

# Celltech Group plc

Interim Report 2002

**Board of Directors**

J B H Jackson (Chairman)

Dr P J Fellner (Chief Executive Officer)

P V Allen (Finance Director)

Dr M G Lee (Research & Development Director)

J W Baker (Non Executive Director)

H R Collum (Non Executive Director)

Sir Tom Blundell (Non Executive Director)

Professor C R W Edwards (Non Executive Director)

Dr M E Jaffe (Non Executive Director)

M G Newmarch (Non Executive Director)

Dr P Read (Non Executive Director)

# Highlights

## > Financial\*

- Turnover: **£155.6 million** (+16%)
- Operating profit before other income: **£10.1 million** (+36%)
  - R&D investment: £45.1 million (+8%)
  - Increase in insurance costs: £2.7 million
- Net profit before taxation: **£11.9 million** (2001: £27.4 million, including £17.5 million initial payment from Pharmacia)
- Cash and liquid resources (at 30 June 2002): **£98.8 million**

## > New product pipeline

- **CDP 870:** Pharmacia is initiating Phase III development in rheumatoid arthritis, with initial patient dosing scheduled to begin in October 2002. Celltech has obtained encouraging Phase II results in Crohn's disease
- **CDP 571:** two large Phase III Crohn's disease studies have been completed; discussions are planned with regulatory authorities
- **PDE4 inhibitor:** Merck is continuing to progress a potent selective PDE4 inhibitor, which arose from their collaboration with Celltech, in Phase II studies in asthma and chronic obstructive pulmonary disease
- **CDP 323:** a novel small molecule orally-active integrin antagonist, has been entered into development as a potential treatment for immune and inflammatory disorders
- Strategic manufacturing alliances have been established with Biochemie (Novartis) and BioReliance for long-term supply of PEGylated antibody fragment-based products

## > Discovery programmes and technology

- A new collaboration with Amgen on novel antibody fragment-based osteoporosis treatments
- Access to Seattle Genetics' linker and cytotoxic drug technology, for new approaches to cancer and other applications

## > Pharmaceutical business

- Product sales: **£116.8 million** (+10%)
- Acquisition from Pharmacia, in July 2002, of rights to Dipentum in US and Europe; to be promoted by new Celltech specialist sales forces

\*The operational profit and loss account, which excludes goodwill amortisation and is set out on page 6, has been used when discussing the financial performance of the Group. Sales and royalties are stated at constant exchange rates.

## Overview

Celltech's long-term business strategy is centred upon its commitment to innovative R&D as the principal route to creating new shareholder value, supported by revenues from its cash-generative pharmaceutical business. This business enables Celltech's R&D investment to be sustained at an internationally competitive level, whilst maintaining the Company's profitability.

In parallel, Celltech focuses upon retaining pipeline value through its partnering arrangements, which include co-marketing rights and profit-sharing elements. Celltech's partnering strategy also enables it to manage pipeline risk effectively, by pursuing a broad portfolio of products. The Company's business model, with its strong balance sheet and self-financing profile, enables it to consistently pursue the development of its pipeline, independent of capital market conditions.

Celltech's business has continued to progress well since its last Annual Report. Extensive progress has been made with key pipeline products, in particular the anti-TNF $\alpha$  antibody fragment CDP 870, where Pharmacia is initiating Phase III development in rheumatoid arthritis, with patient dosing scheduled to begin in October 2002. In addition, Celltech has obtained encouraging results with CDP 870 in two Phase II studies in Crohn's disease.

Celltech's partners continue to progress other important new treatments in mid- or late-phase clinical studies. These include Merck, which is progressing a potent, selective PDE4 inhibitor for respiratory diseases in Phase II studies, and Bristol-Myers Squibb which is continuing to evaluate BMS 275291 as a novel lung cancer treatment in Phase II/III studies.

Following the announcement of Phase III results with CDP 571 in Crohn's disease in July, Celltech intends to seek guidance from US and European regulatory authorities with regard to their likely requirements for marketing approval for the acute treatment of active Crohn's disease, and for its clinical management on an as-needed basis.

Recent additions to the pipeline, CDP 484 for arthritis and CDP 791 for cancer, are advancing well towards entry into initial clinical studies. A further novel small molecule orally-active product candidate, CDP 323, a potent VLA4 antagonist, has recently been entered into preclinical development, as a new potential treatment for a range of serious immune and inflammatory disorders.

