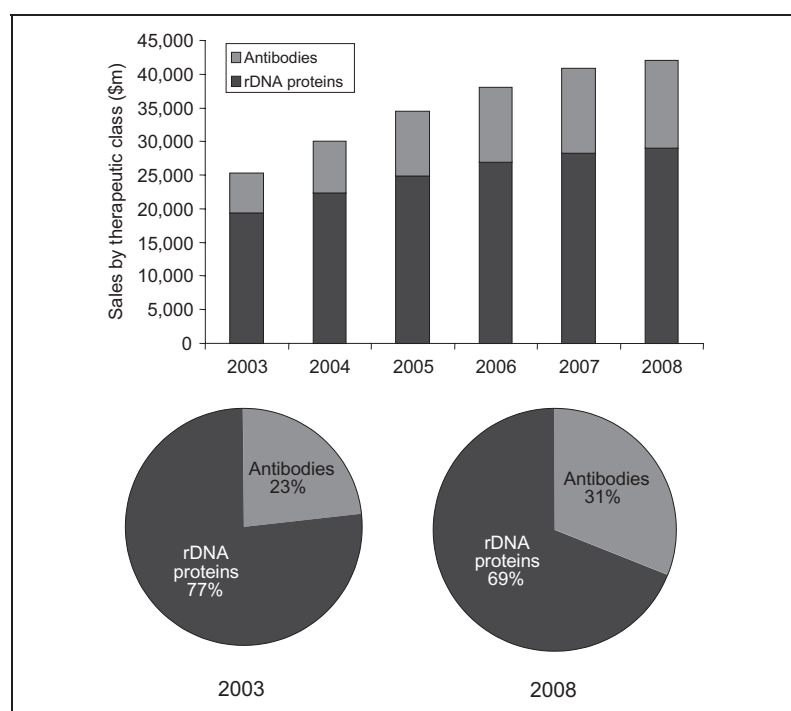
driven by the therapeutic recombinant protein product class. This market represents the most mature biotechnology sector and currently encompasses 112 players involved in the discovery and development of new therapeutic protein products. These companies are set to drive strong market growth, leading to a market valuation of close to US\$45bn by 2008. Following the success of recombinant proteins, therapeutic antibodies represent the second largest wave of innovation created by the biotechnology industry over the past 20 years. Relative to the therapeutic protein sector, the monoclonal antibody market has attracted a greater number of players, with over 200 companies currently involved in their discovery, development, delivery and marketing.

With biogeneric threat biased towards the therapeutic protein sector and a



**Figure 1:** Forecast revenue trends for the biotech blockbusters according to therapy area, 2003–08

Source: Datamonitor, company-reported information



**Figure 2:** Forecast revenue trends for the biotech blockbusters according to therapeutic class, 2003–08

Source: Datamonitor; company-reported information

greater number of its lead products facing increasing maturity over the forecast period, the therapeutic protein market is set to record a slower growth in sales over the forecast period compared to the monoclonal antibody market.

Monoclonal antibody blockbusters are set to generate a significantly higher CAGR of 17.3 per cent, versus 8.4 per cent for therapeutic protein market.

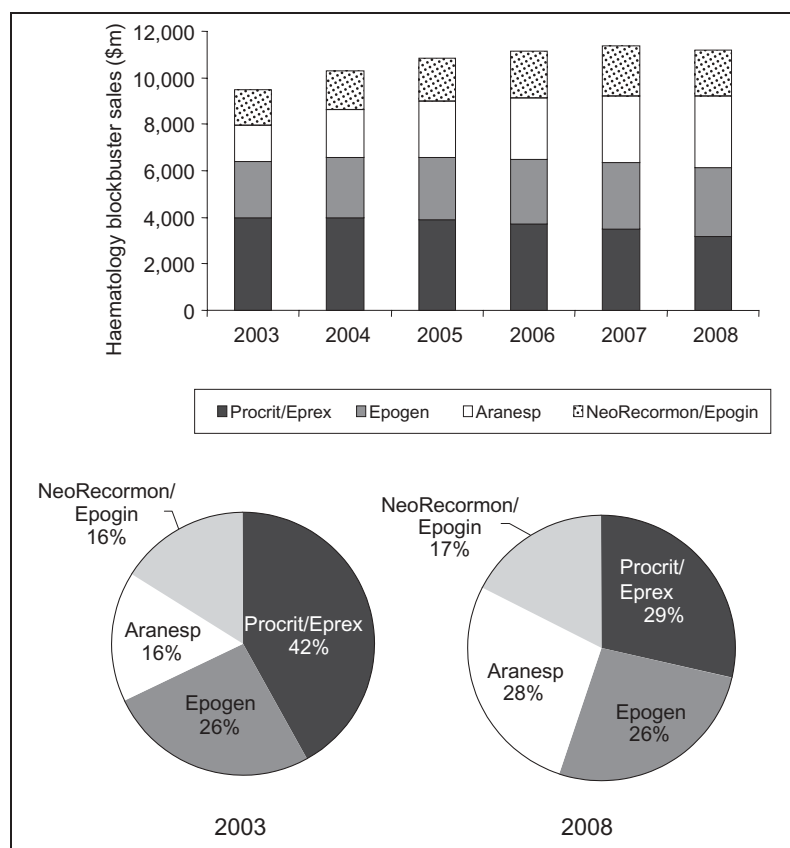
More specifically, as Figure 2 illustrates, antibody blockbuster sales are forecast to almost double from US\$7.7bn in 2004 to US\$13.2bn in 2008, while their contribution to total blockbuster sales will increase from 23 per cent in 2003 to 31 per cent in 2008. The growth will be driven by Rituxan, Humira and Avastin. The three antibodies are forecast to generate combined sales of more than US\$7.8bn or almost 60 per cent of total antibody blockbuster sales in 2008.

