
EU financial accounts reports

Colin Aaronson

Acambis plc: Interim results for the year ended 31st December, 2003

Acambis is a profitable and cash-generative biotechnology company that is focused on building a substantial franchise in the vaccine space. Its results for the period have benefited significantly from its contract to supply 155 million doses of its ACAM2000 smallpox vaccine to the US Centers for Disease Control and Prevention (CDC). During the year ended 31st December, 2003, Acambis generated profit before taxation (before exceptional items) of £46.8m on sales of £169.1m compared with a profit of £9.6m on sales of £79.7m for the whole of 2002. The pre-tax profit for the year was £39.4m, after taking account of an exceptional cost of £7.4m following a settlement with BTG International Limited to discharge all rights and obligations under a technology licence agreement established in 1994. The profit was earned mainly in the third quarter, with £22.2m earned during the three months ended 30th September, 2003, the company having earned £20.6m for the six months ended 30th June, 2003. Research and development expenditure increased from £16.5m in 2002 to £19.1m in 2003, the result of the progression of the company's products to the later stages of development.

The company had cash and short-term investments of £125.2m at 30th September, 2003, having generated £113m during the year. Apart from its profitability, the cash position benefited from a reduction of stock of £30.2m (primarily the result of the transfer of stock to the CDC) and a reduction in short-term debtors of £41.7m. Net assets at 31st December amounted to £86.9m.

The cash Acambis is generating will be

used, in part, to develop its travel vaccine franchise, as well as to maintain and develop its pipeline in order to deliver sustainable growth. In August it acquired Berna Products Corporation (BPC), a US-based sales, promotion and distribution organisation for its travel vaccine franchise. BPC made operating profits of US\$1m in 2002 through sales of its oral typhoid vaccine Vivotif[®] which is licensed in over 50 countries worldwide and is the only orally administered typhoid drug available. The results for the year include a contribution from sales of Vivotif[®] in the last four months of 2003. Sales of Vivotif[®] increased by 30 per cent, on a like-for-like basis compared with the equivalent period in 2003. Acambis also completed a Phase III paediatric clinical trial of ARILVAX[™], a yellow fever vaccine for which it has US marketing rights. On 19th February, however, the company announced a delay in the process of submitting a Biologics License Application to the US Food and Drugs Administration pending the upgrade of the plant where ARILVAX[™] is manufactured.

The company's Modified Vaccinia Ankara (MVA) smallpox vaccine is a weakened form of the current generation of smallpox vaccines and is aimed at individuals with weakened immune systems. The company believes that there is a substantial opportunity for it to sell its MVA vaccine as demonstrated by the indication given by the US government's Department of Health and Human Services that it intends to purchase 60 million doses of MVA at a cost of US\$15 per dose. Acambis also believes that its ChimeriVax-West Nile vaccine against the West Nile virus also represents a significant opportunity. Infection by West Nile resulted in the death of 284

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individuals in the USA in 2002. On 6th November, 2003, Acambis announced the start of a Phase I trial.

Other products under development include a tetravalent (four-component) dengue vaccine and ChimeriVax JE vaccine against Japanese encephalitis that had completed two Phase II trials at the time of the six-monthly interim report on 16th September, 2003, and for which the company was expecting to start Phase III trials around the end of 2004. Acambis has signed a memorandum of understanding with the WHO for the development of this vaccine.

Acambis's share price performed slightly below the sector (increase of 13 per cent) and the market as a whole during 2003 (increase of 12 per cent; FTSA-100), increasing by approximately 10 per cent, from 277p to 305p. By 10th March, 2004, however, the share price had reached over 360p. In January, Acambis announced that profits for 2003 as a whole would be £12m less than expected owing to a delay in shipping vaccines to the US CDC as a result of a heightened security alert at the end of December. This effectively transfers profits to 2004. However, with the completion of the CDC contract, sales and profits are expected to fall until the company sees the benefit of new products coming from its pipeline.

The shares fell back to 300p after the announcement on 13th April it was suspending the recruitment of additional volunteers for the Phase III trials of its investigational vaccine ACAM2000. This was a precautionary measure after the discovery of three myopericarditis cases in both ACAM2000 and Dryvax® (the comparator vaccine being used in the trials) vaccination subjects.

Alizyme plc: Results for the six months ended 30th June, 2003

Alizyme is a biotechnology company based in Cambridge, UK, whose drug development programme focuses on therapies for the treatment of obesity, constipation-predominant irritable bowel

syndrome (C-IBS) and mixed-syndrome irritable bowel syndrome (m-IBS), ulcerative colitis and mucositis resulting from chemotherapy or radiotherapy. The company does not yet have any turnover.

