### FORM 6-K

### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13s – 16 or 15d – 16 of the Securities Exchange Act of 1934

For the month of March 2005

## **Acambis plc**

(Translation of registrant's name into English)

Peterhouse Technology Park 100 Fulbourn Road Cambridge CB1 9PT England

(address of principal executive offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F).

Forms 20-F Form 40-F

(Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934).

Yes No

(If []Yes[] is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- ).

#### **Enclosure:**

Acambis announces details of preliminary results meeting and conference call on 8 March 2005. Acambis looks towards year of investment in 2005.

#### Acambis announces details of preliminary results meeting and conference call on 8 March 2005

**Cambridge, UK and Cambridge, Massachusetts** [] **21 February 2005** [] Acambis plc ("Acambis") (LSE: ACM, NASDAQ: ACAM) will hold a meeting and conference call for analysts at 9.30 am on Tuesday, 8 March 2005.

The analyst meeting will be held at the offices of Financial Dynamics, Holborn Gate, 26 Southampton Buildings, London WC2A 1PB. For details, contact Mo Noonan at Financial Dynamics on +44 (0) 20 7269 7116. An instant replay of the call will be available until 8 April 2005 on telephone numbers UK: +44 (0) 20 7365 8427 and US: +001 (617) 801 6888. The pin code is 47500729.

An audio webcast of the call will also be available via Acambis' website at <a href="www.acambis.com">www.acambis.com</a>. The webcast replay will be available until Wednesday, 8 March 2006.

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#### **Enquiries:**

#### **Acambis plc**

Lyndsay Wright, VP Communications and Investor Relations: Tel +44 (0) 1223 275 300

#### **Financial Dynamics**

Mo Noonan: Tel +44 (0) 20 7269 7116

#### **About Acambis**

Acambis is a leading developer of vaccines to prevent and treat infectious diseases. Recognised internationally as the leading producer of smallpox vaccines, Acambis is developing an investigational smallpox vaccine and manufacturing emergency-use stockpiles of this investigational vaccine for the US Government and other governments around the world. Acambis is establishing a travel vaccines franchise through its US-based subsidiary Berna Products Corporation, which markets Vivotif®, the world's only licensed oral typhoid vaccine, in North America. Acambis has a number of other potential travel vaccines in development and is also developing an investigational vaccine against the West Nile virus, which has spread to 47 US States in the last five years.

Acambis is based in Cambridge, UK and Cambridge, Massachusetts, US. Its primary listing is on the London Stock Exchange (ACM) and its shares are listed in the form of American Depositary Receipts on NASDAQ (ACAM). More information is available at <a href="https://www.acambis.com">www.acambis.com</a>.

#### "Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

The statements in this news release that are not historical facts are forward-looking statements that involve risks and uncertainties, including the timing and results of clinical trials, product development, manufacturing and commercialisation risks, the risks of satisfying the regulatory approval process in a timely manner, the need for and the availability of additional capital. For a discussion of these and other risks and uncertainties see "Risk factors" in the Company's 2003 Annual Report and 2003 Form 20-F, in addition to those detailed in the Company's filings made with the Securities and Exchange Commission from time to time. These forward-looking statements are based on estimates and assumptions made by the management of Acambis and are believed to be reasonable, though are inherently uncertain and difficult to predict. Actual results or experience could differ materially from the forward-looking statements.

#### EMBARGO: NOT FOR PUBLICATION OR BROADCAST BEFORE 7.00 AM GMT ON TUESDAY, 8 MARCH 2005

#### Acambis looks towards year of investment in 2005

**Cambridge, UK and Cambridge, Massachusetts** [ **8 March 2005** [] Acambis plc ("Acambis") (LSE: ACM, NASDAQ: ACAM) announces its preliminary results for the fourth quarter and year ended 31 December 2004.

#### **Key points**

- > 2004 financial performance
  - o Revenue of £85.5m (2003: £169.1m) in line with £80-90m guidance range
  - o Pre-tax profit ahead of consensus forecasts at £26.2m (2003: £39.6m)
  - o Cash and short-term investments balance >£100m at year end
- > Smallpox franchise:
  - o ACAM2000 warm-base manufacturing proposal submitted
  - o Work progressing well under second US Government MVA contract
- > R&D pipeline:
  - o ARILVAX: BLA filing delayed; discussions ongoing with Chiron
  - o ChimeriVax-JE bridging trial fully recruited; plans underway for Phase III trials later this year
  - o ChimeriVax-West Nile Phase I trial fully recruited
  - o ChimeriVax-Dengue moving into next stage of clinical development
- > BPC performing to expectations during first full year of Acambis ownership
- > Board and senior management team strengthened with increased industry experience

		Year ended 31 December		Three months ended 31 December	
	2004	2003	2004	2003	
Revenue	£85.5m	£169.1m	£23.1m	£21.0m	
Profit/(loss) before tax	£26.2m	£39.6m	£4.4m	£(3.3)m	
Earnings/(loss) per share (basic)	18.6p	34.7p	4.7p	(0.8)p	
Earnings/(loss) per ADR (basic)	\$0.71	\$1.24	\$0.18	\$(0.03)	
Cash and short-term investments	£101.8m	£125.2m	£101.8m	£125.2m	

<sup>\*</sup> Calculated on the basis of one ADR to two ordinary shares.

Gordon Cameron, Chief Executive Officer of Acambis, said:

"With the ups and downs of 2004 now behind us, we are looking forward to 2005 as a year of investment, aimed at driving our product pipeline forward and expanding our product portfolio. With clear strategic goals and our strengthened management team in place, we expect to make good progress in 2005 towards our aim of establishing Acambis as one of the leading players in a new generation of vaccine companies."

