

ACAMBIS PLC
Form 6-K
April 30, 2004

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 April 2004

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:

Annual Report and Notice of AGM posted
ACAM2000 clinical trials update
Director shareholding
Increase in Director's shareholding
Schedule 10 Notification of Major Interests in Shares

Annual Report and Notice of AGM posted

Cambridge, UK and Cambridge, Massachusetts 8 April 2004 Acambis plc (Acambis or the Company) (LSE: ACM, NASDAQ: ACAM) announces that its Annual Report for the year ended 31 December 2003 has been posted to shareholders and is available from the Company Secretary, Acambis plc, Peterhouse Technology Park, 100 Fulbourn Road, Cambridge CB1 9PT.

Posted with the Annual Report is a notice convening the 2004 Annual General Meeting (AGM) of the Company to be held at 10.00 am on 12 May 2004 at the offices of Weil, Gotshal & Manges, One South Place, London EC2M 2WG, and a proxy form relating to the AGM.

In addition to the normal resolutions proposed at the AGM, there will be a resolution to authorise the re-purchase of up to 10% of the Company s issued share capital.

Copies of the Annual Report, the Notice of Annual General Meeting and the proxy form have been submitted to the UK Listing Authority, and will shortly be available for inspection at the UK Listing Authority s Document Viewing Facility, which is situated at Financial Services Authority, 25 The North Colonnade, Canary Wharf, London E14 5HS (telephone number: +44 (0) 20 7676 1000).

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Enquiries:

Acambis plc

Elizabeth Brown, Company Secretary

Tel: +44 (0) 1223 275 300

ACAM2000 clinical trials update

Cambridge, UK and Cambridge, Massachusetts 13 April 2004 Acambis plc (Acambis) (LSE: ACM, NASDAQ: ACAM) announces that it has suspended the recruitment of additional volunteers into its Phase III clinical trials involving its investigational smallpox vaccine ACAM2000 and Dryvax®, the comparator smallpox vaccine being used in the trials. This precautionary measure was taken after three suspected myopericarditis cases were discovered in both ACAM2000 and Dryvax®-vaccinated subjects. Myopericarditis is a condition where there is an inflammation of the heart and surrounding tissues.

Acambis independent Data and Safety Monitoring Board (DSMB) recommended that enrolment into the studies be suspended pending further review and until additional data can be obtained. As a precaution, Acambis has also suspended another, smaller study vaccinating individuals with ACAM2000 and Dryvax®. Once this analysis is completed, including the involvement of the DSMB, Acambis will be enlisting the assistance of the US Food and Drug Administration and the US Centers for Disease Control and Prevention to determine the next steps.

The two Phase III clinical trials are designed to compare the safety, tolerability and efficacy of ACAM2000 with Dryvax®, the currently licensed smallpox vaccine that was widely used during the worldwide smallpox eradication program. In each of these trials the ratio of individuals receiving ACAM2000 and Dryvax® is 3:1.

The first Phase III trial involves subjects that have never received smallpox vaccine. To date, 1,132 individuals have been vaccinated. Three cases of suspected myopericarditis have been recognized in this study. The DSMB has indicated that the cases occurred in both ACAM2000 and Dryvax®-vaccinated subjects.

The second Phase III trial involves subjects that have previously been vaccinated against smallpox. To date, 1,752 individuals have been vaccinated. No cases of myopericarditis have been recognized in this study to date.

Additional smaller studies involving ACAM2000 and Dryvax® have identified two other possible cases of myopericarditis. These cases are also being actively investigated and followed up.

Findings from the US smallpox vaccination program for civilians and the military revealed data supporting a causal association between myopericarditis and smallpox vaccinations. An ongoing investigation is occurring to determine if there is any relationship between the smallpox vaccine and myopericarditis, and individuals with a diagnosis of a heart condition have been temporarily deferred from receiving the smallpox vaccine.

These cardiac adverse events represented an important and, apparently, previously under-recognized complication of vaccination. As a result, Acambis instituted an intensive level of safety monitoring of subjects in its Phase III trials. This includes frequent active monitoring of cardiac symptoms, serial EKG evaluations, and blood tests for cardiac injury.

In this setting, it is difficult to determine whether the three recent cases reported suggest a higher frequency of cardiac adverse events than expected from previous recent experience. Surveillance for adverse events both during the era of routine vaccination and in the recent civilian and military vaccination programs was not as intense as is being performed in these controlled clinical trials. Nevertheless, subject safety is paramount and therefore the decision was made to suspend enrolment in these trials.

