

CELLTECH GROUP PLC  
Form 6-K  
August 19, 2003

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 6-K

Report of Foreign Private Issuer

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

For the month of August, 2003

Commission File Number: 1-10817

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## CELLTECH GROUP PLC

(Translation of registrant's name into English)

208 Bath Road, Slough, Berkshire SL1 3WE ENGLAND

(Address of principal executive offices)

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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  Form 40-F

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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:

**SIGNATURES**

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

CELLTECH GROUP PLC

(Registrant)

By:

/s/ PETER ALLEN

Peter Allen

Chief Financial Officer

Dated: 19 August, 2003

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Embargoed for release at 7am

19 August 2003

CELLTECH GROUP PLC

INTERIM REPORT FOR THE SIX MONTHS ENDED 30 JUNE 2003

As a leading European biotechnology company with a strong R&D-centred business model, Celltech is well positioned in its goal of becoming a global biotechnology leader. Celltech has in place a number of important features to facilitate this transition, in particular its self-financing profile and its emerging specialist marketing capabilities, which will enable it to fully capitalise on the launch of its own biotechnology products.

In the near term this transition will be achieved through the successful development and commercialisation of CDP 870 alongside Pfizer, the world's leading pharmaceutical company. In parallel, Celltech continues to build long-term shareholder value through the accelerated development of its early stage pipeline. Celltech has achieved a high and sustained level of productivity in its research activities, which will both replenish and grow its early stage development pipeline and create substantial future value for shareholders. In order to maximise the value creation for its shareholders, Celltech will prioritise its R&D resources towards its most exciting opportunities, and will continue to partner selected programmes with leading companies whose critical expertise and resources will enable leverage of the maximum value from these products.

Highlights in the first half of 2003 are as follows:

Strong financial performance: net profit before tax (excluding exceptional items and goodwill) increased by 76% to £20.9 million.

CDP 870 Phase III in Crohn's disease on track: Phase III development, incorporating patient stratification using C-reactive protein levels, scheduled to start during the second half of 2003. In light of the more attractive profile of CDP 870 in Crohn's disease, remaining activities with CDP 571 have been discontinued.

Further progress in early stage pipeline: four products scheduled to enter Phase I testing during 2003. CDP 791 (cancer) and CMC-544 (Non-Hodgkin's lymphoma) have recently entered Phase I trials, with CDP 484 and CDP 323 scheduled to enter Phase I trials during the second half of 2003. In addition, several new products are expected to enter preclinical development during the next 12 months.

Successful acquisition of Oxford GlycoSciences (OGS): high quality oncology and inherited storage disorder programmes to be retained, with integration activities due to be substantially completed by the end of 2003.

Strategic review: following the appointment of Dr. Goran Ando in April 2003, Celltech has begun implementation of a number of initiatives designed to streamline its pharmaceuticals business and further strengthen its R&D capabilities, resulting in exceptional charges totalling £18.8 million in the first half of 2003.

Dr. Goran Ando, Chief Executive Officer, commented: Celltech has truly world-class scientific capabilities, with substantial opportunities to build a leading position in the treatment of immune and inflammatory disorders and a credible global presence in oncology. During the next few years we will substantially strengthen our development and commercialisation capabilities to ensure we fully capitalise on the value generated from our pipeline. I am delighted with the continued strong financial performance seen in the first half of 2003, which underpins our self-financing profile. Notwithstanding the recent disappointments in two of our partnered programmes, our pipeline continues to be strong and

will enable us to create substantial long-term value for shareholders.

#### Financial results

Turnover: £158.1 million (+8% at constant exchange rates)

Product sales: £111.4 million (+0% at CER)

Royalty income: £46.7 million (+34% at CER)

Operating profit before other income (pre exceptional items and goodwill): £19.4 million (+92%)

Net profit before taxation (pre exceptional items and goodwill): £20.9 million (+76%)

Earnings per share (pre exceptional items and goodwill): 6.4p (+78%)

Exceptional restructuring charges of £18.8 million (see below)

Net funds at 30 June 2003: £156.5 million, including £31 million PowderJect convertible debt due for early repayment in September 2003.

Turnover grew by 8% to £158.1 million (2002: £146.5 million at CER), with product sales remaining steady at £111.4 million and strong growth in royalty income to £46.7 million (2002: £34.9 million at CER), primarily driven by growth in antibody engineering revenues. The impact of the weakening US dollar has been partially mitigated by gains on foreign exchange contracts of £5.8 million, included within royalty income. Operating profit, excluding other income, exceptional items and goodwill, showed strong growth to £19.4 million, driven primarily by efficiencies introduced into the US pharmaceutical business during the second half of 2002 and the growth in royalty income.

#### Development pipeline

Recent advances in Celltech's pipeline products include the following highlights:

##### CDP 870 – new anti-TNF-alpha therapy for inflammatory diseases

Celltech plans to initiate Phase III development of CDP 870 in Crohn's disease during the second half of 2003. The Phase III programme will involve over 1000 patients in total and will incorporate both acute and chronic clinical endpoints. Phase II data in Crohn's disease presented at the recent Digestive Disease Week (DDW) meeting highlighted that treatment with CDP 870 may be especially beneficial in those patients with elevated levels of C-reactive protein (CRP), a commonly measured inflammatory marker. In light of this finding, the Phase III programme will incorporate patient stratification using baseline CRP levels when determining response to treatment with CDP 870.

