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# US Financial accounts reports

Glenn Crocker and Ian Oliver

## **Amgen Inc (NASDAQ: AMGN): Results for the year to 31st December, 2001**

Amgen was one of the founding fathers of the global biotechnology industry and yet the company is still only 20 years old, reinforcing just how rapidly the biotechnology sector has grown from nothing to a multi-billion dollar industry. Amgen belongs to the elite band of profitable biotechnology companies, largely as a result of worldwide sales of its blockbuster products Epogen<sup>®</sup> and Neupogen<sup>®</sup>. Epogen<sup>®</sup>, marketed since 1989, stimulates the production of red blood cells and its main indication is for the treatment of anaemia associated with chronic renal failure in dialysis patients. Neupogen<sup>®</sup>, marketed since 1991, selectively stimulates the production of neutrophils, and is used to decrease the incidence of infection in cancer patients undergoing chemotherapy.

The continuing strength of the company is its late stage pipeline of products, for which significant research and development investment is funded out of cash from operations. And yet even at a valuation in excess of US\$50bn, Amgen still felt it needed greater mass and so towards the end of 2001 announced the acquisition of Immunex, valued at US\$18bn.

2001 results demonstrated continued growth in product sales. Amgen derives revenues from direct sales, transactions with its joint ventures, such as Kirin-Amgen Inc., and royalty income from licence agreements with third parties, such as Johnson & Johnson. Total revenues increased 10.6 per cent from US\$3,629m in 2000 to US\$4,016m in the year ended 31st December, 2001. Over half Amgen's total sales are from Epogen<sup>®</sup>, direct sales of which increased by 7.4 per cent to US\$2,109m mainly as a result of higher prices and growth in the

US dialysis patient population. Neupogen<sup>®</sup> direct sales increased 10 per cent to US\$1,346m on the back of worldwide demand growth.

Despite the increased contribution from sales, net income before tax increased by only 0.7 per cent to US\$1,686m. The company increased its investment in research and development to US\$865m (22 per cent of sales) and general expenses increased by US\$144m over 2000 owing to marketing and consulting expenses on new product launch support. Additional charges in 2001 included a US\$39.5m inventory write-off and US\$203.1m net of costs primarily related to the termination of certain collaboration agreements with third parties.

Basic earnings per share dropped from US\$1.11 to US\$1.07, amplified by a 1.5 per cent increase in the average number of shares in issue during the year. The company's management is actively taking steps to reduce the dilution effect of the significant number of share options available to employees, by repurchasing shares from the market. US\$2bn is available for such repurchases in the two years to December 2002, and the directors used US\$738m in 2001.

2001 has been an exciting year for Amgen, with both product development success and failure hitting the headlines, as is expected in the rollercoaster ride to product marketing acceptance. The company's critical mass and breadth of development projects have allowed it to weather such highs and lows.

Successes have been focused in the third and fourth quarters of 2001. The company has developed a red blood cell-stimulating protein, darbepoetin alfa, that can be used in similar indications as Epogen<sup>®</sup> but can be administered less frequently as it stays in the body longer. The product received approval in the

Glenn Crocker  
Ernst Young,  
Compass House,  
1880 Newmarket Road,  
Cambridge CB5 8DZ, UK

Tel: +44 (0) 1223 461200  
Fax: +44 (0) 1223 557008  
E-mail: glenn.crocker@  
cc.ernsty.co.uk

USA in September 2001 and sales, under the name Aranesp™, totalled US\$41.5m in 2001.

A significant element of Amgen's effort is directed through its Inflammation Research Program aimed at the discovery of products to relieve the symptoms of rheumatoid arthritis. This is an area also actively targeted by other companies, and the Company was boosted by the Food and Drug Administration (FDA) approval in November 2001 of the IL-1 receptor antagonist Kineret™ for the treatment of severely active rheumatoid arthritis. This is the first product to be successfully born out of the acquisition of Synergen Inc. in 1994. In the EU, approval was granted in March 2002 for use of the product in conjunction with methotrexate where methotrexate alone is not effective. Analysts forecast peak annual sales of US\$360m.

