ACAMBIS PLC Form 6-K February 04, 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 January 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).

Form 20-F x

Form 40-F o

(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 o

No x

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

Enclosure:

Schedule 5 blocklisting six monthly return
Schedule 10 notification of major interests in shares
Smallpox vaccine and trading update
Notice of results
Board change
Disclosure of interest
Acambis announces outcome of strategic review of projects and operations

#### **SCHEDULE 5**

#### **BLOCKLISTING SIX MONTHLY RETURN**

1. Name of company Acambis plc

2. Name of scheme

Acambis 1995 Unapproved Share Option Scheme

- 3. Period of return: From 01 July 2003 to 31 December 2003
- Number and class of shares(s)(amount of stock/debt security)not issued under scheme at end of last period: 179,969
- Number of shares issued/allotted under scheme during period:
   174 060
- Balance under scheme not yet issued/allotted at end of period: 5,000
- Number and class of share(s)(amount of stock/debt securities)originally listed and the date of admission: 33,916,280 ordinary shares of 10p each

Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records: 105,637,848

1. Name of company

Acambis plc

2. Name of scheme

Acambis 1996 Approved Share Option Scheme

- 3. Period of return: From 01 July 2003 to 31 December 2003
- Number and class of shares(s)amount of stock/debt security) not issued under scheme at end of last period: 479,508
- 5. Number of shares issued/allotted under scheme during period: 17.808
- Balance under scheme not yet issued/allotted at end of period: 461,700
- 7. Number and class of share(s)(amount of stock/debt securities) originally listed and the date of admission: 33,916,280 ordinary shares of 10p each

Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records: 105,637,848

1. Name of company

Acambis plc

Name of scheme

Acambis 1995 Savings-Related Share Option Scheme

3. Period of return: From 01 July 2003 to 31 December 2003

4.

Number and class of shares(s)amount of stock/debt security) not issued under scheme at end of last period: 44,571

- 5. Number of shares issued/allotted under scheme during period: 4,469
- 6. Balance under scheme not yet issued/allotted at end of period: 40,102

7. Number and class of share(s)amount of stock/debt securities) originally listed and the date of admission:

33,916,280 ordinary shares of 10p each

Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records: 105,637,848

Name of company

Acambis plc

2. Name of scheme

Acambis 1999 Share Option Plan

- 3. Period of return: From 01 July 2003 to 31 December 2003
- 4. Number and class of shares(s) (amount of stock/debt security) not issued under scheme at end of last period: 1,534,345
- 5. Number of shares issued/allotted under scheme during period:

610,619

6. Balance under scheme not yet issued/allotted at end of period:

923,726

7. Number and class of share(s)amount of stock/debt securities) originally listed and the date of admission:

33,916,280 ordinary shares of 10p each

Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records:

105,637,848

1. Name of company

Acambis plc

2. Name of scheme

OraVax 1990 Stock Incentive Plan

- 3. Period of return: From 01 July 2003 to 31 December 2003
- Number and class of shares(s)amount of stock/debt security) not issued under scheme at end of last period: 143,706
- 5. Number of shares issued/allotted under scheme during period:

Nil

6. Balance under scheme not yet issued/allotted at end of period:

143,706

7. Number and class of share(s) (amount of stock/debt securities) originally listed and the date of admission:

33,916,280 ordinary shares of 10p each

Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records:

105,637,848

Name of company

Acambis plc

2. Name of scheme

OraVax 1995 Stock Incentive Plan

3. Period of return: From 01 July 2003 to 31 December 2003

 Number and class of shares(s)amount of stock/debt security) not issued under scheme at end of last period: 150,000

5. Number of shares issued/allotted under scheme during period:

 Balance under scheme not yet issued/allotted at end of period: 150,000

7. Number and class of share(s)amount of stock/debt securities) originally listed and the date of admission:

33,916,280 ordinary shares of 10p each Date of admission: 30 November 1995

Please confirm total number of shares in issue at the end of the period in order for us to update our records:

105,637,848

Contact for queries: Elizabeth Brown

Address: Acambis plc, Peterhouse Technology Park, 100 Fulbourn Road, Cambridge CB1 9PT

