

Edgar Filing: ACAMBIS PLC - Form 6-K

ACAMBIS PLC
Form 6-K
May 09, 2006

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 May 2006

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 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:

1st Quarter Results

Results for the first quarter ended 31 March 2006

Cambridge, UK and Cambridge, Massachusetts - 9 May 2006 - Acambis plc
("Acambis") (LSE: ACM, NASDAQ: ACAM) announces its results for the three months
ended 31 March 2006.

Summary of the year to date

> R&D programmes progressing well:

Edgar Filing: ACAMBIS PLC - Form 6-K

- o ChimeriVax-JE:
 - Pivotal Phase 3 trials fully recruited
 - Regulatory approvals received for first of two paediatric trials in India
 - o ChimeriVax-West Nile: dose-ranging component of Phase 2 trial fully recruited
 - o C. difficile: Phase 1 trial in elderly subjects fully recruited
 - o R&D expenditure increased in line with expectations; significant investment made in progressing ChimeriVax-JE Phase 3 trials ahead of schedule
- > ACAM2000:
- o Submission of Biologics License Application to US Food and Drug Administration completed
 - o Active discussions ongoing with CDC on warm-base manufacturing for US Government
- > MVA3000:
- o Continuing to progress through stages of US Government procurement process; contract award expected around end of second quarter
 - o International Trade Commission hearing on dispute with Bavarian Nordic underway; scope narrowed to patent dispute
- > Strong sales of Vivotif(R) typhoid vaccine suggest successful customer retention
- > Chairman to stand down later in 2006
- > Cash and cash equivalents of GBP49.8m at 31 March 2006

Key trading highlights*

	Three months ended 31 March	
	2006	2005
Revenue	GBP6.0m	GBP6.0m
R&D costs	GBP9.8m	GBP7.2m
Loss before tax	GBP (11.4)m	GBP (5.8)m
Basic loss per share	(10.5)p	(4.1)p
Basic loss per ADR	\$(0.36)	\$(0.15)

* Prepared under the Group's accounting policies based on International Financial Reporting Standards

Gordon Cameron, Chief Executive Officer of Acambis, said:

"Since the beginning of 2006, we have continued to make good progress in our development programmes, including completing recruitment of subjects into our

Edgar Filing: ACAMBIS PLC - Form 6-K

pivotal Phase 3 ChimeriVax-JE trials and submitting the ACAM2000 product licence application to the US FDA. We are looking forward to further pipeline progress in the coming months and to important decisions on the US Government smallpox vaccine contracts we are pursuing."

A conference call for analysts will be held today at 9.00 am BST. For details, contact Mo Noonan at Financial Dynamics on telephone number +44 (0) 20 7269 7116. An instant replay of the call will be available until 16 May 2006 on telephone number UK: +44 (0) 20 7365 8427 and US: + 1 (617) 801 6888. The pin code is 47328347. A webcast of the call will also be available via Acambis' website at www.acambis.com. The webcast replay will be available for 12 months until 9 May 2007.

Chairman's statement

OVERVIEW

Since the beginning of the year, we have made good progress in our clinical trials and in our efforts to secure additional contracts in the smallpox vaccine arena.

During the period we had a particularly heavy level of investment in the pipeline, which ensured our key proprietary programmes continued on track. This included achieving full recruitment of subjects in the Phase 1 trial of our C. difficile vaccine, the dose-ranging component of the Phase 2 trial of ChimeriVax-West Nile and the two Phase 3 trials of ChimeriVax-JE, the latter being completed ahead of schedule. The level of our R&D investment reflects the fact that our pipeline is now becoming increasingly advanced and as we continue to progress our proprietary programmes towards commercialisation we will be evaluating partnering opportunities.

In terms of the smallpox franchise, we are making good progress towards agreeing a warm-base manufacturing contract with the US Government and are continuing through the stages of the US Modified Vaccinia Ankara (MVA) procurement process. In April, we completed submission of the Biologics License Application (BLA) to apply for licensure of ACAM2000 in the US. In addition, the first hearing in the MVA dispute with Bavarian Nordic (BN) is underway at the International Trade Commission (ITC) in Washington.

During the period, we reached the advanced stages of pursuing a major acquisition, which ultimately was not successful. This resulted in a one-off charge to administration expenses, referenced in 'Trading results' below. We continue to review further opportunities to expand our pipeline and/or our operations.