Pfizer continues to conduct a large Phase III programme with CDP 870 in rheumatoid arthritis (RA), assessing its efficacy with regard to both signs and symptoms and structural damage.

##### CDP 791 – potent angiogenesis inhibitor

CDP 791, a PEGylated antibody fragment targeting the VEGF pathway, recently entered Phase I clinical trials. As previously highlighted, Celltech is currently discussing potential partnerships with companies possessing substantial skills and resources in oncology development, in order to maximise the value from this programme.

##### CMC-544 – new approach for Non-Hodgkin's lymphoma

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This antibody-targeted cytotoxic treatment was recently entered into Phase I clinical trials in Non-Hodgkin's lymphoma by Celltech's partner, Wyeth.

**PDE4** novel oral treatment for respiratory diseases

Following the discontinuation of Phase II trials in asthma and COPD with their lead PDE4 inhibitor, Merck continue to progress back up compounds in Phase I clinical trials, which Celltech believes are encompassed within the existing collaboration.

**CDP 484** potent anti-inflammatory treatment

CDP 484, a PEGylated antibody fragment targeting the inflammatory cytokine interleukin-1-beta, is planned to enter Phase I trials for RA in the second half of 2003. CDP 484 will be studied in a broad population of RA patients, with a particular focus on the large and rapidly growing segment of patients eligible for treatment with biological agents who fail to respond to anti-TNF-alpha therapies.

**CDP 323** novel oral treatment for inflammatory diseases

CDP 323, a potent oral inhibitor of alpha-4 integrins, is scheduled to enter Phase I trials in the second half of 2003. Celltech intends to explore the utility of CDP 323 in a wide range of inflammatory disorders, including RA, multiple sclerosis (MS) and inflammatory bowel disease (IBD).

In addition, Celltech has entered into a new strategic manufacturing alliance with Lonza for long-term supply of PEGylated antibody fragment-based products. This agreement, which complements Celltech's existing manufacturing alliances with Biochemie (now Sandoz) and BioReliance, provides Celltech with flexibility in meeting accelerated development timelines for its early stage development portfolio.

Celltech's product pipeline is as follows:

<b>Product</b>	<b>Disease indication</b>	<b>Status</b>	<b>Partner(s)</b>
<b>Immune and inflammatory disorders</b>			
CDP 870	Rheumatoid arthritis	Phase III	Pfizer
CDP 870	Crohn's disease	Phase II	Pfizer
PDE4 inhibitor	Asthma/COPD	Phase I	Merck
CDP 484	Inflammatory disease	Preclinical	
CDP 323	Inflammatory disease	Preclinical	
<b>Cancer</b>			
CDP 860	Cancer	Phase II	
CDP 791	Cancer	Phase I	
CMC-544	Non-Hodgkin's lymphoma	Phase I	Wyeth
<b>Other</b>			
Zavesca	Gaucher disease	Approved	Actelion/Teva
CDP 923	Inherited storage disorders	Phase I	

Strategic review of Celltech's business

During the first half of 2003, Celltech has implemented a number of initiatives designed to streamline its pharmaceuticals business and further strengthen its R&D capabilities, as follows:

European sales force restructuring

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In support of its strategy of focusing sales and marketing resources towards specialist prescribing

audiences, Celltech has created new specialist marketing organisations in the UK and France during the first half of 2003, and has ceased promotion to primary care practitioners in these territories. The impact of this initiative will be a net reduction of approximately 100 positions, giving rise to exceptional charges of £4.3 million.

#### Restructuring of US manufacturing operations

Celltech's satellite manufacturing facility in Santa Ana, California is no longer considered economic and will close during the second half of 2003, with residual manufacturing operations being transferred to its Rochester facility. This has given rise to an exceptional charge of £5.0 million, reflecting redundancy costs and short-term lease commitments, in addition to writing down the book value of the facility.

#### Integration of OGS

Celltech's integration of OGS is progressing well, highlighting its successful track record in rapid and decisive integration of acquisitions. The first half financials reflect exceptional charges relating to redundancy charges, R&D projects to be discontinued and corporate costs totalling £2.0 million. In addition, provisions have been made against a number of onerous contracts, reflected as an adjustment to the value of the net assets acquired. Celltech believes that the acquisition of OGS will be cash neutral.

#### Discontinuation of CDP 571

Following the discontinuation of the development of CDP 571, Celltech has written off stock with a book value of £7.5 million. There is no cash impact associated with this write off. Separately, Celltech has previously announced settlement of its long-term CDP 571 manufacturing arrangement with Lonza, which will not result in any additional charges.

Exceptional charges reflected in the first half financial results are as follows:

European sales force restructuring	£ 4.3m
Closure of Santa Ana	£ 5.0m
Write-off of CDP 571 stock	£ 7.5m
OGS integration	£ 2.0m
Total exceptional charges	£ 18.8m

The total cash impact of the above will be approximately £9.0 million of which £2.8 million has been paid in the half year.