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#### **Enquiries:**

Acambis plc	On 8 March 2005	Thereafter
Gordon Cameron, CEO	+44 (0) 20 7831 3113	+1 (617) 761 4200
David Lawrence, CFO	+44 (0) 20 7831 3113	+44 (0) 1223 275 300
Lyndsay Wright, VP Communications and IR	+44 (0) 20 7831 3113	+44 (0) 1223 275 300
Financial Dynamics		
David Yates/Lucy Briggs	+44 (0) 20 7831 3113	+44 (0) 20 7831 3113

**Analyst meeting and conference call:** An analyst meeting and conference call will be held today at 9.30 am GMT at the offices of Financial Dynamics, Holborn Gate, 26 Southampton Buildings, London WC2A 1PB. For details, contact Mo Noonan at Financial Dynamics on telephone number +44 (0) 20 7269 7116. An instant replay of the

conference call will be available from shortly after the meeting until midnight on 8 April 2005 on the following telephone numbers: UK: +44 (0) 20 7365 8427; or US: +1617 801 6888. The pin code for the replay is 47500729.

Webcast: A live and archived audio webcast of the call will be available at www.acambis.com.

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#### **CHAIRMAN'S STATEMENT**

#### **REVIEW OF 2004**

With good news and progress in some areas and disappointments in others, 2004 was a year of mixed fortunes for Acambis.

Much attention was directed during the year to our high-profile ACAM2000 investigational smallpox vaccine project as we faced not only a five month-long clinical hold on our two Phase III trials but also the US Government's unexpected decision not to place an anticipated order for a further 26.5 million doses.

However, the clinical hold on ACAM2000 was lifted in September and we are working towards submitting a Biologics License Application ("BLA") to the US Food and Drug Administration ("FDA") during 2005, under the fast-track status we were granted at the end of 2004. We also succeeded in winning ACAM2000 contracts with three other governments during 2004 and have submitted a proposal to the US Government to provide it with an ongoing production readiness capability, known as "warm-base" manufacturing.

We were delighted to be awarded in September a second US Government contract for development and manufacture of our Modified Vaccinia Ankara ("MVA") attenuated smallpox vaccine, which also received fast-track status from the FDA during the year. This second contract, potentially worth up to \$131m, ensures we continue to be very well positioned to bid for future US Government stockpiling contracts.

We also became the first company to report results from a human clinical trial of a West Nile vaccine candidate, from which further results are expected during the first half of 2005. In addition, based on the data from our Phase I trial, the ChimeriVax-Dengue vaccine is advancing to the next stage of clinical development.

On the management front, following his appointment as Chief Executive Officer in February 2004, Gordon Cameron is providing strong leadership in driving forward our strategy and operations. Together with David Lawrence, who joined us as Chief Financial Officer from Chiron Vaccines in August, and our Chief Scientific Officer, Tom Monath, our team of Executive Directors represents a strong combination of diverse knowledge and experience, and is well equipped to manage our next phase of growth.

#### **SMALLPOX FRANCHISE UPDATE**

#### ACAM2000

Preparations for the possibility of a smallpox outbreak continue to have a high profile internationally. In November 2004, the World Health Organization ("WHO") published a report on smallpox that is to be put before the World Health Assembly in May 2005. In it, the WHO highlighted that "timely administration of vaccine according to well-established epidemiological principles has historically been effective in rapidly containing smallpox outbreaks. Vaccine stocks currently held by countries are, however, unevenly distributed and of uncertain quality. The report outlined plans for a five million-dose vaccine stockpile to be held by the WHO in Geneva and for a "virtual" stockpile of up to 200 million doses that countries pledge to make available to the WHO in the event of an outbreak. It also supports the concept of maintaining "standby capacity", i.e., warm-base manufacturing, in at least two countries around the world.

The US Government continues to take the lead in preparations. Although we were disappointed that the US Centers for Disease Control and Prevention ("CDC") did not place additional orders under the current 182.5 million-dose contract for ACAM2000, we are confident that the US Government remains committed to smallpox preparedness.

We have submitted a proposal to the CDC for Acambis to provide the US Government with an ongoing warm-base manufacturing capability. It proposes that this activity commence in 2005 and continue for several years thereafter. We await a final decision on our proposal from the CDC.

Since the lifting of the clinical hold in September, which had been placed on the Phase III trials in April by the FDA following identification of a small number of cases of the heart-related condition, myocarditis, we have been closing out the trials and analysing the safety and efficacy data. We are on schedule to file the BLA with the FDA in the second half of 2005 and hope to have a decision on our application during 2006. Cost savings associated with closing the trials early had a positive effect on the gross margin for this fixed-price contract.

We believe that if ACAM2000 is approved by the FDA, licensure could be instrumental in achieving further sales to other governments. In 2004, our share of sales to other governments generated £6m in revenue to Acambis and we are confident that, based on an assessment of discussions currently ongoing, we will be able to achieve at least a similar level of sales in 2005. Since the beginning of the year, we have already completed one further government contract.

#### Vaccinia immune globulin ("VIG")

During the year, we received our first government order for Cangene's investigational C-VIG and are in discussions with a number of other governments. As a treatment for adverse reactions to smallpox vaccination, VIG is recommended for any government stockpiling smallpox vaccines. We act as Cangene's agent outside North America and Israel. Cangene has submitted a BLA to the US FDA to seek licensure of C-VIG.

#### Modified Vaccinia Ankara

Acambis is currently evaluating MVA, an attenuated smallpox vaccine, in human clinical trials under a US Investigational New Drug application. The clinical trials are being conducted to assess whether MVA is safe and effective for use by the proportion of the population for whom standard smallpox vaccines are contraindicated. In the US, this represents up to 20% of the population.

In September, we were one of two companies to win a second US Government contract, for the development and manufacture of our investigational MVA vaccine from the National Institute of Allergy and Infectious Disease ("NIAID"), part of the US National Institutes of Health. We are co-developing our MVA vaccine candidate with Baxter Healthcare ("Baxter"). Our contract is potentially worth up to \$131m.