Name of person making return: Elizabeth Brown

Telephone: 01223 275300

Position of person making return: Company Secretary

#### **SCHEDULE 10**

#### NOTIFICATION OF MAJOR INTERESTS IN SHARES

- 1. Name of company Acambis plc
- Name of shareholder having a major interest Morley Fund Management Limited (a subsidiary of Aviva plc)
- 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

BNY Norwich Union Nominees Ltd 1,462,266 shares

Chase GA Group Nominees Ltd 3,853,279 shares

Chase Nominees Ltd 323,474 shares

CUIM Nominees Ltd 1,726,925 shares

RBSTB Nominees Ltd 185,983 shares

BNY (Nomines) Ltd 416,993 shares

Chase Nominees Ltd 762,600 shares

CUIM Nominee Ltd 154,940 shares

Vidacos Nominees Ltd 2,282,703 shares

- 5. Number of shares / amount of stock acquired 4,995,600 shares
- 6. Percentage of issued class 4.73%
- 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 19 December 2003
- 11. Date company informed 22 December 2003
- 12. Total holding following this notification 11,169,163 shares

- 13. Total percentage holding of issued class following this notification 10.57%
- 14. Any additional information N/A
- 15. Name of contact and telephone number for queries

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

 Name and signature of authorised company official responsible for making this notification Elizabeth Brown

Date of notification

23 December 2003

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# Smallpox vaccine and trading update

Cambridge, UK and Cambridge, Massachusetts 15 January 2004 - Acambis plc ( Acambis ) (LSE: ACM, NASDAQ: ACAM) announces an update on its smallpox vaccine programme.

At the time of its third quarter results announcement in November 2003, Acambis provided an update on the contract with the US Government to supply quantities of the ACAM2000 investigational smallpox vaccine for its emergency-use Strategic National Stockpile. Acambis indicated that the remaining doses of the investigational vaccine to be delivered under the 155 million-dose order with the US Centers for Disease Control and Prevention ( CDC ) and approximately 18 million of the additional doses ordered by the CDC were expected to be delivered during the fourth quarter of 2003.

A large delivery of vaccine was scheduled to take place during the last week of December 2003. Shortly before the delivery was due to occur, Acambis was informed by the CDC that the US Government was concerned about the movement of vaccine during a period of heightened security alert. As a result, CDC said it would be unable to take delivery of the shipment of vaccine on the scheduled date. With the US national security threat level now having been lowered, a revised shipment date of early February to deliver these remaining vaccine doses has been scheduled with the CDC.

As a result, unaudited pre-tax profits for the year ended 31 December 2003 are estimated to be £12m lower as compared to previous guidance. Consequently, pre-tax profits for the year ended 31 December 2004 are expected to be around £12m higher as compared to previous guidance. Acambis will provide a fuller update to 2004 guidance when it announces its preliminary results for the year ended 31 December 2003 on Tuesday, 2 March 2003.

Unaudited cash and short-term investments at 31 December 2003 were slightly higher than previously anticipated at around £125m.

Acambis is continuing its programme to evaluate the safety and efficacy of its ACAM2000 smallpox vaccine. In December, it initiated Phase III trials to evaluate the safety and efficacy of ACAM2000 in comparison with a previously licensed vaccine, Dryvax®. The two Phase III trials will include people who have previously been vaccinated against smallpox and those who are naïve to smallpox vaccination.

-ends-

#### **Enquiries:**

Acambis plc

Gordon Cameron, Acting Chief Executive Officer and Chief Financial Officer:

Tel: +1 (617) 761 4200

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. Recognised internationally as the leading producer of smallpox vaccines, 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 oral typhoid vaccine, in North America. Acambis has a number of other potential travel vaccines in development. A licence application has been submitted to the US Food and Drug Administration for a vaccine against yellow fever and clinical trials are being conducted for vaccines against Japanese encephalitis, travellers diarrhoea and dengue fever. Acambis recently became the first company to start human clinical trials of a vaccine targeting the West Nile virus, which has spread to 45 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 <a href="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 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.