Amgen also submitted its application to market its longer lasting white blood cell booster Neulasta™ in 2001, and received US regulatory approval in January 2002. The new product, which is expected to be launched in the second quarter of 2002, has similar indications to Neupogen® but is administered as a single dose per chemotherapy cycle, rather than as a daily injection for up to two weeks after a chemotherapy dose. This has significant advantages for the patient and medical centre administration, and the company expects a significant proportion of Neupogen® sales to be replaced by Neulasta™ as healthcare providers transition their use.

Despite some positive product developments, Amgen's revenues are still dominated by Epogen and Neupogen, and it is probable that this was one of the reasons why, in December 2001, the company entered into the agreement to acquire Immunex. Immunex shareholders will receive 0.44 Amgen shares plus US\$4.50 cash per Immunex share, this values the acquisition at US\$17.6bn. The Immunex acquisition will strengthen the company's expertise in Immunology research, coupled with existing resources

in the development of antirheumatic drugs. The transaction will push the combined entity into the top tier of global pharmaceutical companies, measured by market value and the combined entity will have forecast revenues in excess of US\$5bn.

The outlook for Amgen Inc. is particularly bright, according to analysts' projections and the chief finance officer's (CFO) forecasts. Excluding Immunex, sales growth is projected at just under 20 per cent for 2002, while earnings per share is predicted at US\$1.41 per share for 2002 and US\$1.67 per share for 2003. Adding Immunex is expected to reduce earnings by 5 per cent or less in 2003 and add to earnings in 2004. This is contingent on sales on Enbrel, Immunex's flagship rheumatoid arthritis drug, reaching US\$1.6bn in 2003 and peaking at around US\$3bn a year by 2005. Sales in 2001 were US\$750m.

The key short-term challenge for the enlarged entity is to increase Enbrel manufacturing capacity, for which a new facility is being constructed in Rhode Island, and realise merger-related administrative cost savings. Time will tell whether Enbrel realises its forecast sales potential but the proposed acquisition looks set to diversify Amgen's risk profile further while significantly increasing its cash-generating capability.

May 2002

### **Chiron Corporation (NASDAQ: CHIR): Results for the year to 31st December, 2001**

Chiron Corporation was incorporated in 1981 by three prominent biochemistry professors of the San Francisco Bay Area's leading universities, with the aim of developing and commercialising a new generation of diagnostic, therapeutic and vaccine products. It is based in Emeryville, California.

Today, it has grown into a diversified biotechnology company with three main business units: biopharmaceuticals,

vaccines and blood testing. It owes much of its initial success to the discovery and cloning of hepatitis B antigens, used to develop the first genetically engineered vaccine. This is the key ingredient in Merck's Hepatitis B vaccine, Recombivax HB<sup>®</sup>. Work extended in this area to hepatitis C, with the development of a blood screening test which has largely eliminated new cases of cross-infection from blood transfusion. Among Chiron's other previous successes, it is the first company to have cloned and sequenced the entire genome of HIV, allowing scientists around the world to study the disease and develop treatments.

Novartis AG currently owns 42 per cent of the common stock of Chiron Corporation and has an agreement whereby it cannot increase its interest over 55 per cent, without initiating a 'buy-out transaction' for the remaining outstanding stock. At the approval of a majority of the independent board directors, this threshold may be increased to 79.9 per cent.

The results for the year to 31st December, 2001, showed a 17.4 per cent increase in revenues to US\$1.1bn.

The Biopharmaceuticals division delivered US\$442.4m total revenues (2000: US\$324.7m). The key element was US\$338m of product sales (2000: US\$239.8m), of which the contribution of TOBI<sup>®</sup>, a tobramycin solution for the treatment of *Pseudomonas aeruginosa* lung infections in cystic fibrosis patients, increased from US\$27.8m to US\$123.1m based on a full year's availability. It was included in Chiron's results from the end of the third quarter of 2000 on acquisition of Pathogenesis Corporation.