Under the principal part of this contract, worth approximately \$76m, we are conducting a series of clinical trials and demonstrating our ability to scale up our production processes by delivering 500,000 doses of vaccine. The second part of the contract, which is an option awardable at the discretion of the NIAID, would be worth approximately \$55m and require delivery of a further 2.5 million doses of MVA. Work is progressing well under this principal part of the contract and, with the clinical testing programme, will continue through 2007, with the majority of the work being conducted during 2005 and 2006.

Successful performance under this contract is critical to establishing a strong competitive position when bidding for the larger stockpiling contract that the US Government has indicated it intends to issue under Project Bioshield, which was signed into law in July 2004. The US Government has not yet indicated when it will issue a Request for Proposals inviting tenders for the MVA stockpiling contract or its timeline for contract award. We are monitoring the situation closely and remain confident that, together with our partner, Baxter, we are in a strong competitive position in bidding for the contract.

#### TRAVEL VACCINE FRANCHISE UPDATE

In its first full year as an Acambis subsidiary, Berna Products Corporation ("BPC") performed extremely well, with its sales of the oral typhoid vaccine, Vivotif®, well ahead of the previous year's. Furthermore, sales in 2005 to date are ahead of the equivalent period in 2004.

#### **CLINICAL DEVELOPMENT UPDATE**

#### $ARILVAX^{TM}$

We have US marketing rights to this yellow fever vaccine from its owner and manufacturer, Chiron Vaccines. Having completed all clinical trials required to apply for licensure of ARILVAX in the US, we submitted a BLA to the FDA in December 2003. However, we withdrew the application in February 2004 because Chiron Vaccines had indicated the requisite Pre-Approval Inspection by the FDA of its manufacturing facility would not be possible within the 10-month BLA review timeframe. Following a project review, we will not now be in a position to resubmit the BLA within the previously indicated timescale of the first half of 2005. At this stage, it is premature to indicate when the resubmission will take place. The revised timelines and regulatory strategy are the subject of discussion between the companies.

#### ChimeriVax-JE

Japanese encephalitis ("JE") is a mosquito-borne viral disease that affects much of Asia and parts of Australia. According to the WHO, 50,000 human cases of JE are reported annually in Asia, resulting in 15,000 deaths, although the true incidence is probably higher as surveillance and reporting rates are poor.<sup>2</sup>

ChimeriVax-JE is the most advanced of the vaccines we are developing based on our proprietary ChimeriVax<sup>™</sup> technology. JE vaccines have been available for many years but there is a recognised need for development of a second-generation JE vaccine that is safer, requires fewer doses and can be used more readily in developing countries<sup>3</sup>. The major markets for ChimeriVax-JE would be endemic populations and travellers/military personnel from overseas who are visiting endemic regions.

The "bridging" trial that we are conducting is now fully recruited. This follows our strategic decision in 2003 to bring commercial-scale manufacture of ChimeriVax-JE in-house and to finalise scale-up of our manufacturing process to optimise a stable, freeze-dried formulation prior to undertaking Phase III clinical testing. The bridging trial aims to confirm that the new material has a clinical profile similar to that seen in previous trials of the vaccine. Once complete, we plan to initiate Phase III trials in the second half of 2005.

#### ChimeriVax-West Nile

West Nile, which is a mosquito-borne virus closely related to JE, is causing particular problems in the US where it was first identified in 1999. Since then, there have been more than 16,000 cases and 650 deaths related to West Nile virus<sup>4</sup>.

In May 2004, we became the first company to publish results from a human clinical trial of a West Nile vaccine with data from the first cohort of a Phase I trial. Of the 15 subjects vaccinated with ChimeriVax-West Nile in the first cohort, 100% developed West Nile-neutralising antibodies within 21 days of receiving a single inoculation. These data were published following the unblinding of data from the first cohort vaccinated in our Phase I trial. Two adverse events were noted, which we believe were caused by strenuous exercise. A paper on this subject was recently published in *Human Vaccines* (1:1, Jan-Feb 2005). The protocol was consequently amended to include a placebo group instead of a yellow fever comparator. Two further cohorts, making a total of 80 subjects, have now been recruited and vaccinated in the trial. We elected not to recruit subjects for the final, lowest-dose cohort as we felt the data would not have been useful to product development objectives and timelines. Data analysis is ongoing and we expect to publish preliminary results from the completed trial in the first half of 2005 and to initiate the next phase of trials in the second half of the year, using material manufactured by Acambis.

#### ChimeriVax-Dengue

Dengue is a mosquito-borne viral infection that, in recent years, has become a major health concern. The WHO estimates that there are approximately 50 million dengue infections each year and that more than 500,000 cases of the more severe form of the disease, dengue haemorrhagic fever, require hospitalisation each year<sup>5</sup>. As there are four distinct dengue virus serotypes, a successful vaccine will need to protect against all four.

Rights to Acambis' tetravalent (four-component) ChimeriVax-Dengue vaccine are licensed to sanofi pasteur ("SP"), which fully funds the development programme. We are entitled to milestone payments and a royalty on any sales. Preliminary safety data are available from a Phase I trial of our tetravalent vaccine. SP is expected to publish the data when comprehensive validated Phase I safety and immunogenicity data are available. As planned in the licence agreement between Acambis and SP, responsibility for manufacturing and for further clinical testing is with SP. SP is proceeding to the next phase of clinical trials and is engaged in industrial scale-up of the product, Acambis will continue to be involved in the programme through to licensure of the product as part of a joint steering committee.

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#### C. difficile

Clostridium difficile ("C. difficile") bacteria are often found in institutional settings such as hospitals and nursing homes. Treatment with antibiotics can permit these bacteria to over-populate the colon and cause C. difficile-associated diarrhoea ("CDAD") by releasing two toxins. CDAD can be recurrent and life-threatening.