I have now been a member of Acambis' Board for over 10 years and Chairman for more than seven of those years. Based on good corporate governance practices, I have decided that I will stand down from the Board and as Chairman of Acambis later in the year and will announce the appointment of my successor at that time. Acambis is a very different company now from when I joined the Board and I am pleased to have played a part in its growth during that time. I am confident that it will continue to go from strength to strength and wish its Board, our employees and our shareholders every success.

SMALLPOX FRANCHISE UPDATE

ACAM2000: BLA submitted, warm-base manufacturing RFP received

In April, we completed submission of the ACAM2000 BLA to the US Food and Drug

Edgar Filing: ACAMBIS PLC - Form 6-K

Administration, which we began in January. The BLA was submitted on a "rolling" basis under the fast-track status awarded to the programme by the FDA. Based on a priority review status, we anticipate the FDA will complete its review before the end of this year.

We are in active discussions with the US Centers for Disease Control and Prevention (CDC) and the scope of work required to provide the US Government with a warm-base manufacturing capability. Warm-base manufacturing is intended to maintain our facilities on a long-term basis in a state of readiness to produce doses of ACAM2000. We reported in September 2005 that the CDC had indicated to us that it would be proceeding with a warm-base manufacturing contract during US Government Fiscal Year 2006, which runs through to 30 September 2006. We continue to be on track to achieve that timeline.

MVA3000: procurement process continues, ITC hearing underway

In October 2005, we submitted our response to a US Government RFP to procure a stockpile of MVA smallpox vaccine. We are continuing to progress through the negotiation stage of the procurement process, recently submitting our responses to the Department of Health and Human Services' technical and business questions. Based on indications received from the US Government, we now expect the award of contract(s) to be made around the end of the second quarter of this year.

In the ongoing litigation with BN regarding MVA, the hearing at the ITC commenced yesterday (8 May 2006) and is scheduled to continue through to 17 May. Of the three courts to which BN submitted complaints, the ITC is the first to hold a hearing.

In advance of the ITC hearing, all parties submitted Motions for Summary Determination to the judge presiding over the ITC case. As a result, the judge ordered the termination of BN's trade secrets claim. This initial determination may be subject to Commission review. The termination was based on a question of jurisdiction as the confidential disclosure agreement that was signed between Acambis and BN in February 2002 contains a mandatory arbitration clause requiring any such disputes between the two companies to be settled in arbitration in Frankfurt, Germany under the rules of the International Chamber of Commerce.

In addition, the judge has determined that BN's claim that Acambis wrongfully obtained MVA material from the National Institutes of Health and wrongfully converted that material into MVA3000 is not part of the ITC's investigation. The trade secrets claim continues to be part of the action brought before the District Court of Delaware.

The initial determination terminating the investigation regarding the trade secrets claim and other rulings by the judge have narrowed the scope of the ITC hearing such that its entire focus is now the patent dispute, which we consider to be the principal question in the litigation. The judge's initial determination on the case is expected in the third quarter of 2006, after which his decision will be reviewed by a panel of ITC Commissioners who are required to rule on the decision by the end of November.

RESEARCH AND DEVELOPMENT UPDATE

ChimeriVax-JE: enrolment of Phase 3 trials completed ahead of schedule

In April, we announced that we had completed enrolment of subjects into both of our pivotal Phase 3 trials of our ChimeriVax-JE vaccine against Japanese encephalitis. More than 2,800 subjects have been enrolled into the safety and efficacy trials, which are being conducted in Australia and the US. Enrolment in the multi-centre trials was completed ahead of schedule.

Edgar Filing: ACAMBIS PLC - Form 6-K

We have now received the approvals necessary to enable us to conduct the first of two paediatric trials in India of ChimeriVax-JE.

Clostridium difficile (C. difficile): second Phase 1 trial on track

In February, we announced preliminary results from the first of two Phase 1 trials of our vaccine candidate against C. difficile, which is a leading cause of hospital-acquired infections. We are making good progress with our second Phase 1 trial and have completed the enrolment of subjects. We initiated the trial towards the end of 2005 to assess the safety and immunogenicity of the vaccine candidate in the elderly, the main target population.

ChimeriVax-West Nile: dose-ranging component of Phase 2 trial fully recruited

We are continuing to progress the Phase 2 trial of ChimeriVax-West Nile, our vaccine candidate against the West Nile virus. The first component of the trial, a dose-ranging study in healthy young adults, is now fully recruited. This will identify the optimal dose for the second stage of the trial, which is a safety and immunogenicity study in healthy elderly subjects.

