ACAMBIS PLC Form 6-K November 12, 2003

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FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

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

For the month of October 2003

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:

Notification of major interests in shares (19 September) Notification of major interests in shares (22 October) Statement re BTG (24 October) Acambis commences first human clinical trial of West Nile vaccine (6 November)

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 $\frac{\text{SCHEDULE 10: NOTIFICATION OF MAJOR INTERESTS IN SHARES}}{\text{SIGNATURE}}$

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SCHEDULE 10: NOTIFICATION OF MAJOR INTERESTS IN SHARES

1. Name of company

Acambis plc

2. Name of shareholder having a major interest

FMR Corp. (and its direct and indirect subsidiaries incorporating Fidelity Management Trust Company (FMTC)), Fidelity International Limited (FIL) (and its direct and indirect subsidiaries incorporating Fidelity Investment Services Limited (FISL)) and Mr Edward C Johnson 3d

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

State Street Nominees Ltd. 8,000 shares*
Brown Brothers Harriman 6,000 shares*
State Street Bank & Trust 4,300 shares*
Chase Manhattan Bank London 2,845,508 shares**
JP Morgan 21,500 shares
HSBC 696,305 shares
Bank of New York London 42,300 shares
Chase Manhattan Bank London 173,268 shares
Chase Nominees Ltd 132,150 shares
Bankers Trust 39,520 shares
Citibank 110,590 shares

- * For this holding, FMTC acts as the management company
- ** For this holding, FISL acts as the management company

For all the other holdings listed, FIL acts as the management company.

5. Number of shares / amount of stock acquired

N/a

6. Percentage of issued class

N/a

7. Number of shares / amount of stock disposed

971,905

8. Percentage of issued class

0.93%

9. Class of security

Ordinary shares of 10p each

10. Date of transaction

N/a

11. Date company informed

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18 September 2003

12. Total holding following this notification

4,079,441 ordinary shares

13. Total percentage holding of issued class following this notification

3.89%

14. Any additional information

N/a

15. Name of contact and telephone number for queries

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

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

Elizabeth Brown

Date of notification

19 September 2003

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SCHEDULE 10 NOTIFICATION OF MAJOR INTERESTS IN SHARES

NOTIFICATION OF MAJOR INTERESTS IN SHARES
1. Name of company
Acambis plc
2. Name of shareholder having a major interest
Barclays 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
The legal entities holding these shares are as follows:
Barclays Private Bank and Trust Ltd 1,403 shares Barclays Life Assurance Co Ltd 198,097 shares Barclays Global Investors Australia Ltd 46,085 shares Barclays Global Investors, N.A. 1,316,128 shares Barclays Global Investors Ltd 3,628,862 shares
5. Number of shares / amount of stock acquired
N/A
6. Percentage of issued class
N/A
7. Number of shares / amount of stock disposed
1,006,528
8. Percentage of issued class
0.96%
9. Class of security
Ordinary shares of 10p each
10. Date of transaction
17 October 2003

12. Total holding following this notification

11. Date company informed

22 October 2003

5,190,575

13. Total percentage holding of issued class following this notification

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4.95%

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

22 October 2003

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Statement re BTG

Cambridge, UK and Cambridge, Massachusetts 24 October 2003 Acambis plc (Acambis) (LSE: ACM, NASDAQ: ACAM) announces that it has agreed a settlement with BTG International Limited (BTG) concerning payments due under an Assignment Consideration Agreement (the Agreement). Signed in 1997, the Agreement relates to a technology license agreement between Acambis and BTG originally established in 1994. The Agreement provided for Acambis to pay 2% of its reported turnover to BTG potentially until 2024.

Under the terms of the settlement, Acambis will pay £12m to BTG to discharge all past and future rights, obligations and claims under the Agreement.

Of the settlement payment, Acambis estimates £4.6m relates to historic amounts due and payable under the Agreement since January 2002 when discussions between Acambis and BTG about the Agreement were initiated. The balance of £7.4m relates to potential future payments from the fourth quarter (Q4) of 2003 onwards. Acambis will book the £7.4m balance during Q4 2003 as an exceptional item against operating profit. The full payment will be made from cash before the end of 2003.

Acambis had accrued for 100% of the potential costs relating to the Agreement between January 2002 and the end of September 2003, recording these within cost of sales. In addition, it had factored in the full potential liability in its future margin and earnings guidance. This 2% payment was factored into Acambis guidance on gross operating margins. As a result of the termination of the Agreement, gross margins are expected to improve by approximately 2% from 2004 onwards, as compared to previous guidance.

