ACAMBIS PLC
Form 6-K
January 17, 2007

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 2007

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 X Form 40-F

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

Yes No X

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

Enclosure:

1. Acambis receives CRL from FDA announcement made on 17 January 2007

Acambis receives Complete Response Letter from FDA on ACAM2000 Biologics Licence Application

Cambridge, UK and Cambridge, Massachusetts - 17 January 2007 - Acambis plc (Acambis) (LSE: ACM) announces that it has received a Complete Response Letter from the US Food and Drug Administration (FDA) in response to its Biologics Licence Application (BLA) for its ACAM2000 smallpox vaccine. The response is part of the normal review process by the FDA and the letter was received ahead of the First Action Due Date of 14 February 2007.

The FDA is requesting additional information that it requires to complete its review of the BLA. Acambis is consulting with the FDA and preparing its

response, which it intends to submit as soon as possible. The planned Vaccines and Related Biological Products Advisory Committee meeting will be rescheduled to enable the committee to review the additional information.

Gordon Cameron, Chief Executive Officer of Acambis, commented:

"Throughout the review process to date, our discussions with the FDA have been positive and constructive, and we intend to respond fully to the agency as soon as possible. Although licensure is a pre-cursor to securing the formal long-term warm-base manufacturing contract for ACAM2000, in preparation for that we recently delivered a further 10 million-dose order, worth $30 million, to the CDC, making a total of 192 million doses delivered to date. We remain confident that we will be able to finalise and commence the warm-base manufacturing contract during 2007."

-ends-

Enquiries:

Acambis plc:
Gordon Cameron, Chief Executive Officer
David Lawrence, Chief Financial Officer
Lyndsay Wright, VP, Communications and IR
Tel: +44 (0) 1223 275 300

Brunswick
Jon Coles / Justine McIlroy / Margherita Lupi
Tel: +44 (0) 20 7404 5959

About ACAM2000

Acambis currently supplies ACAM2000, its investigational smallpox vaccine to governments, under a US FDA Investigational New Drug (IND) application. To date, Acambis has supplied more than 200 million doses of ACAM2000 to 15 governments.

- ACAM2000 is derived from Dryvax(R), a first-generation vaccine used during the global eradication programme
- It is manufactured using modern cell-culture techniques, designed to comply with current Good Manufacturing Practice (GMP) standards
- It is a clonal vaccine - based on a single type of vaccinia virus which has been well characterised
- It is routinely manufactured under animal serum-free conditions to minimise the chance of any passenger viruses or animal proteins being present
- It is grown in a continuous cell line providing a predictable, standardised manufacturing process
- It has completed Phase 1, 2 and 3 clinical testing under an IND from the US FDA
- A Biologics License Application (BLA) was filed with the FDA in 2006.

About Acambis
Acambis is a leading biotechnology company targeting infectious diseases with novel vaccines. Acambis' development-stage pipeline includes vaccines that could either offer improvements over existing products or target unmet medical needs. As well as ChimeriVax-JE, Acambis' proprietary ChimeriVax technology, developed in association with St Louis University, has also been used to develop ChimeriVax-West Nile, which is undergoing Phase 2 clinical testing, making it the most advanced investigational vaccine against the West Nile virus. Acambis also has the only vaccine in development against Clostridium difficile bacteria, a leading cause of hospital-acquired infections. Recognised internationally as the leading producer of smallpox vaccines, Acambis is developing an investigational smallpox vaccine, ACAM2000, and is manufacturing emergency-use

stockpiles of this investigational vaccine for the US Government and other governments around the world.

Acambis is based in Cambridge, UK and Cambridge, Massachusetts, US, and is listed on the London Stock Exchange (ACM). 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 management" in the Company's 2005 Annual Report and "Risk factors" in its Form 20-F, in addition to those detailed on the Company's website and 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.

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: 17 January 2007 ACAMBIS PLC

By: /s/ Lyndsay Wright
Name: Lyndsay Wright
Title: VP, Communications and IR.