The other key products in this segment are Betaseron<sup>®</sup>, a treatment for multiple sclerosis, Proleukin<sup>®</sup>, the first approved treatment for metastatic renal cell carcinoma in over 20 years and Platelet Derived Growth Factor (PDGF), the active ingredient in Johnson&Johnson's gel treatment for diabetes-related foot ulcers.

Betaseron<sup>®</sup> product sales improved by

17 per cent to US\$96.4m, driven by increasing worldwide use of beta interferon therapy for multiple sclerosis. Royalties on European sales via Schering AG also improved (up 10 per cent on 2000).

Proleukin<sup>®</sup> sales in 2001 were dented by pressure on cost savings in European healthcare authorities and a weakening of the euro. However, this product still generates 30 per cent of biopharmaceutical product sales. Cost pressures are expected to continue into 2002.

Chiron generated a 20 per cent increase in royalty and license fee revenues to US\$59.8m in this segment. It continues to derive value from its recombinant insulin and glucagon products, and hepatitis C virus patents for which new agreements were signed in 2001 with Japan Tobacco Inc. and Bristol-Myers Squibb.

Research and development activity in biopharmaceuticals focused on a number of clinical trials, including Proleukin<sup>®</sup> for the treatment of HIV and recombinant tissue factor pathway inhibitor for treatment of severe sepsis. Late in 2001, the company began collaborating with Inhale Therapeutic Systems Inc. to develop an inhaled tobramycin product. Costs were reduced in the gene therapy area as the company's San Diego facility was sold in January 2001. Total cost increased by 20 per cent to US\$266m, a significant portion of biopharmaceuticals revenues earned in the year.

US\$403m revenues were delivered from Chiron's mature vaccine product range (2000: US\$395m). Sales of Menjugate<sup>™</sup>, for vaccination against meningococcal meningitis (serogroup C bacterium), began in 2000 and were given an immediate boost when the NHS ordered US\$101m of product for commencement of a universal vaccination programme in the UK. This bulk ordering did not continue into 2001, as expected, but reductions to the UK were offset by sales commencing to Canada. Chiron is exploring opportunities for penetration into other countries.

Other vaccine product sales increased 14 per cent to US\$260.2m mainly from vaccines against tick-borne encephalitis, influenza and rabies. Royalties from hepatitis B virus vaccines have suffered from competition by multivalent vaccine products.

Vaccine research and development costs were stable at US\$61.7m as the company continued clinical trials on various vaccine programmes. In April 2001, collaboration with Rhein Biotech and GreenCross Vaccine began to develop certain paediatric combination vaccines. This is seen as a growth area, as health authorities look for lower-cost solutions to widespread multi-virus immunisation programmes.

The blood-testing sector generated US\$185m of revenues (2000: US\$139m) which included a steady US\$84m contribution from equity in its unconsolidated joint business with Ortho-Clinical Diagnostics Inc., which sells immunodiagnostic products. Chiron continues to manufacture bulk reagents and antigens for this business, generating US\$20.3m in 2001. The growth in this sector has arisen from Chiron's collaboration with Gen-Probe Inc., which is the only manufacturer of nucleic acid testing products using transcription-mediated amplification technology. Test

and instrument product sales more than doubled to US\$48.4m.

Future nucleic acid test sales look promising as all US customers renewed their purchase agreements in third quarter of 2001, mostly with price increases. Significant R&D effort in 2001 supported the completion of data submission to the FDA for Procleix<sup>TM</sup> instruments and assays. The company was rewarded in February 2002 when approval was given for the HIV-1/HCV assay, and this product is expected to generate a significant increase in revenues in 2002.

Total net income from continuing operations was US\$175m, up from US\$16m in 2000. This was despite a full year's goodwill and intangible assets amortisation expense of US\$38.4m as a result of the acquisition of Pathogenesis Corporation in September 2000 (US\$9.6m was charged in 2000). This acquisition caused a significant reduction in the 2000 result as US\$172m of purchased in-process technologies on Pathogenesis' balance sheet was written off.

In February 2002, the company acquired Matrix Pharmaceutical, Inc. to strengthen its biopharmaceuticals segment in the treatment of cancer.

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