## Haematology

Recombinant erythropoietin protein products dominate the haematology therapy area over the forecast period. More specifically, according to Figure 3, haematological blockbusters due to Procrit's and Epogen's maturation are forecast to generate flat sales from US\$9.5bn in 2003 and US\$10.3bn in 2004 to US\$11.2bn in 2008.

Amgen developed erythropoietin alpha, and despite the strong pressure to generate revenues from licensing agreements to drive company growth, Amgen retained rights for marketing Epogen in the US dialysis haematology market. Instead, the company out-licensed the rights for US/chemotherapy plus the European markets to Johnson and Johnson, who market erythropoietin alpha under the name Procrit/Epex.

Johnson & Johnson's strong marketing power which, in combination with its broad geographical market dominance in the USA and Europe, has resulted in the high penetration of Procrit/Epex in the haematology market and established the product as the leading sales generator



**Figure 3:** Forecast revenue trends for the biotech blockbusters in haematology, 2003–08. The lack of accurate therapy area sales data prevents an accurate determination between oncology and haematology; the haematology market includes total sales produced by the haematology brands

Source: Datamonitor, company-reported information

over the forecast period. Behind Procrit/Eprex is Amgen's Epogen, Amgen's erythropoietin alpha, which dominates the US dialysis haematology market. Both Epogen and Procrit/Eprex are mature products, and Epogen is set to experience low sales growth over the forecast period.

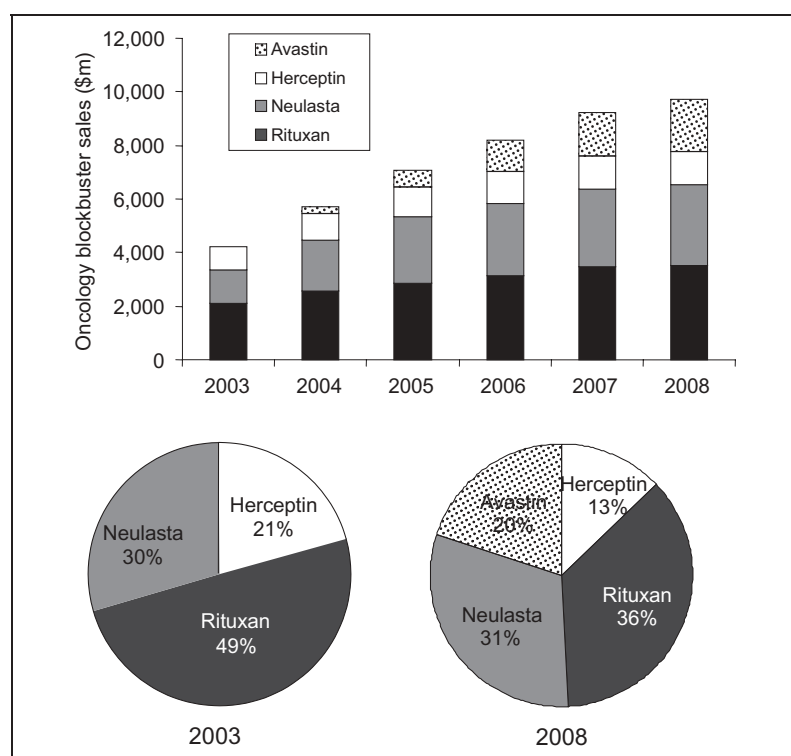
However, Amgen's marketing strategy for Aranesp is focused towards cannibalising Procrit/Eprex. Aranesp is Amgen's next-generation haematology/oncology erythropoietin product, which has an extended half-life and improved dosing regime.