The vaccine we are developing aims to stop the recurrence of CDAD, which occurs in approximately one in five CDAD patients after standard treatment. However, the rising incidence and severity of this infection may also justify clinical development towards a primary prevention indication. We have previously conducted Phase I trials of our vaccine but discontinued these when we found that the vaccine lot in use was losing its potency four years after manufacture. We have recently completed the development of a new, more robust and scaleable in-house manufacturing process. We are now returning to clinical testing with two Phase I trials planned to commence in the first half of 2005.

#### **BUSINESS DEVELOPMENT UPDATE**

As part of our efforts to develop a more predictable revenue stream, we are pursuing opportunities to acquire, in-license or co-market products. We are particularly interested in revenue-generating products that can be sold through BPC, where these can be channelled through the existing infrastructure at marginal cost. We are also looking to leverage our clinical and regulatory expertise and manufacturing infrastructure to partner in projects with companies that are seeking to benefit from such capabilities or experience.

Our balance sheet strength, and particularly our cash and short-term investments balance of more than £100m, gives us considerable flexibility in pursuing such opportunities.

#### **BOARD AND MANAGEMENT CHANGES**

Following Gordon Cameron's appointment to the role of CEO in February 2004, we recruited David Lawrence to fill Gordon's previous position as CFO. Through his previous roles at Chiron and GlaxoSmithKline, David brings to Acambis considerable industry knowledge, as well as strong management and financial skills.

At the end of 2004, Nick Higgins stood down from the Board after 11 years with the Group to pursue alternative career opportunities within the industry. On behalf of the Board, I would like to record our thanks to Nick for the significant contribution he made to the growth and development of Acambis, particularly through the many commercial initiatives in which he was involved.

During the year, the Board was strengthened through the appointment of two Non-executive Directors, Ross Graham, previously CFO of Misys plc, and Dr Randal Chase, previously President of Shire Biologics. Their financial and vaccine industry experience, respectively, are major assets to the Board.

We also welcomed Dr Joan Fusco into the senior management team as Senior Vice President, Operations, with responsibility for key operational areas of Manufacturing, Development and Quality. Joan was previously a Vice President in Baxter's vaccines division and has gained extensive technical, commercial, project management and operational experience during her 18 years in the vaccine industry. Through the appointments of Joan, David Lawrence, Ross Graham and Randal Chase, we have significantly expanded our commercial and industry expertise.

#### **EMPLOYEES**

We continue to monitor headcount closely to ensure it matches the current and future needs of the business. At 31 December 2004, our Group headcount was 270 (2003  $\square$  320). The decrease seen in 2004 was a result of the closure of the UK Research department, announced in January 2004, following the decision to consolidate our Research operations in the US.

#### **FINANCIAL REVIEW**

The financial results for the year ended 31 December 2004 are presented below. A high-level summary of the results for the three months ended 31 December 2004 is also shown.

#### Trading results

Revenue for the year was £85.5m (2003 - £169.1m), which is in line with the £80-90m range given at the time of our third-quarter results in November. As in 2003, the main sources of revenue were the fixed-price 155 million-dose ACAM2000 contract with the CDC and its order for an additional 27.5 million doses of the vaccine. The reduction compared with 2003 reflects the fact that the majority of the work under the 155 million-dose contract was undertaken in 2002 and 2003. During the year, we continued to record revenue from sales of ACAM2000 to other governments. We also recorded revenues from our two contracts with the NIAID in respect of our MVA programme, the second of which was awarded in September 2004, from sales of Vivotif and from SP for our ChimeriVax-Dengue vaccine programme.

Cost of sales in 2004 decreased to £34.3m (2003 - £98.4m), in line with revenues. These relate to all of the above revenue except costs on the ChimeriVax-Dengue programme, which are recorded within R&D costs.

Our gross profit margin for the year increased sharply to 59.9% (2003 - 41.8%). This represents the change in the mix of revenues recorded in the two years. It was also impacted by the reassessment of costs under the 155 million-dose contract following the decision to close out the two Phase III clinical trials early and expensing of certain costs to R&D costs as the manufacturing facility was used to support our proprietary vaccine development programmes.

Expenditure on R&D increased significantly in the year to £28.9m (2003 - £19.9m) as a result of the progression of our projects into later stages of development and the process development and manufacturing work for our R&D projects.

Sales and marketing costs, which include both Acambis' internal sales and marketing infrastructure and our BPC operation, which we acquired in August 2003, were £2.7m (2003 - £1.3m). The increase principally reflects a full year of costs in 2004 associated with BPC. Administrative costs, including amortisation of goodwill, increased to £5.1m (2003 - £4.5m) as a result of the acquisition of BPC.

During the year, the Group recorded two items related to the Canton manufacturing facility. Firstly, in May, we announced that we had reached a c.£10.6m (\$19.0m) settlement with Baxter in respect of the termination of the Canton manufacturing agreement. £10.2m of that income has been recorded as exceptional other operating income during the year. The balance of £0.4m is recorded within interest receivable and similar income to reflect the staged-payment nature of the agreement, with £0.2m recorded during 2004 and the remaining £0.2m to be recorded during 2005. The first £5.1m (\$9m) due under this agreement was received in 2004 and the second instalment of £2.9m (\$5m) was received in January 2005. The third and final instalment of c.£2.6m (\$5m) is payable in January 2006. Secondly, as a result of this agreement with Baxter, we also recorded during the year a non-cash impairment charge of £1.9m (\$3.5m) as an exceptional administrative item, which related to certain of the fixed assets in the plant for which, as a result of terminating our agreement with Baxter, we no longer had a use. The net income recorded by these two transactions was £8.3m (2003 - £nil).

The Group recorded a further exceptional administrative item of £0.7m (2003 - £nil) associated with the restructuring of the Research operations and the closure of the UK Research department, announced in January 2004.

