
Financial accounts reports

Colin Aaronson

Cambridge Antibody Technology plc: Interim results for the six months ended 31st March, 2004

Cambridge Antibody Technology plc (CAT) has established itself as a leader in the development of human monoclonal antibodies as new treatments for disease, based upon its own antibody technology. By mid-June 2004 it had one drug, HUMIRA™, a treatment for rheumatoid arthritis, approved in 41 countries including the USA and the UK, drug treatments for five conditions in Phase III and a number of other drugs at Phase I or II, or at the preclinical stage.

HUMIRA™ was the first CAT-derived antibody to receive approval for marketing and the first human monoclonal antibody approved for the treatment of rheumatoid arthritis. It was isolated and optimised by CAT in collaboration with Abbott Laboratories. HUMIRA™ neutralises Tumour Necrosis Factor alpha – a protein produced by cells of the immune system that is primarily responsible for inflammation, damage and destruction of the joints in rheumatoid arthritis. HUMIRA™ is in Phase II and Phase III trials for a number of other conditions including psoriasis and Crohn's disease. CAT's pipeline also includes Trabio™, a potential treatment to prevent or reduce the production of excessive scar tissue following, for example, glaucoma surgery. Trabio™ is a human IgG4 monoclonal antibody that neutralises Transforming Growth Factor beta 2 – a protein produced in response to injury in the eye and believed to be responsible for the formulation of excessive scar tissue, which is the main reason for failure of glaucoma surgery. CAT estimates that there are 250,000 operations annually in the USA and Europe that could benefit. However,

if successful, Trabio™ could actually increase the size of that market.

Sales for the six month period amounted to £8.5m, up from £4.0m during the comparative period to 31st March, 2003. Included in revenue was royalty revenue amounting to £2.9m in respect of sales of HUMIRA™ by Abbott during the year ended 31st December, 2003. Abbott reported that HUMIRA™ had achieved full year sales of US\$280m in 2003 with forecast sales of US\$700m in 2004 and US\$1.2bn in 2005. In November 2003 CAT commenced legal proceedings against Abbott Biotechnology Limited and Abbott GmbH concerning the level of royalties payable to CAT. A trial has been set for November 2004, the results of which could also affect the level of royalties due to CAT in respect of HUMIRA™. Licence fees of £2.2m, milestone payments and contract research fees of £1.1m and other income of £400,000 made up the balance of revenues.

CAT made an operating loss of £20.0m during the period, after research and development expenditure of £21.5m (comparative period 2003: £21.3m). Interest of £2.1m was earned in the six-month period; cash balances and short-term investments closed at £108.6m. Net cash outflow from operations of £15.8m was covered by the proceeds from the issue of shares (£14.1m) and interest received. The company anticipates a net cash outflow of less than £21m for the present financial year, most of which will take place in the second half. Given its level of cash and short-term investments, the company is under no immediate pressure to raise any further funds through the issue of shares. The share price started 2004 at around 470 pence and has stayed within a range of between approximately

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450 pence and 570 pence. By mid-June 2004 it had returned to 480 pence.

Crucell NV: Results for the year ended 31st December, 2003

Crucell is a biotechnology company developing vaccine and antibody products to prevent and treat infectious diseases. Based in the Netherlands, its shares are quoted on Euronext and NASDAQ. Crucell has developed three proprietary technologies to discover and develop vaccines and antibodies. The company's pipeline includes potential vaccines for influenza and West Nile virus, recombinant vaccines for Ebola and Malaria. All four product groups are at the preclinical stage.

Crucell earned revenue of €7.4m in 2003 compared with €9.6m in 2002. Revenue is based upon payments under contracts from licensees and partners. Such payments are lumpy and volatile, and the company expects volatility in revenue to continue. Despite reduced turnover, the company made a reduced loss at €23.4m (2002: loss of €58.7m). The main reason for this was that the 2002 comparative included goodwill impairment of €30.9m. There were also cost savings – administration and sales expenses fell by €2.7m and research and development expenditure fell from €24.3m to €22.3m. Crucell had cash balances of €87.2m, meaning that with a burn rate of approximately €20m per annum, there is no immediate need for a fundraising.

In Crucell's case, as with most early stage biotechnology companies, past financial performance is not helpful in anticipating future performance. The long-term prosperity of this company clearly will depend on the products coming out of its pipeline.

MediGene AG: Results for the year ended 31st December, 2003

MediGene AG is a biotechnology company that is located in Martinsreid,

Germany, and San Diego, California and its primary focus is on developing novel approaches to the treatment of tumours. The company's shares are listed in Frankfurt.

MediGene is the first German biotechnology company with a drug on the market; Eligard[®] is an LH-RH agonist (luteinising hormone-releasing hormone) which significantly and consistently reduces the testosterone level in the body, thus suppressing tumour growth in patients suffering from advanced, hormone-dependent prostate cancer. Eligard[®] is marketed by the Japanese pharmaceuticals group Yamanouchi and MediGene will receive payments of up to €23.5m plus royalties on sales.

Turnover for the year ended 31st December, 2003, was €1.7m, down from €3.2m for 2002. Income, which comprised reimbursements received from the company's strategic alliances with pharma partners for research and development expenses, was reduced principally because of the termination of its research cooperation with Schering. Net pre-tax loss was reduced from €38.9m to €31.0m through cost-cutting measures, including an approximate €5m reduction in research and development expenditure.

MediGene's pipeline also includes Polyphenon[®] E Ointment for the treatment of genital warts, one of the most common venereal diseases worldwide. Approximately 14 million people in North America and 15 million people in Europe are believed to be infected by human papilloma viruses (HPV 6 or 11) that cause genital warts. The company completed a Phase III European trial involving 500 patients and expects to complete a US Phase III trial by the end of 2004. The active ingredient is an extract of green tea leaves.

The company believes that Polyphenon[®] E has an annual sales potential in excess of €100m with possible applications for other skin conditions. The company started a Phase II trial in

April for treatment of actinic keratosis, a precursor to skin cancer. The company believes this could increase potential annual sales of Polyphenon[®] E by €200m and there are other potential applications that could further increase sales.

Other treatments under development include AAV, a vaccine for the treatment of malignant melanoma which is being developed with Aventis and NV1020 for the treatment of liver metastases. NV1020 is a modified herpes simplex type 1 virus (HSV) that has been genetically engineered to replicate aggressively in cancer cells to kill them while sparing normal cells (Phase I study completed).

A cost-cutting exercise resulted in MediGene putting on hold the development of G207, a potential treatment for malignant brain tumours. G207 is a modified herpes simplex virus that has been genetically engineered to

replicate in and kill cancer cells while sparing normal cells. A Phase I study has been completed. The company has stated that the project will not be continued without external funding.

The company anticipates turnover of €8m for 2004, a loss reduced to €15m and a cash balance at the end of the year of €25m. This last figure includes €16.7m raised in March 2004. The results for the three months to 31st March, 2004, showed increased turnover of €3.9m and a reduced loss of €1.4m. Although encouraging, it is the potential from the company's pipeline that has underpinned an impressive share price performance that has seen Medigene's share price almost double between July 2003 and June 2004.

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