Influenza: on track for clinical trials in 2007

We are continuing pre-clinical activities on our universal pandemic influenza vaccine and are on track to initiate our first clinical trial with the vaccine candidate in 2007.

ARILVAX(TM)

Novartis AG has now completed its acquisition of Chiron Vaccines, which owns and manufactures ARILVAX(TM), the yellow fever vaccine to which we have US sales rights. Discussions about how to resolve the outstanding issues on the programme have now transferred to representatives of Novartis.

VIVOTIF(R)

Sales of Vivotif(R), the oral typhoid vaccine to which we have North American distribution rights, continue to be strong, in spite of the competitor vaccine being back on the market, suggesting that we have successfully retained some of the additional customers gained last year.

FINANCIAL REVIEW

The financial results, prepared under the Group's accounting policies based on International Financial Reporting Standards, for the three months ended 31 March 2006 ("Q1") are presented below. The narrative reflects a comparison of our activities in 2006 and 2005, and, unless otherwise stated, the comparative figures in parentheses relate to the equivalent period in 2005.

Trading results

Revenue in Q1 was GBP6.0m (2005 - GBP6.0m). The main sources of revenue were our fixed-price 155 million-dose smallpox contract with the CDC, our two contracts with the NIAID for MVA3000 and product sales of Vivotif.

Cost of sales was GBP4.2m (2005 - GBP3.9m) and represented costs on all of the above programmes. Our gross profit margin in Q1 was 30.0% (2005 - 35.0%).

R&D costs were in line with management expectations and consistent with the full year guidance provided in March. Costs increased in Q1 to GBP9.8m (2005 - GBP7.2m) as a result of the progression of our projects into later stages of development, most notably the costs to recruit all subjects into the

Edgar Filing: ACAMBIS PLC - Form 6-K

Phase 3 trials for ChimeriVax-JE. In addition, process development and manufacturing work for our R&D projects continues to be expensed to R&D costs.

Sales and marketing costs in Q1 remained at GBP0.6m (2005 - GBP0.6m). Administrative costs increased to GBP3.2m (2005 - GBP1.1m). The majority of the year-on-year increase related to one-off aborted acquisition costs.

The pre-tax loss increased for the period at GBP11.4m (2005 - GBP5.8m) principally as a result of the increased R&D costs to progress the pipeline.

Balance sheet highlights

i) Cash/debtors

This quarter saw an unusually high level of cash consumption. In addition to our normal operational expenditures, we made large payments relating to the Phase 3 trials for ChimeriVax-JE, litigation expenses relating to MVA and aborted acquisition costs. The short-term investments and cash balance of the Group at 31 March 2006 stood at GBP49.7m (31 December 2005 - GBP68.0m). Trade and other receivables decreased to GBP6.7m at 31 March 2006 (31 December 2005 - GBP20.6m), in part as a result of payments received in Q1 from the NIAID, under the MVA3000 contract, for the shipment of 500,000 doses of MVA3000 vaccine.

ii) Inventory/current liabilities

Inventory levels remained constant at GBP3.6m at 31 March 2006 (31 December 2005 - GBP3.6m). Inventory principally represents work-in-progress and finished goods in relation to our ACAM2000 and Vivotif vaccines.

Current liabilities at 31 March 2006 reduced significantly to GBP26.0m (31 December 2005 - GBP46.8m), principally due to large trade creditor payments made during the period, most notably to Baxter for the production of the 500,000 doses of MVA3000. 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, has historically given rise to a difference between invoices submitted and amounts recognised as revenue. At 31 March 2006 this difference had fully unwound (31 December 2005 - GBP2.0m).

iii) Lease financing and overdraft facilities

The combined balance on our US dollar-denominated financing facilities reduced in the three months to 31 March 2006 to GBP10.9m (31 December 2005 - GBP12.8m) as a result of the lease-financing facility continuing to be paid down. The balance on this facility was GBP5.3m at 31 March 2006 (31 December 2005 - GBP7.2m). The balance on the ARILVAX(TM) overdraft facility at 31 March 2006 was GBP4.0m (31 December 2005 - GBP4.0m). The remaining balance at 31 March 2006 was GBP1.6m (31 December 2005 - GBP1.6m) which relates to the discounted value of the future payments for the Rockville fill/finish facility acquired in 2005, payable between 2006 and 2017.

BOARD CHANGES

Since the beginning of the year, there have been two changes to our Board of Directors.