-ends-

Enquiries:

Acambis plc

Dr John Brown, Chief Executive Officer Tel: +44 (0) 1223 275 300

Lyndsay Wright, Director of Communications

Gordon Cameron, Chief Financial Officer

Tel: +1 (617) 761 4200

Financial Dynamics

David Yates/Jonathan Birt Tel: +44 (0) 20 7831 3113

Notes to editors:

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 single dose oral typhoid vaccine, in North America. Acambis has a number of other potential travel vaccines in development and is conducting clinical trials of vaccines against yellow fever, Japanese encephalitis and dengue fever. Acambis is also preparing to start 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 www.acambis.com.

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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 most recently ended 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.

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Acambis commences first human clinical trial of West Nile vaccine

Cambridge, UK and Cambridge, MA 6 November 2003 Acambis (LSE: ACM, NASDAQ: ACAM), a leading developer of vaccines against infectious diseases, announces the start of a Phase I trial of its investigational vaccine against West Nile virus, ChimeriVax-West Nile.

Since 1999 when it was first identified in the US, the West Nile virus has swept through 45 States, causing disease in more than 12,000 people and resulting in the deaths of several hundred individuals. In 2003 alone, it has affected more than 8,200 people and caused 182 deaths. The virus has also spread south to Central America and the Caribbean, and north into Canada where it has been identified in seven provinces.

Acambis used its proprietary ChimeriVaxTM technology to develop the investigational ChimeriVax-West Nile vaccine and has conducted a series of successful pre-clinical studies on the vaccine. Acambis has now started a Phase I clinical trial in humans.

The trial is being conducted in Lenexa, Kansas under a US Food and Drug Administration Investigational New Drug application. The trial is a randomised, double-blind out-patient study in 60 healthy adult volunteers. It will test the safety, tolerability and immunogenicity of ChimeriVax-West Nile vaccine.

The 60 volunteers will receive either a single vaccination with one of the three different dose levels of ChimeriVax-West Nile being tested or a licensed yellow fever vaccine that is being used as a control in the trial. Safety and tolerability will be judged by recording adverse reactions to the vaccine and immunogenicity will be measured in terms of antibody levels and T cell responses generated against West Nile virus.

Dr John Brown, Chief Executive Officer of Acambis, commented:

Since arriving in New York in 1999, West Nile virus has become established as an endemic and epidemic disease that poses as a significant threat to human health and a preventive vaccine could become a major factor in the fight against this virus. Acambis began work on this project within months of the virus being diagnosed in the US and we are pleased to be the first company to start clinical trials to evaluate of a vaccine against West Nile.

Acambis work on ChimeriVax-West Nile has been partly financed by a \$3 million grant from the US National Institutes of Health, awarded to Acambis in August 2000.

-ends-

Enquiries:

Dr John Brown, Chief Executive Officer Lyndsay Wright, Director of Communications Tel: +44 (0) 1223 275 300

Gordon Cameron, President of Acambis Inc. and Chief Financial Officer

Tel: +1 (617) 761 4200

Notes to editors:

Acambis plo

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

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markets Vivotif®, the world s only oral typhoid vaccine, in North America. Acambis has a number of other potential travel vaccines in development and is conducting clinical trials of vaccines against yellow fever, Japanese encephalitis and dengue fever. Acambis is also preparing to start 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 www.acambis.com. More information on Acambis West Nile project can be found at www.acambis.com/westnile.

ChimeriVaxTM

ChimeriVax is a proprietary technology that Acambis is using in the development of a number of potential vaccines. Currently, Acambis is conducting clinical trials on three vaccines developed using this technology: ChimeriVax-JE against Japanese encephalitis; ChimeriVax-Dengue against dengue fever; and ChimeriVax-West Nile against the West Nile virus.

West Nile virus

West Nile virus was first identified in 1937 in the West Nile district of Uganda from which it takes its name. Since then, it has been seen in Africa, Europe, the Middle East, west and central Asia, Oceania and, most recently, North America. Recent human outbreaks have occurred in Algeria (1994), Romania (1996/7), Czech Republic (1997), the Democratic Republic of Congo (1998), Russia (1999), US (1999-2002) and Israel (2000).

West Nile was first detected in New York in the summer of 1999. That year, the city experienced 62 cases of West Nile infection and seven people died. Although human cases of West Nile were found only in New York City during 1999, the virus was detected in animals and birds in the states of Connecticut, New Jersey, New York and Maryland. By the end of 2000, the virus had been found in a further nine states taking the total number of infected states to 13. That year, the virus caused severe infections in 18 people and for two of them it was fatal. During 2001, the virus spread through another 16 states, killing nine and causing severe illness in 66.

This year, the virus has had a greater impact than in any of the previous years. It has spread to a total of 45 US states, and there have been more than 8,200 human infections and 182 deaths.

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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 most recently ended 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.

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SIGNATURE

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

Date: 12 November 2003 ACAMBIS PLC

By: /s/ Lyndsay Wright

Name: Lyndsay Wright

Title: Director of Communications