Together with Amgen's strategy of retaining marketing rights for all indications in both the USA and Europe, these factors should drive significant

growth of Aranesp into the super-blockbuster territory (>US\$2.5bn) by 2006. Roche's NeoRecormon/Epogin is a recombinant erythropoietin beta that has built a significant revenue stream derived from the European erythropoietin market. It is set to experience low growth over the forecast period, not helped by its lack of US approval.

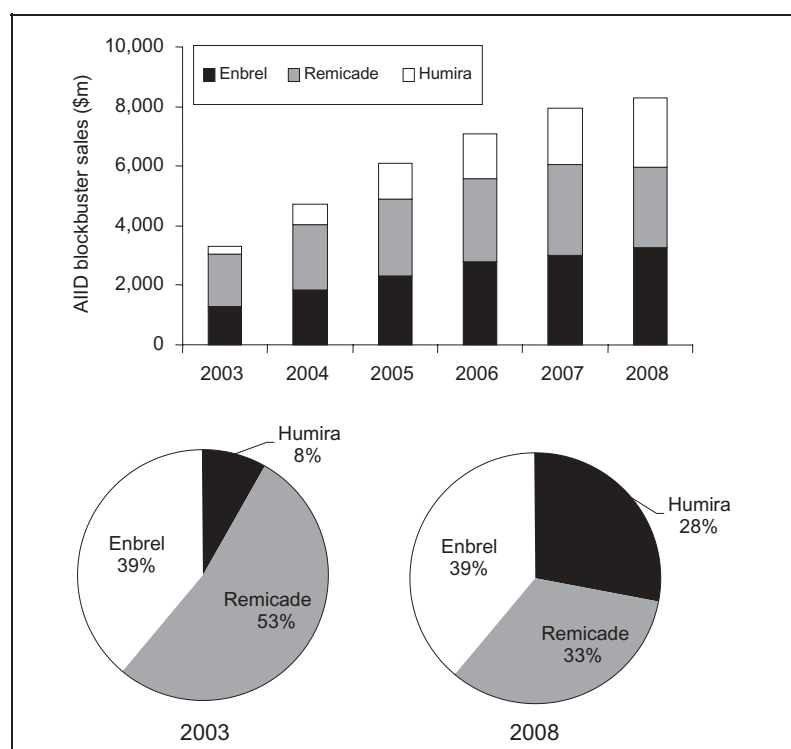
## Oncology

In contrast to the haematology therapy area, oncology blockbusters shown in Figure 4 over the forecast period are all monoclonal antibodies, with the exception of Neulasta. In part, this can be explained by grouping erythropoietins into the haematology franchise, despite their use for cancer-related conditions such as chemotherapy-related anaemia. Oncology blockbusters are forecast over the next four years to increase their sales from US\$4.2bn in 2003 and US\$5.7bn in 2004 to US\$9.7bn in 2008. In 2003, oncology was the leading therapy area within the monoclonal antibody sector, both in terms of commercial success and pipeline development, and it is set to remain in this position over the forecast period. Of the total monoclonal antibody market, Datamonitor has identified 193 oncology programmes representing 51.3 per cent of the monoclonal antibody portfolio, which encompasses preclinical to marketed products. The leading oncology biotherapeutic blockbuster, both in 2003 and 2008, is Roche/Genentech/Biogen-IDEA's non-Hodgkin's lymphoma monoclonal antibody, Rituxan/Mabthera. The product is facing increasing maturity and stronger biotherapeutic competition, resulting in a low growth rate over the forecast period. Second to Rituxan is Neulasta, Amgen's next-generation recombinant human granulocyte colony-stimulating factor protein, indicated for neutropenia. Sales are set to strongly increase, following the cannibalisation of Neupogen, at a CAGR of 19 per cent over the forecast period.