#### Integration of OGS

Celltech completed its acquisition of the issued share capital of OGS on 18 July 2003. The financial results of OGS have been consolidated within Celltech's financial results with effect from 1 May 2003.

Celltech has completed its comprehensive review of OGS activities, and is progressing rapidly with its integration programme, which is planned to be substantially complete by the end of 2003. As previously highlighted, Celltech will adopt a number of OGS oncology research programmes within its own pipeline, and will retain approximately 40 research staff working in the oncology area, substantially strengthening Celltech's existing oncology research activities. The costs associated with these activities will be accommodated within Celltech's existing R&D budget.

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Celltech also intends to undertake further development of OGT-923 (now renamed CDP 923), a second-generation product for the treatment of certain inherited storage disorders. Celltech believes CDP 923 represents an attractive commercial opportunity for in-house development. The first generation product,

Zavesca (miglustat) has now been approved in the US, Israel and Europe for the treatment of mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option. Zavesca will be marketed by Actelion in the US and Europe and by Teva in Israel.

Celltech is undertaking discussions with a number of interested parties regarding the disposal of the proteomics contract service business. It is anticipated that the disposal will be completed by the end of 2003. This business is currently self-funding and hence will not deplete Celltech's cash resources. Celltech has also entered discussions regarding the spin out or divestment of OGS' anti-fungal research programme.

At the time of its acquisition by Celltech on 1 May 2003, OGS had cash and liquid resources of £126.6 million. Celltech anticipates that, after restructuring charges, including staff redundancies, obligations under existing contracts and advisers' fees, its acquisition of OGS will be cash neutral.

Peter Allen, CFO and Deputy CEO, commented: We have delivered on our promise of a rapid integration of OGS, and believe that Celltech will derive substantial long-term value from this acquisition, which has been undertaken at broadly nil net cost. In particular, we see significant potential in OGS' oncology activities and inherited storage disorders franchise, and are pleased that we have been able to attract a substantial number of high quality OGS scientific staff to Celltech.

#### Pharmaceutical operations

The pharmaceuticals business performed well in the first half of 2003, with sales steady at £111.4 million (2002: £111.6 million at CER), notwithstanding a weak 2002/3 cough/cold season and the impact of Metadate CD wholesaler inventory stocking during the first half of 2002. Following its relaunch through Celltech's newly formed specialist sales forces in the US and Europe, Dipentum has performed strongly with sales of £7.7 million. The US primary care sales force restructuring during 2002 has substantially increased the profitability of the US business, with sales and marketing expenditure decreasing by 16% to £32.5 million. Celltech has also restructured its sales forces in the UK and France, where it no longer requires a primary care presence, such that they will exclusively support specialist-focused products such as Dipentum.

Commenting on the outlook for Celltech, Dr. Goran Ando said: We see an exciting period ahead for Celltech, with the continued clinical progress of CDP 870, and reaching important milestones with our early stage development pipeline. Celltech has in place all of the components required to transform it into a top tier global biotechnology company.

#### Contacts:

Dr. Goran Ando	Chief Executive Officer	(44) (0) 1753 534655
Peter Allen	Deputy CEO and CFO	
Richard Bungay	Director of Corporate	

#### Communications

Jon Coles	Brunswick (London)	(44) (0) 207 404 5959
Fiona Fong	Brunswick (London)	

Celltech Group plc (LSE: CCH; NYSE: CLL) is one of Europe's largest biotechnology companies, with an extensive late stage development pipeline and a profitable, cash-generative pharmaceutical business. Celltech also possesses drug discovery capabilities of exceptional strength, including a leading position in antibody engineering. More details can be found at [www.celltechgroup.com](http://www.celltechgroup.com).



*Celltech desires to take advantage of the Safe Harbor provisions of the US Private Securities Litigation Reform Act of 1995, with respect to forward-looking statements contained within this document. In particular certain statements with regard to the anticipated timing of clinical trials with CDP 870 and other development products, the ability of Celltech and its partners to successfully develop and launch CDP 870, the ability to enter product collaborations on suitable terms or at all, the status of Celltech's collaboration with Merck on phosphodiesterase-4 inhibitors, and the financial impact of the integration of OGS by Celltech, are all forward-looking in nature. By their nature forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. In addition to factors set forth elsewhere in this document, the following factors, although not exhaustive, could cause actual results to differ materially from those the Company expects: pricing and product initiatives of the Company's competitors, including the introduction of branded competition or generic substitution for the Company's products, unanticipated difficulties in the design or implementation of clinical trials, studies and investigations, results from clinical trials, studies and investigations that are inconsistent with previous results and the Company's expectations, failure to obtain and maintain required approvals for products from governmental authorities, unavailability of raw materials or other interruptions in production or product distribution both internal and external, unexpected difficulties in the scale-up of production to viable commercial levels, unexpected fluctuations in production yields for development products or marketed products, fluctuations in currency exchange rates, inability of the Company to market existing and new products effectively, the failure of the Company's development, manufacturing and marketing partners to perform their contractual obligations and the risk of substantial product liability claims. Other factors that could affect these forward-looking statements are described in the Company's reports filed with the US Securities and Exchange Commission. The forward-looking statements included in this document represent the Company's best judgment as of the date hereof based in part on preliminary information and certain assumptions which management believes to be reasonable. The Company disclaims any obligation to update these forward-looking statements.*

#### INTERIM REPORT FOR THE SIX MONTHS ENDED 30 JUNE 2003

#### Chief Executive's Statement

In this, the first report to shareholders since my appointment as Chief Executive in April, I am outlining my initial impressions of Celltech and the areas we intend to focus on as we continue to build the company.