Interest receivable increased significantly in 2004 to £4.6m (2003 - £2.1m) as a result of higher average levels of cash and interest rates throughout the period. In 2004, the Group sold its investment in Medivir AB for £0.7m, resulting in a loss of £0.1m in 2004. Interest payable reduced marginally in 2004 to £0.9m (2003 - £1.0m), representing primarily interest payable on the lease-financing facility that was put in place for the reactivation of our manufacturing plant. During 2004, an exchange gain of £0.3m (2003 - £0.4m) was recorded as a result of the revaluation of the amounts outstanding under our US dollar-denominated debt facility for our ARILVAX programme.

Pre-tax profit for 2004 was £26.2m (2003 - £39.6m). The reduction seen in 2004, which is in line with expectations, is principally a result of lower level of activities on the ACAM2000 155 million-dose CDC contract.

In 2004, we recorded a tax charge of £6.4m (2003 - £3.9m). The effective tax rate for 2004 was 24.4% (2003 - 9.8%). This is lower than previously expected as a result of more effective utilisation of group tax losses.

#### Capital expenditure

Capital expenditure in 2004 was lower at £3.6m (2003 - £6.0m). Expenditure during the year related predominantly to the cost of redeveloping and expanding areas of our US R&D facility. We expect expenditure levels in 2005 to be similar to those seen in 2004.

#### Balance sheet highlights

#### i) Cash/debtors

Cash and short-term investments of the Group at 31 December 2004 amounted to £101.8m (2003 - £125.2m). The reduction in cash during the year is a result of the working capital movement associated with our 155 million-dose CDC smallpox vaccine contract.

During the year, Debtors: amounts receivable within one year increased to £15.6m (2003 - £12.3m), principally as a result of the amount owed by Baxter for settlement of the Canton manufacturing agreement.

#### ii) Stock/Creditors: amounts falling due within one year

Stock held at 31 December 2004 amounted to £6.0m (2003 - £18.2m). The reduction seen in the year is a result of having shipped ACAM2000 vaccine doses to our largest customer, the CDC, to complete the 155 million-dose order and fulfil the 27.5 million-dose order, and also to other governments. The balance principally represents work-in-progress and finished goods in relation to our ACAM2000 smallpox vaccine.

Our adopted method for recognising revenue under the ACAM2000 contract with the CDC, which involves the recognition of revenue in line with the degree of completion of the contract, continues to give rise to a significant difference between invoices submitted and amounts recognised as revenue. During the year, the amount recorded as deferred income under this contract reduced significantly to £16.5m (2003 - £49.5m) as a result of activities being completed on the contract. This is included within the total Creditors: amounts falling due within one year of £46.2m (2003 - £96.9m). This level of creditors will reduce further during 2005 as revenues under the 155 million-dose contract continue to be recognised.

#### iii) Lease financing and overdraft facilities

We have two US dollar-denominated financing facilities. The balance on our Canton lease-financing facility at 31 December 2004 was £9.4m (2003 - £12.6m). The reduction represents capital repaid in the period in accordance with the terms of the facility. The balance on the ARILVAX overdraft facility at 31 December 2004 was £3.6m (2003 - £3.9m).

#### Fourth quarter results

The following section summarises the financial highlights for the three months ended 31 December 2004 ("Q4"). Unless stated otherwise, the comparative figures in parentheses relate to the equivalent three-month period in 2003.

Revenues in Q4 increased marginally to £23.1m (2003 - £21.0m) and principally represented income from the ACAM2000 155 million-dose contract and sales of ACAM2000 vaccine to other governments. Cost of sales was marginally lower in Q4 at £10.6m (2003 - £11.3m), representing the higher gross margin percentage seen in 2004 over 2003. R&D costs increased to £7.4m (2003 - £4.7m), the increase being primarily attributable to the costs to support the process development and manufacturing work being carried out on our proprietary vaccine development projects. In Q4, we recorded £0.8m (2003 - £0.8m) of sales and marketing costs. Administrative costs remained static at £1.4m in Q4 (2003 - £1.4m).

Q4 contributed a pre-tax profit of £4.4m (2003 [loss of £3.3m) towards 2004 full-year results.

Capital expenditure decreased in Q4 to £0.7m (2003 - £1.2m).

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#### INTERNATIONAL FINANCIAL REPORTING STANDARDS ("IFRS")

In conjunction with Ernst and Young LLP, we have conducted a preliminary review of the financial implications of applying IFRS, which will be adopted by the Company for its financial results with effect from 1 January 2005. We believe we will not face any issues that are different from other pharmaceutical or biotechnology companies. Work is still ongoing to assess the financial impact of the new accounting standards. We believe that six standards under IFRS will potentially give rise to the main differences from UK GAAP: IFRS2, 'Share Based Payments'; IFRS3, 'Business Combinations'; International Accounting Standard (IAS) 38, 'Intangible assets'; IAS 32, 'Financial Instruments: Disclosure and Presentation'; IAS 39, 'Financial Instruments: Recognition and Measurement'; and IAS 12, 'Income Taxes'. The areas likely to have the most financial impact on Acambis' results are expected to be IFRS2 and IFRS3, which are expected to decrease and increase earnings, respectively.

#### **LOOKING AHEAD: 2005 AND OUR STRATEGY FOR GROWTH**

Operating within the rapidly growing infectious disease arena, Acambis aims to become one of the leading players in a new generation of vaccine companies. We have identified four key components to deliver that goal:

- > Exploit our smallpox franchise to the full;
- > Drive the development of new products;
- > Develop and leverage core capabilities;
- > Improve the predictability of our revenue stream.

Much of our recent success has come from government contracts for ACAM2000 smallpox vaccine, and we will continue to seek to gain maximum benefit from that, as well as the other areas of our smallpox franchise, in particular the MVA opportunity.

The cash generated by the smallpox franchise enables us to drive development of our pipeline of new, innovative vaccines, principally targeting unmet medical needs or offering improvements over existing vaccines. During 2005, we aim to progress each of our clinical development programmes into the next stage of development.