**Figure 4:** Forecast revenue trends for the biotech blockbusters in oncology, 2003–08

Source: Datamonitor, company-reported information



**Figure 5:** Forecast revenue trends for the biotech blockbusters in the area of AIID, 2003–08

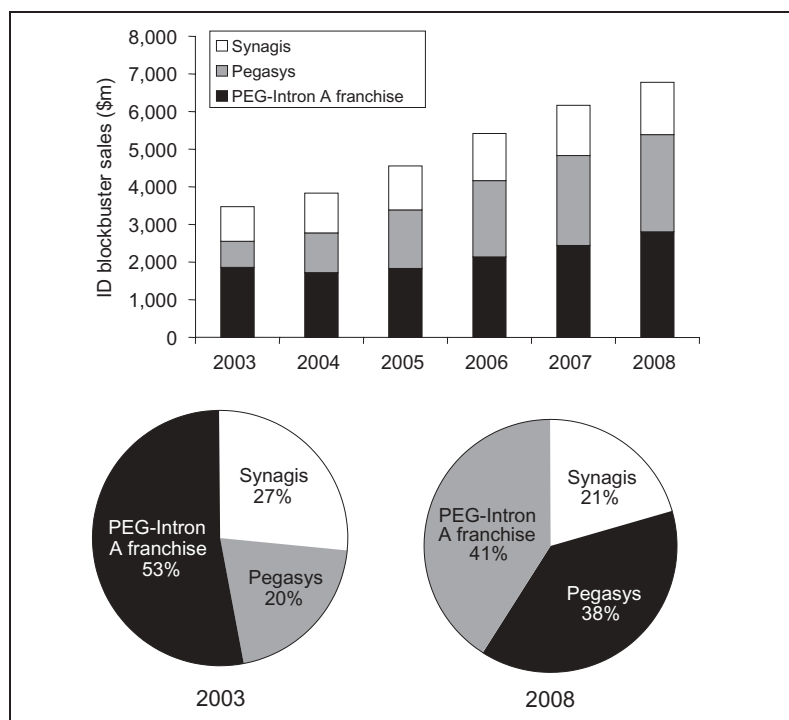
Source: Datamonitor, company-reported information

## Arthritis, inflammation and immune disorders (AIID)

As Figure 5 illustrates, AIID blockbusters are forecast to see their sales growing from US\$3.5bn in 2003 and US\$4.7bn in 2004 to US\$8.3bn in 2008. Within the AIID therapeutic franchise, the lead blockbuster is Johnson & Johnson's chimeric monoclonal antibody, Remicade, indicated for the treatment of Crohn's disease and rheumatoid arthritis. The AIID franchise represents the second leading growth area for the monoclonal antibody market, after oncology. Although Remicade sales are set to experience a moderate growth over the forecast period with a CAGR of 9.5 per cent, the AIID monoclonal antibody pipeline will spawn antibody therapeutics set to show the highest revenue growth, even though it is currently half the size of that for oncology. These products are forecast to achieve almost equal returns with oncology in 2008. Amgen's fusion protein Enbrel, which binds to Tumour Necrosis Factor, is indicated for a wide number of auto-inflammatory conditions, such as rheumatoid arthritis and ankylosing spondylitis.

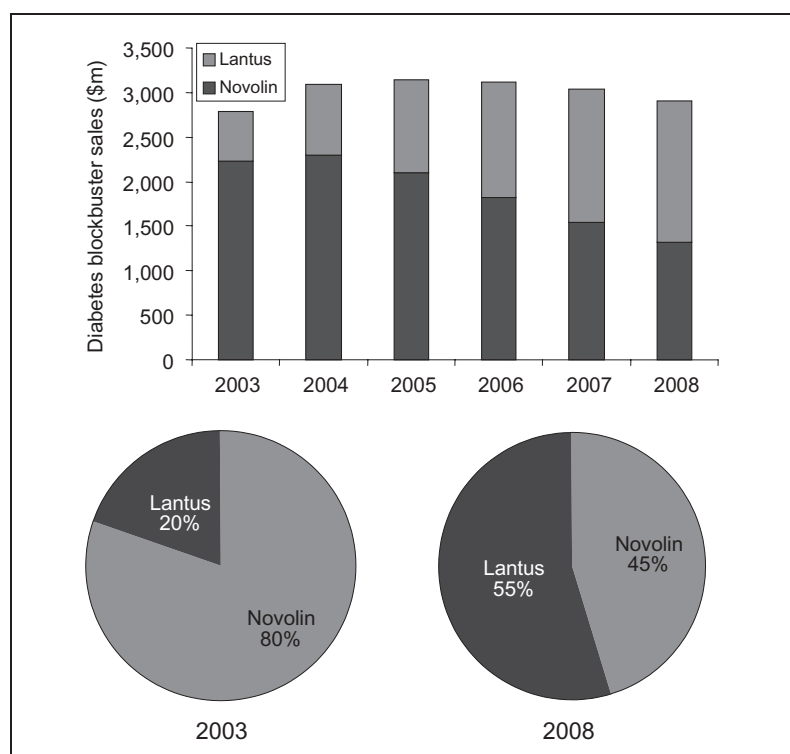
## Infectious disease (ID)