In my first few months at Celltech, I have been able to meet with many of our employees and to explore the business in some depth. It is evident that Celltech has most impressive research capabilities, including a globally competitive position in the design and production of antibody therapeutics. Naturally, our most advanced development candidate, CDP 870, is of considerable importance to Celltech, however I am also extremely excited by the potential of the early stage development pipeline.

Celltech's origins were as a research boutique, feeding innovative new drugs into partnering arrangements with large pharmaceutical companies. Under the leadership of Dr. Peter Fellner, Celltech has undergone substantial transformation during the last few years through a series of acquisitions, highlighting Celltech's impressive integration capabilities. This is most recently evidenced by the rapid and successful integration of Oxford GlycoSciences (OGS). As Celltech advances towards becoming a global biotechnology leader, we need to employ an adaptable business model to ensure we maximise our chances of success. This continuous review of the business model is a feature of all successful companies.

To ensure Celltech is successful in achieving its growth aspirations, we are beginning a process during 2003 of focusing resources towards our most important value drivers, with some of the key changes

highlighted below.

The most critical activity for Celltech in the near term is ensuring our organisation is able to successfully develop and commercialise CDP 870 in Crohn's disease, working alongside Pfizer, which is leading activities in rheumatoid arthritis. We are strengthening our late stage development and specialist marketing capabilities to ensure this is successful, and have put in place an innovative registration programme to deliver the best possible commercial profile for CDP 870 in Crohn's disease.

Celltech is also focusing its R&D resources towards the delivery of a steady stream of high value candidates into development, and is aggressively advancing these products to proof of concept, whilst controlling our overall level of R&D expenditure. Reflecting this, we have recently initiated a Phase I trial with CDP 791 and will shortly initiate a Phase I trial with CDP 484, both of which are innovative studies aimed at quickly achieving proof of concept. We plan to further strengthen all aspects of our development organisation during the next 12 months to ensure delivery of rapid, robust and highly innovative development programmes.

Celltech's self-funding profile is a key component of its business model. We aim to protect and grow key marketed products such as Dipentum and Tussionex through focused sales and marketing, and selected life cycle management. An important component is also the continued tight control of costs, and we aim to minimise those that are not specifically attributable to value generating activities. Celltech's strong financial profile is well-illustrated by its excellent first half results, with net profit before exceptional items and goodwill increasing by 76% over the equivalent period last year. In addition to the continued generation of cash from its operations, Celltech's growth aspirations are underpinned by a strong balance sheet with net funds plus loan notes repayable of £156.5 million at the half year.

Celltech's management team is building action plans behind each of the initiatives outlined above to ensure we are successful in achieving each of our goals. I look forward to updating shareholders on our progress against these plans in future reports.

During my first few months as Chief Executive, I have been impressed most of all by the skill and enthusiasm of people at Celltech. The continued drive of our highly talented employees will help to ensure we are successful in meeting our goal of becoming a global biotechnology leader.

Dr Goran Ando, Chief Executive

18 August 2003

## Overview

As a leading European biotechnology company with a strong R&D-centred business model, Celltech is well positioned in its goal of becoming a global biotechnology leader. Celltech has in place a number of important features to facilitate this transition, in particular its self-financing profile and its emerging specialist marketing capabilities, which will enable it to fully capitalise on the launch of its own biotechnology products.

In the near term this transition will be achieved through the successful development and commercialisation of CDP 870 alongside Pfizer, the world's leading pharmaceutical company. In parallel, Celltech continues to build long-term shareholder value through the accelerated

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development of its early stage pipeline. Celltech has achieved a high level of productivity in its research activities, which will sustain a flow of innovative therapeutic approaches into development, creating substantial future value for shareholders. In order to maximise value creation and to actively manage its risk

profile, Celltech will prioritise its R&D resources towards opportunities with the most potential, including selective partnering of programmes with leading pharmaceutical and biotechnology companies where their critical expertise and resources will leverage the greatest value from these products.

Celltech has continued to make good progress with its new product pipeline during the first half of the year, notwithstanding disappointing results with two of its partnered programmes, BMS-275291 for cancer and the phosphodiesterase4 lead compound for respiratory disease. Celltech is on track to commence Phase III studies with CDP 870 in Crohn's disease during the second half of the year, using an innovative trial design involving pre-identification of patients most likely to benefit from treatment. In light of the more attractive profile of CDP 870 in Crohn's disease, Celltech has decided to discontinue all development activities with CDP 571.