## **Notice of results**

**Cambridge, UK and Cambridge, Massachusetts 15 January 2004** - Acambis plc ( Acambis ) (LSE: ACM, NASDAQ: ACAM) will announce its preliminary results for year ended 31 December 2003 on Tuesday, 2 March 2004.

The results announcement will be released at 7.00 am GMT. A briefing and conference call for analysts will be held at 9.30 am GMT. An audio webcast of the call will also be available via Acambis website at www.acambis.com.

-ends-

**Enquiries:** 

Acambis plc

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

**Financial Dynamics** 

Mo Noonan Tel: +44 (0) 20 7831 3113

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## **Board change**

Cambridge, UK and Cambridge, Massachusetts 23 January 2004 - Acambis plc ( Acambis ) (LSE: ACM, NASDAQ: ACAM) announces the resignation of Non-executive Director, Victor Schmitt.

Mr Schmitt, who has been a Non-executive Director since December 2000, was Baxter International, Inc. s (Baxter) representative on Acambis Board of Directors. His resignation follows Baxter s sale on 18 December 2003 of its shareholding in Acambis.

Alan Smith, Chairman of Acambis, said:

The Board of Acambis would like to thank Victor for the great contribution he has made during his three years as a director. Although Victor is stepping down from the Board, we have a number of commercial arrangements with Baxter and look forward to the continuation of the strong relationship between the two companies.

-ends-

#### **Enquiries:**

Acambis plc

Gordon Cameron, Acting Chief Executive Officer and Chief Financial Officer:

Tel: +44 (0) 1223 275 300

Lyndsay Wright, Director of Communications:

Tel: +44 (0) 1223 275 300

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#### Acambis plc ( the Company )

#### DISCLOSURE OF INTEREST

The Company received notification on 23 January 2004 that Aviva plc and Morley Fund Management Limited (a subsidiary of Aviva plc) have a material interest of 5,867,927 Ordinary shares of 10p each in the Company, representing 5.55% of the issued share capital of the Company.

The notification was prompted by the transfer of stock from material funds to funds not classed as material on 21 January 2004.

The shares are registered as follows:

REGISTERED HOLDERS NO. OF SHARES HELD BNY Norwich Union Nominees Ltd 833,266 (Material) Chase GA Group Nominees Ltd 3,367,279 (Material) Chase Nominees Ltd 323,474 (Material) CUIM Nominee Ltd 1,157,925 (Material) RBSTB Nominees Ltd 185,983 (Material)

Total Material Holding 5,867,927

Aviva plc are is only required to notify interests which are defined as material interests when the holding is equal to 3% or more of the Company s relevant share capital. The term material interests excludes certain categories where Aviva plc does not hold a beneficial interest, for example where the shares are held in an Authorised Unit Trust Scheme or Open Ended Investment Company. Holdings in those categories are therefore not included in the holding notified to the Company.

## Acambis announces outcome of strategic review of projects and operations

Cambridge, UK and Cambridge, Massachusetts 30 January 2004 - Acambis plc ( Acambis or the Company ) (LSE: ACM, NASDAQ: ACAM) announces the results of a strategic review to prioritise its extensive pipeline of development-stage projects. As a consequence of this review, we are restructuring our research operations.

In March 2003, we announced that Acambis had become part of the select group of UK biotechnology companies that had achieved profitability and, at the same time, outlined our strategy for remaining sustainably profitable. Alongside that, we also have a strategy to gain the maximum value from our portfolio by retaining product rights as long as possible. With numerous projects in clinical and pre-clinical development, we have recognised that it is impractical to invest the required resources in all of the projects. This review has enabled us to identify which projects are most likely to generate the maximum return to Acambis, thereby allowing us to focus our resources accordingly.