To maximise the value from our product pipeline, we are continuing to build core capabilities to enable us not only to develop, test and license products but also to manufacture and sell them, wherever possible, and are seeking to leverage these strengths to expand our product portfolio.

In addition, we are seeking to add products through in-licensing, partnering or acquisition, to help us develop sustainable and predictable revenue streams, mitigating the volatility of government contract revenues.

#### **GUIDANCE**

We have in recent years provided guidance on estimated revenues for the year. In 2005, some of our revenues are relatively predictable, particularly from those contracts we have already been awarded relating to ACAM2000 and MVA, and from sales of Vivotif. We estimate these relatively predictable revenues to be around £40m for 2005. However, we are pursuing several additional revenue-generating opportunities in 2005, each of which could have an impact on revenues in 2005 and beyond. In most cases, they relate to contracts still to be awarded by governments. These include US Government contracts for ACAM2000 warm-base manufacturing and for procurement of MVA vaccine, as well as non-US Government sales of ACAM2000 and C-VIG. Consequently, we do not feel it is appropriate to provide guidance on these additional, less predictable 2005 revenues at this stage, although we will review that position as the year progresses.

We expect the overall level of our R&D expenditure in 2005 to be similar to that of 2004. We expect an increase in expenditure on clinical development activities and a lower allocation of manufacturing costs to R&D as compared to 2004.

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#### OUTLOOK

In the Board's view, 2005 is a year of investment aimed at driving our product pipeline forward, further building Acambis' core capabilities and seeking to exploit opportunities to expand the business.

Though we have been a profitable company since 2002, we anticipate that the expected decline in revenues from our ACAM2000 US Government contract, coupled with the level of investment required to develop our product pipeline, may mean that we need to make a choice between remaining profitable in the short-term and making the required R&D investment. Given that choice, it is clearly appropriate that we should invest in the products for the long-term value they can generate.

We have clear goals of building a fully integrated business and maximising our revenue-generating opportunities to enable us to drive forward and expand our product portfolio. With our new management team in place, we are confident that, during 2005, we will make good progress towards our aim of establishing Acambis as one of the leading players in a new generation of vaccine companies.

#### Alan Smith Chairman

This preliminary results statement was agreed by the Board of Directors on 7 March 2005.

#### **Footnotes**

- <sup>1</sup> WHO EB115/36 (23 December 2004)
- <sup>2</sup> WHO Initiative for Vaccine Research (<u>www.who.int</u>)
- <sup>3</sup> Ibid (<u>www.who.int</u>)
- <sup>4</sup> US CDC (www.cdc.gov)
- <sup>5</sup> WHO fact sheet No.117 (<u>www.who.int</u>)

#### **About Acambis**

Acambis is a leading developer of vaccines to prevent and treat infectious diseases. Recognised internationally as a leading producer of smallpox vaccines, Acambis is developing an investigational smallpox vaccine, ACAM2000, and manufacturing emergency-use stockpiles of this investigational vaccine for the US Government and other governments around the world. It is also developing an attenuated smallpox vaccine, MVA, under contracts with the US National Institute of Allergy and Infectious Disease. Acambis is establishing a travel vaccines franchise through its US-based subsidiary Berna Products Corporation, which markets Vivotif®, the world's only licensed oral typhoid vaccine, in North America. Acambis has other potential travel vaccines in development and is also developing an investigational vaccine against the West Nile virus, which has spread to 47 US States in the last six years.

Acambis is based in Cambridge, UK and Cambridge, Massachusetts, US. Its primary listing is on the London Stock Exchange (ACM) and its shares are listed in the form of American Depositary Receipts on NASDAQ (ACAM). More information is available at <a href="https://www.acambis.com">www.acambis.com</a>.

#### "Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

The statements in this news release that are not historical facts are forward-looking statements that involve risks and uncertainties, including the timing and results of clinical trials, product development, manufacturing and commercialisation risks, the risks of satisfying the regulatory approval process in a timely manner, the need for and the availability of additional capital. For a discussion of these and other risks and uncertainties see "Risk factors" in the Company's 2003 Annual Report and 2003 Form 20-F, in addition to those detailed in the Company's filings made with the Securities and Exchange Commission from time to time. These forward-looking statements are based on estimates and assumptions made by the management of Acambis and are believed to be reasonable, though are inherently uncertain and difficult to predict. Actual results or experience could differ materially from the forward-looking statements.

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# Results for the twelve and three months ended 31 December 2004

# **Group profit and loss account**

	Year ended 31 December 2004 (unaudited) £m	Year ended 31 December 2003 (audited and restated*) £m	Three months ended 31 December 2004 (unaudited) £m	Three months ended 31 December 2003 (unaudited and restated*)
Turnover	85.5	169.1	23.1	21.0
Cost of sales	(34.3)	(98.4)	(10.6)	(11.3)
Gross profit Research and development costs	51.2 (28.9)	70.7 (19.9)	12.5 (7.4)	9.7 (4.7)
Sales and marketing costs Administrative costs (including amortisation of	(2.7)	(1.3)	(0.8)	(8.0)
goodwill) Exceptional administrative cost: Canton plant impairment (note 3)	(5.1) (1.9)	(4.5)	(1.4)	(1.4)
Exceptional administrative cost: Restructuring costs (note 4) Exceptional administrative cost: Settlement of BTG	(0.7)	0		
agreement Exceptional other operating income: Settlement of Canton agreement (note 5)	10.2	(7.4)		(7.4)
Group operating profit/(loss)	22.1	37.6	2.9	(4.6)
Interest receivable and similar income	4.8	2.1	1.5	0.8
Amounts released against fixed asset investments		0.5		0.5
Loss on disposal of fixed asset investment	(0.1)			
Interest payable and similar charges	(0.9)	(1.0)	(0.3)	(0.3)
Exchange gain on foreign currency borrowings	0.3	0.4	0.3	0.3
Profit/(loss) on ordinary activities before taxation	26.2	39.6	4.4	(3.3)
Taxation	(6.4)	(3.9)	0.6	2.5
Profit/(loss) on ordinary activities after taxation (being retained profit for the period)	19.8	35.7	5.0	(0.8)
Earnings per ordinary share (basic, note 6)	18.6p	34.7p	4.7p	(0.8)p
Earnings per ADR (basic, note 7)	\$0.71	\$1.24	\$0.18	\$(0.03)
Earnings per ordinary share (diluted, notes 6 and 8)	18.2p	34.2p	4.6p	(0.8)p