Celltech also continues to make exceptional progress with its early stage pipeline, with four products scheduled to enter Phase I studies during the course of 2003, and several innovative products expected to enter preclinical development during the next twelve months.

As Celltech grows its portfolio of antibody fragment based products, it is essential that robust long-term supply arrangements be in place for clinical trials and ultimate commercialisation of these products. Celltech recently entered into a long-term supply agreement with Lonza for the large-scale microbial manufacture of antibody fragment products, complementing its existing manufacturing agreements with Biochemie (now Sandoz) and BioReliance.

Celltech has also made excellent progress with the integration of OGS, which will further strengthen its emerging oncology efforts through the adoption of six OGS oncology research programmes within its own pipeline, along with the retention of approximately 40 research staff working in the oncology area. Celltech also intends to take on the development of OGT-923 (renamed CDP 923), OGS' second-generation product for the treatment of certain inherited storage disorders (ISDs). The recent approvals of Zavesca, OGS' first generation ISD product, in the US and Israel highlight a further area of value for Celltech from this acquisition. The additional costs associated with these activities will be accommodated within Celltech's existing R&D budget, meeting the previously stated goal of providing valuable assets to the Group whilst being both cash and earnings neutral.

An important element of Celltech's strategy is its self-funding profile, with revenues from its mature marketed products portfolio and royalty streams underpinning an internationally competitive level of investment in R&D. Celltech recorded a strong financial performance during the first half of 2003, with overall turnover increasing by 8% to £158.1 million (2002: £146.5 million at constant exchange rates (CER)) and net pre-tax profit before exceptional items and goodwill increasing by 76% to £20.9 million (2002: £11.9 million). On a proforma basis, the earnings per share for the half year were 6.4p (2002: 3.6p). On a statutory basis, the loss per share was 16.5p (2002: loss per share of 12.5p). Net funds at 30 June 2003, including the accelerated repayment due in September of the PowderJect convertible debt, amounted to £156.5 million.

As previously highlighted, Celltech is transitioning its pharmaceuticals business to enable it to successfully market specialist-focused pipeline products. This change is being facilitated partly through the relaunch of Dipentum, a gastrointestinal product acquired last year from Pharmacia, using our newly recruited specialist sales forces. Celltech's product portfolio continues to provide a stable revenue stream, with overall product sales steady at £111.4 million (2002: £111.6 million at CER). Celltech is undertaking focused life cycle management activities to protect and grow revenues from its mature product portfolio.

Royalty income continued to grow strongly during the first half of 2003, increasing by 34 % to £46.7

million (2002: £34.9 million at CER), driven primarily by growth in its antibody engineering revenues. The impact of the weakening US dollar has been partially mitigated by gains on foreign exchange contracts of £5.8 million, included within royalty income.

Operating costs, before exceptional items and goodwill amortisation, were slightly below the level for the equivalent period last year at £94.9 million (2002: £96.7 million).

#### Strategic review of Celltech's business

Celltech has begun implementation of a number of initiatives designed to streamline its pharmaceuticals business and further strengthen its R&D capabilities, in addition to ongoing activities in support of its strategy of focusing sales and marketing resources towards specialist prescribing audiences.

Celltech has created new specialist marketing organisations in the UK and France during the first half of 2003, and has ceased direct promotion to primary care practitioners in these territories. The impact of this initiative will be a net reduction of approximately 100 positions, giving rise to exceptional charges of £4.3 million.

Celltech's manufacturing facility in Santa Ana, California will close during the second half of 2003, with certain manufacturing operations being transferred to its Rochester facility, giving rise to an exceptional charge of £5.0 million.

As highlighted above, Celltech's integration of OGS is progressing as planned. The first half financial results reflect related exceptional charges incurred in the period totalling £2.0 million. In addition, provisions have been made against a number of onerous contracts, reflected as an adjustment to the value of net assets acquired and are detailed further in the notes to the financial statements.

Following the discontinuation of development of CDP 571, Celltech has written off stock with a book value of £7.5 million. There is no cash impact associated with this write off. Separately, Celltech has reached settlement on the cessation of its long-term CDP 571 manufacturing arrangement with Lonza, which will not result in any additional charges to the profit and loss account.

The total exceptional charges reflected in the first half financial results amounted to £18.8 million, and are detailed further in the financial review. The total cash impact is estimated to be £9.0 million with outflows of approximately £2.8 million during the first half of 2003. The majority of this cash outflow will be reflected in the 2003 financials.

#### OPERATIONAL REVIEW

##### New product development

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Celltech is committed to maintaining an internationally competitive investment in R&D, enabling it to pursue a broad product pipeline. Celltech has built substantial expertise in autoimmune and inflammatory diseases, particularly in rheumatoid arthritis (RA) and inflammatory bowel disease (IBD). Celltech intends to further expand this expertise, in both research and development, to include further areas of high unmet medical need, including multiple sclerosis (MS) and systemic lupus erythamatosus (SLE). Celltech is beginning to enhance its development and marketing capabilities so it is able to successfully profile opportunities in specialised disease areas for commercial success. In larger disease markets, such as RA, Celltech is likely to continue its strategy of partnering with global leaders in order to leverage maximum value from its pipeline products.