The review has identified the following high priority projects:

- > Smallpox vaccine franchise
  - -ACAM2000
  - -Modified Vaccinia Ankara (MVA)
  - -Vaccinia Immune Globulin (VIG)
- > ChimeriVax-West Nile vaccine
- > Travel/Endemic vaccines franchise
  - -Vivotif®
  - -ARILVAXTM
  - -ChimeriVax-JE
  - -ChimeriVax-Dengue
- > C. difficile vaccine

Of these nine projects, Acambis expects to be taking seven through clinical trials and/or the regulatory approval process during 2004. The other two, Vivotif® and VIG, are, respectively, a licensed oral typhoid vaccine to which we have North American marketing rights, and a hyperimmune globulin associated with smallpox vaccination that is being developed by Cangene Corporation and for which we act as agent for sales outside North America and Israel.

We plan to pursue the above development projects aggressively and to invest the necessary resources to ensure these projects progress as rapidly as possible through to licensure. Where practicable, we will retain full product rights up to and including the point of licensure. Importantly, we now have internal manufacturing capability and a North American marketing and distribution infrastructure to make and sell respectively many of these products.

In addition, we retain and will continue to develop several earlier-stage research projects that will be the engine of longer-term growth for the company. For commercial reasons, we plan to disclose these projects only at the point at which they progress towards clinical development.

The strategic review also identified several projects in which we have decided not to invest further resources as we do not believe that they will generate the required return on investment for Acambis. They are as follows:

- > HolaVax-ETEC and Campylobacter vaccines for travellers diarrhoea
- > HolaVax-Typhoid vaccine
- > H. pylori vaccine

We will be seeking to renegotiate commercial terms with existing partners, to out-license or to discontinue the above projects. Where appropriate, we may seek to retain strategically important rights, such as North American marketing rights. We have already initiated several discussions to this end.

In addition, for our two immunoglobulin projects, we are in discussions with Cangene Corporation about restructuring our West Nile immunoglobulin agreement and will be seeking a suitable partner for our *C. difficile* immunoglobulin project. Our *C. difficile* and West Nile vaccine projects remain a high priority, as stated above.

As a result of this project prioritisation, an operational review has also been completed and Acambis has decided to consolidate its research activities at its facility in Cambridge, Massachusetts. The research operation in Cambridge, UK will be closed. However, we are retaining clinical and regulatory functions in Cambridge, UK as well as various head office functions, including sales, marketing and business development. Once the operational review is fully implemented later this year, Acambis headcount is expected to reduce by around 40 to around 280 worldwide.

This is consistent with our overall refocusing of our resources to reflect the development of Acambis as an integrated vaccine company capable of taking products through each stage from research through manufacturing to licensure and sales. Over the last year, this has seen us continue to expand our clinical, regulatory and quality functions in order to meet the increased requirements of the clinical development pipeline and manufacturing facility and the extension of the marketing function, which was first established in November 2002, with the acquisition of Berna Products Corporation.

Gordon Cameron, Acting Chief Executive Officer and Chief Financial Officer of Acambis, commented:

The outcome of this strategic review reflects an extensive assessment of the market opportunities available for the projects we currently have in our development pipeline. We are now in a position to focus our resources on driving forward our key, high-value vaccine projects as quickly as possible.

#### **Enquiries:**

## Acambis plc

Gordon Cameron, Acting Chief Executive Today: +44 (0) 20 7831 3113
Officer and Chief Financial Officer Thereafter: +1 (617) 761 4200
Lyndsay Wright, Director of Communications Today: +44 (0) 20 7831 3113

Thereafter: +44 (0) 1223 275 300

## **Financial Dynamics**

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

Analyst conference call: An analyst conference call will be held today at 9.00 am GMT. 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 the end of the meeting until midnight on Friday, 6 February 2004. To access the instant replay, use the following telephone numbers: from the UK (020) 8288 4459; from the US +1 334 323 6222; and from outside the UK or the US, +44 (0) 20 8288 4459. The pin code for the call is 861642.

**Webcast:** An audio webcast of the call will also be available via Acambis website at www.acambis.com. The webcast replay will be available on the site until midnight on Friday, 30 April 2004.

-ends-

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## SIGNATURE

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

Date: 4 February 2004 ACAMBIS PLC

By: /s/ Lyndsay Wright

Name: Lyndsay Wright

Title: Director of Communications