In February, we were delighted to welcome Dr Peter Fellner to the Board as a Non-executive Director. Peter is a well-known figure in the UK biotechnology industry, having led the development of Celltech Group plc from a small research company into the UK's leading biotechnology company. He was Celltech's Chief Executive Officer from 1990 to 2003 and Chairman from 2003 until its acquisition by the Belgian biopharmaceutical company, UCB SA, in 2004. With his extensive knowledge and experience, we believe his insight and advice will be invaluable

Edgar Filing: ACAMBIS PLC - Form 6-K

as we oversee the continued development of Acambis.

In April, Michael Lytton resigned from the Board after more than five years as a Non-executive Director. Michael has made a valuable contribution to the Board and we would like to record our thanks to him for the insight and advice that he has brought to our discussions throughout that time.

OUTLOOK

In the coming months, we expect to make continued progress in our clinical trials, including initiating a paediatric trial of our ChimeriVax-JE vaccine in India, which is our initial target market. We remain confident that the warm-base manufacturing contract will be finalised within the specified timeframe and also look forward to a positive decision on the US Government MVA smallpox vaccine procurement process and on the MVA dispute currently being heard at the ITC.

Alan Smith
Chairman

-ends-

Contacts

Acambis plc	Today	Thereafter
Gordon Cameron, Chief Executive Officer	+44 (0) 20 7831 3113	+44 (0) 1223 275 300
David Lawrence, Chief Financial Officer	+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/Anna Keeble +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 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. It is also developing an attenuated smallpox vaccine, MVA3000, under contracts with the US National Institutes of Health. Acambis' US-based subsidiary Berna Products Corporation markets Vivotif(R), the world's only licensed oral typhoid vaccine, in North America. Acambis' investigational vaccine against Japanese encephalitis, ChimeriVax-JE, is undergoing Phase 3 clinical testing. It also has the most advanced investigational vaccine against the West Nile virus, which has spread to 48 US States in the last seven years, and a vaccine against Clostridium difficile bacteria, a leading cause of hospital-acquired infections.

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.

About ChimeriVax

Edgar Filing: ACAMBIS PLC - Form 6-K

Acambis' JE and West Nile vaccine candidates have been developed using its proprietary ChimeriVax technology, which was originally developed in collaboration with St Louis University. The ChimeriVax technology is also the basis of a vaccine candidate against dengue fever, which has been licensed to sanofi pasteur.

"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 2004 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.

Results for the three months ended 31 March 2006

Group income statement

	Three months ended 31 March 2006 (unaudited) GBPm	Three months ended 31 March 2005 (unaudited) GBPm	
Revenue	6.0	6.0	
Cost of sales	(4.2)	(3.9)	
Gross profit	<u>1.8</u>	<u>2.1</u>	
Research and development costs	(9.8)	(7.2)	
Sales and marketing costs	(0.6)	(0.6)	
Administrative costs	(3.2)	(1.1)	
Other operating income: Fair value of shares received for grant of licence	-	-	
Operating loss	<u>(11.8)</u>	<u>(6.8)</u>	
Finance income	0.6	1.2	
Finance costs	(0.2)	(0.2)	
Loss on ordinary activities before taxation	<u>(11.4)</u>	<u>(5.8)</u>	
Taxation: UK	-	0.4	
Taxation: Overseas	0.1	1.0	
Loss on ordinary activities after taxation	<u>(11.3)</u>	<u>(4.4)</u>	

Edgar Filing: ACAMBIS PLC - Form 6-K

Basic and diluted loss per share (in pence)	(10.5)p	(4.1)p	
Basic loss per ADR (in \$) (note 2)	\$ (0.36)	\$ (0.15)	
Weighted average number of ordinary shares in issue - basic and diluted	107,266,487	107,159,049	107