Acambis has informed all investigators to suspend recruiting and vaccinations in the trials and will be providing new information on the safety of smallpox vaccination as it becomes available. Investigators also have been informed to notify all subjects who have been vaccinated as part of the trials of the updated information concerning myopericarditis-related risks of vaccination. All volunteers will continue to be monitored as planned, and will be

given full information from the ongoing analysis when completed.

A further update will be provided in due course.

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Enquiries:

Acambis plc

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Lyndsay Wright, Director of Communications: Tel: +44 (0) 1223 275 300

Financial Dynamics

David Yates/ Charlie Armitstead: Tel: +44 (0) 20 7831 3113

About Acambis

Acambis is a leading developer of vaccines to prevent and treat infectious diseases. Acambis is developing a second-generation smallpox vaccine which is currently undergoing clinical trials and, under a unique arrangement given the threat of smallpox being used as a bioterrorist weapon, is 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 a vaccine against the West Nile virus, which has spread to 46 US States in the last four 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 www.acambis.com.

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 Annual Report and Form 20-F for the 2002 fiscal year, 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.

Director Shareholding

Cambridge, UK 14 April 2004 Acambis plc (Acambis) (LSE: ACM, NASDAQ: ACAM) announces the following transaction involving a Directors shareholding in Acambis.

On 13 April 2004, Michael Lytton, Non-executive Director, purchased 4,700 ordinary 10p shares at 316p per share. After this transaction, the shareholding in Acambis held by Mr Lytton had increased from 8,120 to 12,820 shares, representing approximately 0.01% of Acambis issued ordinary share capital.

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Enquiries:

Acambis plc

Elizabeth Brown, Company Secretary Tel: +44 (0) 1223 275 300

Lyndsay Wright, Director of Communications

Increase in Director s shareholding

Cambridge, UK 16 April 2004 - Acambis plc (Acambis) (LSE: ACM, NASDAQ: ACAM) announces the following transactions involving a Director s shareholding in Acambis.

On 15 April 2004, Gordon Cameron, Chief Executive Officer, exercised 30,928 nil-cost shares awarded as matching shares under the Acambis Share Incentive Plan (LTIP), which arose as a result of 123,711 shares having been held by the Trustees of Acambis Employees Trust (the Trustees) on behalf of Mr Cameron for a two-year period. In addition, Mr Cameron exercised 2,500 nil-cost shares awarded as matching shares under the LTIP, which had vested during 2003 that arose as a result of 10,000 shares having been held by the Trustees on behalf of Mr Cameron for one year. Following these transactions, Mr Cameron transferred a total of 167,139 shares that had been held on his behalf by the Trustees into his own name.

Following this transfer, Mr Cameron sold 16,379 shares at 318p per share in order to fund the income tax liabilities arising on the exercise of these awards. As a result of these transactions, his shareholding in Acambis has increased from 228,008 to 242,557 shares, representing approximately 0.23% of Acambis issued share capital.

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Enquiries:

Acambis plc

Elizabeth Brown, Company Secretary Tel: +44 (0) 1223 275 300

Lyndsay Wright, Director of Communications

SCHEDULE 10

NOTIFICATION OF MAJOR INTERESTS IN SHARES

1. Name of company

Acambis plc

2. Name of shareholder having a major interest

Standard Life Investments

3. Please state whether notification indicates that it is in respect of holding of the shareholder named in 2 above or in respect of a non-beneficial interest or in the case of an individual holder if it is a holding of that person's spouse or children under the age of 18

As above

4. Name of the registered holder(s) and, if more than one holder, the number of shares held by each of them

The legal entities holding these shares are as follows:

Stanlife Nominees Limited 3,496,387 shares

5. Number of shares / amount of stock acquired

457,500 shares

6. Percentage of issued class

0.43%

7. Number of shares / amount of stock disposed

N/A

8. Percentage of issued class

N/A

9. Class of security

Ordinary shares of 10p each

10. Date of transaction

15 April 2004

11. Date company informed

16 April 2004

12. Total holding following this notification

3,496,387 shares

13. Total percentage holding of issued class following this notification

3.30%

14. Any additional information

N/A

15. Name of contact and telephone number for queries

Elizabeth Brown tel: 01223 275300

16. Name and signature of authorised company official responsible for making this notification

Elizabeth Brown, Company Secretary

Date of notification

19 April 2004

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