During the six month period Alizyme spent £7.3m on research and development compared with £4.6m for the comparative six month period in 2002, and £509,000 on management and administration, down from £567,000 for the six months ended 30th June, 2002. Over the period under review, cash and short-term investments increased by £10.1m from £5.3m to £15.4m, the result of a £16.1m fundraising drive. In October 2003 a further £11.5m was raised through an institutional placing.

The profit and loss account balance at 30th June, 2003, was a negative £(41.8)m, implying expenditure on research and development of less than £50m since the company's formation in 1995, a performance that compares favourably with industry standards. Research and development accounts for approximately 90 per cent of operating expenditure. Alizyme presently has four products within its pipeline.

Renzapride is a potentially effective treatment for both c-IBS and m-IBS that successfully completed Phase IIb trials in 510 patients with c-IBS. In September the company announced successful preliminary results from a Phase IIb trial of patients with m-IBS. COLAL-PRED is a treatment for ulcerative colitis. Activity during the period concentrated on preparing for the commencement of Phase III clinical trials. Alizyme's obesity treatment ATL-962 is a gastrointestinal lipase inhibitor. In September the company announced successful preliminary results of its Phase IIb trial in clinically obese patients, which allows for the preparation for Phase III clinical development. In January Takeda Chemical Industries Ltd exercised its rights to a licence and development agreement for Japanese rights to ATL-962. Alizyme has now received from Takeda US\$5m in respect of this

therapeutic and may receive up to an additional US\$37m depending on milestones and other events. During the period under review the company has progressed the development of its ATL-104 mucositis treatment in anticipation of Phase IIa proof of concept clinical trials in cancer patients.

The market's view of Alizyme, its pipeline and its ability to control costs has been reflected in its share price which performed strongly during 2003, increasing from 34p to 173p over the course of the year; it stood at 184p at 9th March, 2004.

The final results were announced on 1st April, 2004, after this paper had gone to print. The share price has since fallen back to below 140p.

Medivir AB (Sweden): Results for the year ended 31st December, 2003

Medivir is a biotechnology company located in Huddinge, Sweden, and Cambridge, UK, that is focused on developing new anti-viral drug compounds and treatments for autoimmune diseases. It was floated on the Stockholm borsen in 1996. Medivir's research is based on proteases and polymerases as target enzymes and its portfolio includes potential treatments for HIV, jaundice, herpes, osteoporosis, rheumatoid arthritis and asthma. Medivir has five projects in clinical development phases: two in Phase I, one in Phase II and two about to enter Phase III. The group has ten activities that are at a preclinical stage.

During the 12 months ended 31st December, 2003, consolidated net sales were SEK 149.0m largely comprising the outlicensing to GlaxoSmithKline of Medivir's MIV-210 (potential treatment for HIV and hepatitis B viruses) and the outlicensing to Boehringer Ingelheim of its MIV-310 candidate drug against multiresistant HIV. Phase I trials of MIV-210 have been completed and MIV-310 is

in Phase II trials. Outlicensing income for the 12 months ended 31st December, 2002, amounted to SEK256.3m. After taking account of a profit on financial investments of SEK69.6m (principally the disposal of its subsidiary, the CCS Group), Medivir reported a net loss before tax of SEK42.7m.

At 31st December, 2003, the group's consolidated net assets amounted to SEK277.8m including cash and other liquid assets of SEK239.2m, which were up from SEK143.9m at 31st December, 2002. The improvement in the group's cash position arose mainly from its sale of subsidiaries which generated SEK114.1m.

The most advanced projects are RP-606 against shingles and ME-609 against labial herpes (cold sores). During the year, the synthesis development process for RP-606, undertaken by Medivir's partner Reliant, has been successful and substance production ahead of upcoming Phase III studies has begun. Medivir has spent time during the year consolidating ME-609's European patents and during the second half has been making preparations ahead of its forthcoming Phase III study. In November, Roche and Medivir entered into two agreements within the field of virology. Within the HIV field, the companies restructured the existing collaborative agreement for MV026048 (a potential treatment in the preclinical phase) and for hepatitis C they entered into a new research partnership agreement. Also in November, Medivir and Hengrui signed a research partnership agreement to develop drugs to combat chronic obstructive pulmonary disease.

The stock market reacted favourably to Medivir, which has seen its share price increase from SEK42.6 to SEK116 over the course of the year. By 9th March, 2004, the shares stood at SEK137.

On 16th March, 2004, the company announced a rights issue. Since then the share price has fallen to below SEK100.

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