Celltech is also building its expertise in oncology to provide a second area of therapeutic focus, which has been further strengthened through its recent acquisition of OGS. Celltech believes that it is able to generate substantial value through the application of its research technology platforms to generate novel new anti-cancer therapies. Since many cancers are typically treated using complex combinations of products, Celltech expects to continue partnering selected programmes where the critical expertise from leading oncology companies can enhance the successful development and commercialisation of its novel therapies.

Celltech's pipeline is underpinned by its state-of-the-art technology platforms, including leading antibody technologies such as its PEGylated antibody fragment and SLAM technologies, and its small molecule screening collaboration with Neogenesis. Celltech continually reviews new technologies to ensure its research activities remain at the leading edge and are able to sustain a steady stream of innovative candidates into development. In parallel, Celltech continuously reviews the balance of its expenditure between research and development to ensure resources are applied to generating both mid- and long-term value.

Product	Status	Indication	Partner
Immune and inflammatory disorders			
CDP 870	III	Rheumatoid arthritis	Pfizer
CDP 870	II	Crohn's disease	Pfizer
PDE4 inhibitor	I	Asthma / COPD	Merck
CDP 484	Preclinical	Rheumatoid arthritis	
CDP 323	Preclinical	Rheumatoid arthritis	
Oncology			
CDP 860	II	Cancer	
CDP 791	I	Cancer	
CMC-544	I	Non-Hodgkin's lymphoma	Wyeth
Other			
Zavesca	Approved	Gaucher disease	Actelion/Teva
CDP 923	I	Inherited storage disorders	

Recent advances with Celltech's development products are outlined in the pages to follow.

#### CDP 870

CDP 870 is Celltech's next-generation anti-TNF alpha approach, being co-developed with Pfizer, a global leader in rheumatology. The anti-TNF alpha market is expected to generate over \$3 billion in revenues in 2003, with substantial future growth anticipated through increased penetration and new disease indications. CDP 870, which utilises Celltech's PEGylated antibody fragment technology, has demonstrated a fully competitive efficacy profile in Phase II studies in RA and Crohn's disease, and has a convenient four-weekly subcutaneous dosing regimen.

Pfizer is responsible for development of CDP 870 in RA and initiated Phase III clinical trials during October 2002. This comprehensive programme, in which patients will be treated for up to 12 months, will assess the efficacy of CDP 870 both as monotherapy and in combination with other disease modifying drugs, including its effect on both signs and symptoms of disease as well as structural damage to joints.

Celltech is responsible for development of CDP 870 in Crohn's disease and plans to initiate Phase III development during the second half of 2003. The Phase III programme will involve over 1000 patients in total and will incorporate both acute and chronic clinical endpoints. Phase II data in Crohn's disease presented at the recent Digestive Disease Week (DDW) meeting highlighted that treatment with CDP 870 may be especially beneficial in those patients with elevated levels of C-reactive protein (CRP), a commonly measured inflammatory marker. In light of this finding, the Phase III programme will incorporate patient stratification using baseline CRP levels when determining response to treatment with CDP 870.

Current timelines envisage completion of the Crohn's disease Phase III programme in time for simultaneous regulatory submissions with the RA indication. Based upon current timelines, CDP 870 has the potential to be the second biological therapy to reach the market in Crohn's disease. Current sales of biological therapies in Crohn's disease are estimated at around \$600m, representing a very large and commercially attractive opportunity for Celltech.

#### CDP 571

As part of the strategic review following the appointment of Dr. Ando as CEO, Celltech has assessed the commercial potential for CDP 571 in light of the encouraging data generated using CDP 870 in Crohn's disease and its superior product profile. In particular, Celltech's review of the potential for CDP 571 on a named patient usage basis concluded that there is no significant patient population in which it would be uniquely helpful. In light of the modest need and commercial opportunity, Celltech does not intend to undertake any further development of CDP 571. As a consequence, Celltech has written off all remaining stocks of CDP 571, amounting to £7.5m, and has terminated its long-term supply agreement with Lonza Biologics, detailed further in the financial review. Celltech and Biogen have agreed to discontinue their collaboration on CDP 571.

#### CDP 484

CDP 484 is a PEGylated fragment targeting IL-1 beta, a key mediator of inflammatory diseases. Preclinical studies using antibodies to IL-1 beta have demonstrated potent anti-inflammatory effects, and it is believed that CDP 484 may have utility in a broad population of RA patients. The programme will have a particular focus on the large and rapidly growing segment of patients eligible for treatment with biological agents who do not respond to TNF alpha blockers, presenting a significant commercial opportunity. CDP 484 is expected to have similar dosing advantages over competitor approaches to that seen with CDP 870, with anticipated subcutaneous dosing every four weeks.

Following recent approval of its clinical trial exemption (CTX) in the UK, Celltech intends to initiate a Phase I clinical trial with CDP 484 during the second half of 2003.