The infectious disease blockbusters will see their sales growing from US\$3.4bn in 2003 and US\$3.8bn in 2004 to US\$6.8bn in 2008 (Figure 6). Within the biotherapeutic blockbusters, the infectious disease sector is driven by therapeutic proteins that target the hepatitis market and, to lesser extent, monoclonal antibodies targeting serious respiratory syncytial virus. The maturation of Biogen/Schering Plough's PEG-Intron A franchise will result in the increasing dominance of the faster-growing Roche's Pegasys within this therapy area over the forecast period. The latter is forecast to contribute 38 per cent of the ID blockbuster sales in 2008, while its sales are forecast to grow from US\$0.7bn in 2003 to US\$2.6bn in 2008.



**Figure 6:** Forecast revenue trends for the biotech blockbusters in the area of infectious disease, 2003–08

Source: Datamonitor, company-reported information



**Figure 7:** Forecast revenue trends for the biotech blockbusters in the area of diabetes, 2003–08

Source: Datamonitor, company-reported information

## Diabetes

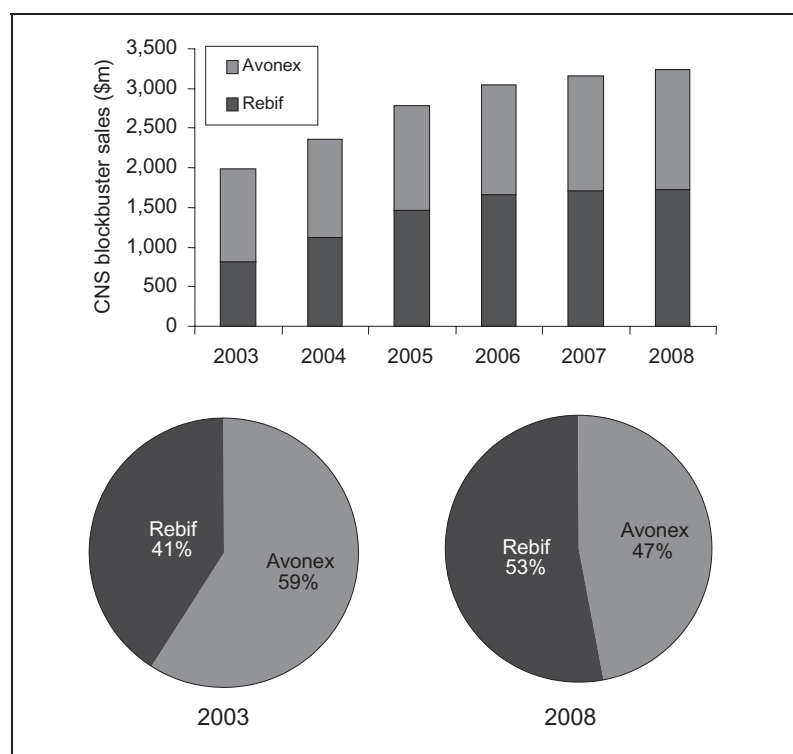
The two leading diabetes blockbusters within the forecast period are both recombinant proteins, developed and marketed by the two leading companies in the recombinant insulin market, Novo Nordisk and Aventis (Figure 7). Both products represent the company's life-cycle management strategies, which have driven the diabetes market from a first-generation recombinant insulin stage to a next-generation modified-release insulin stage.

## CNS

The two CNS blockbusters within the forecast period are both recombinant interferon betas, which are indicated for the treatment of multiple sclerosis (Figure 8 – see overleaf). The interferon market is mature, with both blockbusters launched in 1997. Avonex is set to record lower sales growth relative to Rebif over the forecast period.

## CONCLUSION

Analysis of the biotherapeutic blockbusters indicates that both therapeutic proteins and monoclonal antibodies are set to drive market growth across a broad range of therapeutic indications, over the forecast period. Success in the area of immunotherapies will rely on the growth of the therapeutic antibody market, given the increasingly mature nature of the therapeutic proteins market. While the latter is set to continue driving the haematology and AIID markets, Datamonitor's analysis highlights that the antibody industry is, and will remain, heavily focused on oncology and arthritis, immune and inflammatory disorders.



**Figure 8:** Forecast revenue trends for the biotech blockbusters in the area of CNS, 2003–08

Source: Datamonitor, company-reported information