Group balance sheet as at 31 March 2006

	As at 31 March 2006 (unaudited) GBPm	As at 31 March 2005 (unaudited) GBPm	31 (un
Non-current assets			
Goodwill	14.9	15.4	
Other intangible assets	4.1	4.2	
Property, plant and equipment	18.9	17.9	
Deferred tax asset	0.3	1.2	
Financial assets: available for sale investments	0.6	-	
Other non-current assets	-	0.1	
	<u>38.8</u>	<u>38.8</u>	
Current assets			
Inventory	3.6	5.0	
Current tax assets	0.9	3.5	
Trade and other receivables	6.7	8.5	
Financial assets: derivative financial instruments	0.2	-	
Liquid investments	16.1	21.3	
Cash and cash equivalents	33.6	73.0	
	<u>61.1</u>	<u>111.3</u>	
Current liabilities			
Financial liabilities:			
- short-term borrowings	(4.0)	(3.7)	
- short-term financial liabilities	(5.4)	(3.2)	
Trade and other payables	(4.9)	(6.6)	
Accruals and deferred income	(6.6)	(24.5)	
Income tax payable	(1.8)	-	
Provisions	(1.8)	-	
	<u>(24.5)</u>	<u>(38.0)</u>	
Net current assets	<u>36.6</u>	<u>73.3</u>	
Total assets less current liabilities	<u>75.4</u>	<u>112.1</u>	
Non-current liabilities			
Investment in Joint Venture	(0.3)	(0.3)	

Edgar Filing: ACAMBIS PLC - Form 6-K

Long-term financial liabilities	(1.5)	(5.6)
Other non-current liabilities	-	(0.4)
Deferred tax liabilities	(1.8)	(1.5)
	(3.6)	(7.8)
	71.8	104.3
Shareholders' equity		
Share capital	10.7	10.7
Share premium	98.0	97.8
Other reserves	(0.9)	(2.0)
Retained earnings	(36.0)	(2.2)
	71.8	104.3

Group cash flow statement

	Three months ended 31 March 2006 (unaudited) GBPm	Three months ended 31 March 2005 (unaudited) GBPm	
Operating activities			
Loss on ordinary activities before tax	(11.4)	(5.8)	
Depreciation and amortisation	1.1	1.1	
(Increase)/decrease in working capital	(5.2)	3.3	
Other non-cash movements	(0.4)	0.2	
Net finance costs	(0.4)	(1.0)	
Taxes paid	(0.7)	(5.2)	
	(17.0)	(7.4)	
Cash flows from operating activities			
Investing activities			
Purchase of business operations	-	-	
Purchase of intangibles	(0.1)	-	
Purchase of property, plant and equipment	(0.2)	(0.4)	
	(0.3)	(0.4)	
Cash flows used in investing activities			
Financing activities			
Interest element of finance lease payments	(0.2)	(0.2)	
Interest paid	-	-	
Interest received	0.7	1.1	
Proceeds from issue of shares	-	-	
Purchase of own shares	-	-	

Edgar Filing: ACAMBIS PLC - Form 6-K

Capital element of finance lease payments	(1.7)	(0.8)
Purchase of liquid investments	(6.1)	(12.0)
Sale of liquid investments	8.8	11.5
	1.5	(0.4)
Decrease in cash and cash equivalents	(15.8)	(8.2)
Net foreign exchange difference	0.2	0.2
Cash and cash equivalents opening balance	49.2	81.0
	33.6	73.0

Reconciliation of movements in Group shareholders' equity

	As at 31 March 2006 (unaudited) GBPm	As at 31 March 2005 (unaudited) GBPm
Retained loss for the period	(11.3)	(4.4)
Gain on foreign currency exchange	-	1.0
Revaluation of available for sale investments	-	-
Credit in respect of employee share schemes	0.1	0.2
	(11.2)	(3.2)
New share capital subscribed	-	-
Purchase of Treasury shares	-	-
Net decrease in shareholders' equity	(11.2)	(3.2)
Opening shareholders' equity	83.0	107.5
Closing shareholders' equity	71.8	104.3

Notes

1. Basis of preparation

The financial information for the three months ended 31 March 2006 and 31 March 2005 is unaudited and has been prepared in accordance with the Group's accounting policies, based on IFRS, as adopted by the European Union. IAS 34 has not been applied in preparing these interim results. The financial information for the year ended 31 December 2005 has also been prepared under IFRS and is also unaudited.

Edgar Filing: ACAMBIS PLC - Form 6-K

This summary of results does not constitute the full financial statements within the meaning of s240 of the Companies Act 1985. The 2005 financial statements will be delivered to the Registrar of Companies in due course. The Notice of The Annual General Meeting will be sent to the shareholders on 24 May 2006. The 2006 Annual General Meeting will be held on 23 June 2006.

2. Loss 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 1.7346, 1.8896 and 1.7168 for the three months to 31 March 2006, 31 March 2005 and year to 31 December 2005 respectively.

3. Directors' responsibility

The Directors are responsible for the maintenance and integrity of the Group's website. The Company notes that UK legislation governing the preparation and dissemination of financial information may differ from that required in other jurisdictions.

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: 09 May 2006

ACAMBIS PLC

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