# Group statement of total recognised gains and losses

	Year ended 31 December 2004 (unaudited) £m	Year ended 31 December 2003 (audited and restated*) £m	Three months ended 31 December 2004 (unaudited) £m	Three months ended 31 December 2003 (unaudited and restated*)
Profit/(loss) for the period Loss on foreign currency translation	19.8 (2.5)	35.7 (3.8)	5.0 (2.7)	(0.8) (2.8)
Total recognised gains and losses relating to the period and recognised since the last Annual Report	17.3	31.9	2.3	(3.6)

<sup>\*</sup> See note 2

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# Group balance sheet as at 31 December 2004

	Year ended 31 December 2004 (unaudited)	Year ended 31 December 2003 (audited and restated*)
	£m	£m
Fixed assets		
Intangible assets	16.0	18.4
Tangible assets	17.5	21.0
Investments		0.8
	33.5	40.2
Current assets		
Stock	6.0	18.2
Debtors: amounts receivable within one year	15.6	12.3
Debtors: amounts receivable after one year	2.5	0.1
Short-term investments	70.9	62.0
Cash at bank and in hand	30.9	63.2
	125.9	155.8
Creditors: amounts falling due within one year	(46.2)	(96.9)
Net current assets	79.7	58.9
Total assets less current liabilities	113.2	99.1
Creditors: amounts falling due after one year	(6.8)	(12.3)
Provisions for liabilities and charges		
Deferred taxation	(0.1)	
Investment in joint ventures:		
share of assets	0.9	0.9
☐ share of liabilities	(1.2)	(1.2)
	(0.3)	(0.3)
Net assets	106.0	86.5
Capital and reserves		
Called-up share capital	10.7	10.6
Share premium account	97.8	96.0
Profit and loss account	(2.5)	(20.1)
Shareholders' funds [] all equity	106.0	86.5

\* See note 2

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# Reconciliation of movements in Group shareholders' funds $\hfill\square$ all equity

	Year ended 31 December 2004 (unaudited) £m	Year ended 31 December 2003 (audited and restated*) £m
Retained profit for the period	19.8	35.7
Loss on foreign currency exchange	(2.5)	(3.8)
Credit in respect of employee share schemes (note 2)	0.3	0.2
	17.6	32.1
New share capital subscribed	1.9	8.9
Net increase in shareholders' funds	19.5	41.0
Opening shareholders' funds (31 December 2003: originally £86.9m before prior year adjustment of £0.4m)	86.5	45.5
Closing shareholders' funds [] all equity	106.0	86.5

<sup>\*</sup> See note 2

### **Group cash flow statement**

	Year ended 31 December 2004 (unaudited) £m	Year ended 31 December 2003 (audited and restated*) £m	Three months ended 31 December 2004 (unaudited) £m	Three months ended 31 December 2003 (unaudited and restated*) £m
Net cash (outflow)/inflow from operating activities	(19.5)	119.1	(11.6)	54.5
Returns on investments and servicing of finance				
Interest received	4.3	2.0	1.2	0.9
Interest paid	(0.1)	(0.1)		(0.1)
Interest element of finance lease payments	(0.7)	(8.0)	(0.2)	(0.1)
Net cash inflow from returns on investments and servicing of finance	3.5	1.1	1.0	0.7
Taxation	(1.6)	(5.8)	(0.3)	(3.8)

# Capital expenditure and financial

investment				
Purchase of tangible fixed assets	(3.6)	(6.0)	(0.7)	(1.2)
Proceeds from sale of fixed asset investment	0.7			
Proceeds from sale of fixed assets	0.2			
Net cash outflow from capital expenditure and financial investment	(2.7)	(6.0)	(0.7)	(1.2)
Acquisitions and disposals Purchase of Berna Products Corporation (net of	(0.3)	(3.9)	П	
cash acquired)	(0.3)	(3.9)		
Net cash outflow from acquisitions and disposals	(0.3)	(3.9)	0	
Net cash (outflow)/inflow before management of liquid resources and financing	(20.6)	104.5	(11.6)	50.2
Management of liquid resources	(9.5)	(61.9)	3.0	(12.4)
Financing				
Net proceeds from issue of new shares				
☐ Baxter subscription		7.0		
□ Other	1.9	1.9	1.1	0.8
Capital element of finance lease repaid	(2.5)		(0.9)	
Net cash (outflow)/inflow from financing	(0.6)	8.9	0.2	0.8
(Decrease)/increase in cash for the period	(30.7)	51.5	(8.4)	38.6

<sup>\*</sup> See note 2

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# Reconciliation of operating profit/(loss) to net cash (outflow)/inflow from operating activities

	Year ended 31 December 2004 (unaudited) £m	Year ended 31 December 2003 (audited and restated*) £m	Three months ended 31 December 2004 (unaudited) £m	Three months ended 31 December 2003 (unaudited and restated*) £m
Group operating profit/(loss)	22.1	37.6	2.9	(4.6)
Depreciation and amortisation	7.6	4.4	1.4	1.5
Decrease/(increase) in stock	10.5	28.3	3.6	(3.1)
(Increase)/decrease in debtors	(5.3)	47.9	(6.1)	82.5
Decrease in creditors	(20.4)	(29.5)	(1.2)	(7.7)
(Decrease)/increase in deferred income	(36.4)	29.3	(13.2)	(17.1)
Exchange differences on inter-company balances	(0.6)	(0.3)	(0.2)	(0.4)
Other	3.0	1.4	1.2	3.4
Net cash (outflow)/inflow from operating activities	(19.5)	119.1	(11.6)	54.5