#### CDP 323

CDP 323, a novel small molecule inhibitor of alpha 4 integrins, has shown encouraging efficacy in preclinical models of RA, with efficacy comparable to current gold standard treatments. Celltech plans to initiate Phase I studies using oral administration of CDP 323 during the second half of 2003. Research is also ongoing into the use of CDP 323 as a treatment for MS and Crohn's disease.

#### Merck PDE4

As announced in May 2003, Celltech's partner Merck suspended development of its lead PDE4 inhibitor, which was in Phase II development for asthma and COPD. Merck continues to progress back up compounds in Phase I development, which Celltech believes are encompassed within the existing collaboration.



#### CDP 860

CDP 860, an anti-PDGF beta receptor PEGylated antibody fragment, has recently completed a small Phase II proof-of-concept study to determine whether it is able to increase the permeability of tumours, which may facilitate an increased uptake of chemotherapeutic agents, thereby increasing their effectiveness. This pilot study, in which a single dose of CDP 860 was administered to patients with colorectal and ovarian cancer, indicated that CDP 860 was able to selectively increase blood flow into tumours.

Further development of CDP 860 will require access to significant oncology development expertise, including the exploration of its utility in a broad range of tumour types alongside existing chemotherapeutic regimens. Consequently, Celltech does not intend to carry out further in-house development of CDP 860, and has entered into discussions with potential partners for this programme.

#### CDP 791

CDP 791 is an extremely high affinity PEGylated antibody fragment targeting the VEGF pathway. Data published at the recent ASCO meeting from a clinical trial in colorectal cancer with an anti-VEGF antibody have highlighted the potential for this class of drugs as adjunctive agents to be used alongside existing chemotherapeutic regimens.

Preclinical studies with CDP 791 have demonstrated potent anti-angiogenic activity. Celltech recently initiated Phase I clinical studies with CDP 791 in patients with a range of advanced solid tumours that have failed to respond to standard therapies. This study is designed to provide rapid confirmation of target modulation.

Celltech is pursuing partnering discussions for CDP 791 with companies possessing significant oncology development expertise that have the ability to explore its utility in a broad range of tumour types alongside existing chemotherapeutic regimens.

#### CMC-544

CMC-544 is an anti-CD22 antibody linked to calicheamicin, a potent cytotoxic drug, using technology developed for the FDA-approved drug Mylotarg. Celltech's partner, Wyeth, has recently initiated Phase I studies in Non-Hodgkin's lymphoma with CMC-544.

Under the terms of Celltech's collaboration, Wyeth funds the majority of clinical trial costs for CMC-544, with Celltech receiving a royalty on future sales of the product, if successfully commercialised.

#### Zavesca (miglustat)

Zavesca, acquired by Celltech through its purchase of OGS, is a first generation oral substrate reduction therapy (SRT) for the treatment of ISDs. Zavesca has now been approved in the US, Israel and Europe for the treatment of mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option. Actelion will market Zavesca in the US and Europe, and Teva will market the product in Israel, with Celltech receiving royalties on sales.

#### CDP 923 (formerly OGT-923)

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As part of its integration of OGS, Celltech has assessed the potential for development of OGT-923 (now CDP 923), a second-generation SRT for the treatment of ISDs.

A recently completed Phase I single dose study confirmed findings from preclinical studies indicating that CDP 923 may lack certain of the toxicities of Zavesca. Celltech is initiating a Phase I multiple dose study to confirm these findings, and expects to complete this study by early 2004. If this study confirms

earlier findings, Celltech believes CDP 923 represents an attractive commercial opportunity for in-house development.

#### Early stage pipeline

Celltech continues to make substantial advances with its portfolio of research programmes, encompassing both antibody- and small molecule-based approaches.

In particular, Celltech expects to enter a p38 MAP kinase inhibitor, CDP 146, into preclinical development towards the end of 2003. Celltech has generated a series of potent oral inhibitors of p38 MAP kinase, which have demonstrated potent anti-inflammatory effects in preclinical models. Celltech is undertaking further candidate characterisation and intends to select a development candidate in the second half of 2003. Other discovery opportunities, focused in Celltech's core areas of autoimmune and inflammatory disorders and cancer, are continuing to progress well.

Access to high quality disease targets remains a priority for the Group. Celltech's acquisition of OGS has provided a substantial number of high quality oncology targets, along with a team of skilled scientists, which will significantly enhance its growing focus in this area of high unmet medical need.

#### PHARMACEUTICALS

##### Sales of major products and royalty income

	2003	2002*	
	£ million	£ million	% change
Tussionex	19.2	22.2	-14
Zaroxolyn	12.4	14.1	-12
Metadate CD	10.4	10.3	+1
Dipentum	7.7		nm
Delsym	5.8	3.7	+57
Generic methylphenidate	5.6	6.8	-18
Perenterol	4.2	4.3	-2
Coracten	3.2	2.8	+14
Semprex-D	2.0	1.5	+33
Ionamin	1.7	3.6	-53
Pediapred	1.0	2.1	-52
Other	38.2	40.2	-5
Total product sales	111.4	111.6	0
Antibody engineering	31.2	23.7	+32
Pertactin	3.4	4.6	-26
Asacol	3.1	3.8	-18
Mylotarg	1.5	1.5	0
Other	1.7	1.3	+31
Exchange gains on forward contracts	5.8		
Total royalties	46.7	34.9	+34
Total sales	158.1	146.5	+8
Effect of exchange differences		9.1	

As reported	158.1	155.6	+2
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\* At constant exchange rates (CER)

The current marketed product portfolio continues to provide Celltech with a stable revenue base, with first half 2003 sales steady at £111.4 million (2002: £111.6 million at CER). Excluding the impact of the acquisition of Dipentum in the second half of 2002, first half 2003 sales are lower than the equivalent period in 2002, primarily due to the continued planned reduction of wholesaler inventory levels, a weak cough/cold season in the US and wholesaler stocking of Metadate CD during the comparable period in 2002. Product sales and royalties are reported in the accompanying table at CER. The performances of major products were as follows:

#### Cough/cold products

Tussionex and Delsym, Celltech's 12-hour acting cough/cold products, performed strongly in the first half of 2003, notwithstanding a weak US cough/cold season. Tussionex, a prescription-only anti-tussive agent, increased its prescription market share by 7%, with the impact of the weak season leading to slightly lower sales at £19.2 million (2002: £22.2 million at CER). Delsym, an over-the-counter cough medicine, continued to respond well to the introduction of a new pack size during 2002, with sales increasing by 57% to £5.8 million (2002: £3.7 million at CER).

Development of Codeprex, a codeine-based 12-hour acting product that will complement the cough/cold product range, continues according to plan with launch expected in 2004.

The cough/cold range represents an important component of Celltech's existing business. Celltech will continue to fully support these products through both targeted life cycle management initiatives and continued promotion using its 170 representative US primary care sales force.

#### Zaroxolyn

This diuretic for the treatment of congestive heart failure maintained prescription levels, with sales slightly lower at £12.4 million (2002: £14.1 million at CER) due to a planned reduction in wholesaler inventory levels.

Celltech currently undertakes limited promotion of Zaroxolyn following the expiry of patent protection for this product during 2002.

#### Methylphenidate products

The attention deficit hyperactivity disorder (ADHD) market continues to be affected by the launch of new medications and formulations, and high levels of promotion from a number of companies. During 2002, Celltech repositioned Metadate CD, its once-daily formulation of methylphenidate, as a niche product, and has implemented a series of measures designed to maintain current sales levels with minimum promotional effort. This included publication of head-to-head data versus the leading once-daily methylphenidate product, Concerta, which demonstrated significant efficacy advantages for Metadate CD, and the introduction of 10mg and 30mg capsules to complement the existing 20mg capsule.

In Europe, Celltech has successfully completed bioequivalence studies for Equasym XL, the European brand name for Metadate CD, with regulatory filings having been made in the UK and the first launches planned in key European markets during 2004.

Whilst ADHD is not a core focus for Celltech, this franchise continues to be highly profitable and these products will continue to be promoted through the general sales force in the US and the specialist-focused sales forces in certain European territories.

Dipentum

Celltech acquired Dipentum, used in the treatment of ulcerative colitis, from Pharmacia in 2002. This product was relaunched in Europe during late 2002 and in the US at the beginning of 2003. Initial sales performance has been strong, particularly in the US where sales increased by 80% over the first half of 2002, prior to Celltech's acquisition of the product. Celltech expects to grow sales of Dipentum substantially during the next few years, and this product provides an excellent opportunity for Celltech to build relationships with the IBD prescriber base ahead of the launch of CDP 870.

During the first half of 2003, Celltech has continued to reshape its pharmaceuticals business to reflect the future focus of its pipeline products, whilst taking measures to ensure the stability and profitability of the current marketed product range, which provides important cash flows to help support the Group's innovative R&D efforts.

During 2002 Celltech created a new 30 person gastrointestinal sales force in the US, initially to market Dipentum, which covers approximately half of the prescribing base for currently marketed biological products in Crohn's disease. It is Celltech's intention to double the size of this sales force ahead of the launch of CDP 870, enabling coverage of the majority of prescribers of biological products in this area.

Following changes made during the last two years, Celltech has a significant commercial presence in most major European territories. During 2003, Celltech has significantly restructured its UK and French sales forces to focus primarily on specialist-based promotion. The new UK sales force comprises 25 representatives, focusing primarily on Dipentum, Coracten and ADHD products, in addition to NHS and Primary Care Trust liaison activities. Celltech's specialist organisation of 23 representatives in France and Belgium will focus on Dipentum and ADHD products. These changes have given rise to a significant reduction in the overall number of representatives in these markets, with the costs of reorganisation reflected as an exceptional charge in the first half financials, detailed in the financial review. Following these changes, Celltech's global sales organisation is now predominantly specialist-focused, with primary care sales forces remaining in the US, detailing mainly Celltech's range of cough/cold products, Germany and Spain.

Celltech is undertaking a range of life cycle management initiatives to enhance revenues and to protect against generic competition when patents expire on its portfolio of mature marketed products. Following the successful introduction of Dipentum, Celltech will also continue to seek new specialist product opportuni