<sup>\*</sup> See note 2

### Analysis of net funds/(debt)

	1 January 2004 £m	Cash flow £m	Non-cash movement (note 9) £m	Exchange movement £m	31 December 2004 £m
Cash	63.2	(30.7)		(1.6)	30.9
Liquid resources	62.0	9.5		(0.6)	70.9
	125.2	(21.2)		(2.2)	101.8
Overdraft facility	(3.9)			0.3	(3.6)
Finance lease	(12.6)	2.5	(0.2)	0.9	(9.4)
Net funds/(debt)	108.7	(18.7)	(0.2)	(1.0)	88.8

#### Notes

#### 1. Basis of preparation

The financial information for the twelve months ended 31 December 2004 is unaudited, and, with the exception of the adoption of UITF 38 (see note 2), has been prepared in accordance with the accounting policies set out in the Annual Report for the year ended 31 December 2003. The financial information for the two three month periods ended 31 December 2004 and 31 December 2003 are also unaudited. The financial information relating to the years ended 31 December 2004 and 31 December 2003 does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985. The data relating to the year ended 31 December 2003 has been extracted from the full report for that year which has been filed with the Registrar of Companies. The report of the auditors on these accounts was unqualified. Statutory accounts for the year ended 31 December 2004 will be delivered to the Registrar of Companies for England and Wales in due course. The report of the Auditors on the 2004 accounts has yet to be signed.

#### 2. Restatement of prior year numbers

The Group has adopted UITF 38 "Accounting for ESOP Trusts" in the period by means of a prior year adjustment. As a result of the change in accounting policy, the cost of own shares is presented as a deduction from the profit and loss reserve, included in shareholders' funds. Previously own shares held were included within investments and were stated at the lower of cost and realisable value. The effect for the Group is a decrease to shareholders' funds and investments at 31 December 2003 of £0.4m, and a decrease at 31 December 2004 of £0.1m. The consequent change in the basis of calculation of the share option compensation charge has resulted in an additional charge for the twelve and three months ended 31 December 2004 of £nil and £0.1m respectively (2003  $\Box$  credit of £0.2m and £0.1m).

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#### 3. Exceptional administrative cost: Canton plant impairment

As a result of the settlement of the Canton manufacturing agreement (see note 5), the Group recognised that certain assets would be disposed of. In the second quarter of 2004, a non-cash impairment charge of £1.9m (2003 - £nil) was recorded which relates to certain of the fixed assets in the facility for which, as a result of our agreement with Baxter Healthcare Corporation, the Group no longer had a use. That amount is shown as an exceptional administrative item.

#### 4. Exceptional administrative cost: Restructuring costs

In January 2004, the Group decided to consolidate its research activities to its facility in Cambridge, Massachusetts, US, which resulted in the closure of its research facility in Cambridge, UK. Costs associated with this restructuring charged in the twelve months ended 31 December 2004 were £0.7m (2003 - £nil) and are shown as an exceptional administrative item.

#### 5. Exceptional other operating income: Settlement of Canton agreement

In May 2004, the Group reached a \$19m (c. £10.6m) agreement with Baxter Healthcare Corporation to terminate the Canton manufacturing agreement. The first \$9m (c. £5.1m) was received in May 2004 and two additional payments of \$5m each were agreed. The first for £2.9m was received in January 2005, and the other for c. £2.6m is due in January 2006. As a result, in 2004, the Group recorded exceptional other operating income of £10.2m (2003 - £nil). In 2004, £0.2m was recorded within interest receivable and similar income reflecting the staged payment nature of the agreement.

#### 6. Earnings per ordinary share (basic)

The basic earnings per ordinary share for the twelve and three months ended 31 December 2004 are based on a Group profit of £19.8m and £5.0m respectively (2003 - £35.7m and loss of £0.8m (restated, see note 2)). This has been calculated on the weighted average number of ordinary shares in issue and ranking for dividend during the period of 106,300,080 and 106,829,271 for the twelve and three months ended 31 December 2004 respectively (year ended 31 December 2003  $\square$  102,823,221; 2003  $\square$  104,539,627).

#### 7. Earnings per ADR (basic)

Each American Depository Receipt ("ADR") represents two ordinary shares. The basic earnings per ADR is calculated by multiplying the earnings per ordinary share by a factor of two and then multiplying by the prevailing US dollar exchange rate at the end of the relevant period. The exchange rates used are 1.9199 and 1.7905 for 31 December 2004 and 31 December 2003 respectively.

#### 8. Earnings per ordinary share (diluted)

Diluted earnings per ordinary share for the twelve and three months ended 31 December 2004 are based on the weighted average number of ordinary shares outstanding of 108,649,389 and 109,178,579 respectively (year ended 31 December 2003 [] 104,393,147), after adjusting for the effect of all dilutive potential ordinary shares. Basic and diluted earnings per ordinary share were the same for the three months ended 31 December 2003 as the Group was loss making during this period.

#### 9. Non-cash movement

In December 2001, the Group entered into a lease-financing arrangement with Baxter Healthcare Corporation in respect of the Group's manufacturing plant. During the year ended 31 December 2004 interest payable on the finance lease was charged to the Group profit and loss account, but was not fully paid in the period. The unpaid element for the year ended 31 December 2004 of £0.2m (2003 - £0.2m) is shown as a non-cash movement on the analysis of net funds/(debt).

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#### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant Peptide Therapeutics Group has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: 11 March 2005 ACAMBIS PLC

By: /s/ Lyndsay Wright

Name: Lyndsay Wright

Title: Director of Communications