Celltech is making significant progress towards refocusing its pharmaceutical business, which will play an important role in the future in leveraging value from its current pipeline products. The acquisition of promotional rights from Pharmacia for Dipentum, a treatment for inflammatory bowel disorders, will enable Celltech to accelerate the transformation of this business into one that is able to support marketing of novel products to specialist prescribing audiences. Celltech will establish small specialist gastroenterology sales forces in the US and Europe, initially to market Dipentum. It is intended that these sales forces will ultimately market CDP 571 and CDP 870 in Crohn's disease.

The existing pharmaceutical business, which along with Celltech's royalty income provides a consistent revenue stream to support Celltech's substantial investment in R&D, continued to perform well, with sales and royalties increasing by 16% to £155.6 million in the first half of 2002.

Operating profit, excluding other income and goodwill charges, showed strong underlying growth of 36% to £10.1 million, notwithstanding an 8% increase in R&D investment to £45.1 million. The operating income statement also includes an additional charge of £2.7 million for insurance costs, including a charge of

£1.5 million related to the liability for self-insured risk underwritten by the newly created captive insurance company, in response to large rises in insurance costs since September 2001. Excluding this charge, operating profit before other income and goodwill charges would have grown by 73% compared to the same period in 2001.

Profit before tax is markedly influenced by R&D-related milestone payments from collaborators, which can vary significantly year on year. Pro-forma earnings per share were 3.6p, compared to 8.3p in the first half of 2001, which included an initial CDP 870 collaboration payment of \$25 million (£17.5 million; EPS effect of 5.3p) from Pharmacia. Sales, marketing and distribution expenses increased by 25% to £38.8 million, reflecting both the effect of the US sales force expansion in the first half of 2001, and of the Thiemann acquisition. This figure is expected to be lower in the second-half following the restructuring of the US sales force announced in July 2002. This restructuring, which reduced Celltech's US general sales force from 350 to 170 representatives, was carried out following the conclusion of the planned post-launch promotion period for Metadate CD, and an appraisal of its ongoing in-market performance. Following the sales force restructuring, Celltech expects Metadate CD to make a significant positive financial contribution to the business. The restructuring will not result in any exceptional charges in the second-half financial results.

Celltech has continued to invest significantly in its discovery programmes and technology. It has entered into an important collaboration with Amgen to develop new treatments for osteoporosis, based upon the exploitation of a novel Celltech target, and using its antibody fragment technology. In March 2002, Celltech gained access to Seattle Genetics' novel linker and cytotoxic drug technology, enabling Celltech to pursue cytotoxic approaches in its core disease areas of immune/inflammatory disorders and cancer. This complements technology acquisitions made during 2001 from Abgenix and Neogenesis, which are now fully integrated into Celltech's discovery operations, and have both produced extremely encouraging results to date.

In order to ensure that Celltech has robust long-term availability of products for preclinical and clinical development, and for in-market supply, it has entered into two strategic manufacturing agreements during 2002. A recent agreement with Biochemie, a Novartis subsidiary, provides Celltech with flexible capacity for the large-scale manufacture of PEGylated antibody fragments, whilst its agreement with BioReliance, announced in March 2002, will provide supplies of products for preclinical and early stage clinical trials.

# Operational Review

## Celltech development pipeline

Product	Phase	Indication	Partner
<b>Immune and inflammatory disorders</b>			
CDP 571	III	Crohn's disease	Biogen
CDP 870	III	Rheumatoid arthritis	Pharmacia
	II	Crohn's disease	–
PDE4 inhibitor	II	Asthma/COPD	Merck
CDP 484	Preclinical	Arthritis	–
CDP 323	Preclinical	Immune/inflammatory disorders	–
<b>Cancer</b>			
BMS 275291	II/III	Lung cancer	Bristol-Myers Squibb
CDP 860	II	Cancer	–
CMC-544	Preclinical	Non-Hodgkin's lymphoma	Wyeth
CDP 791	Preclinical	Cancer	–
<b>Other</b>			
AAVCF	II	Cystic fibrosis	Targeted Genetics

## NEW PRODUCT DEVELOPMENT

Celltech continues to invest substantial resources in its drug discovery efforts, and in vigorously developing the innovative pipeline products arising from these programmes. Celltech is committed to maximising the returns it will receive from these pipeline products, by undertaking most or all of the development of certain products itself, and partnering others with leading pharmaceutical or biotechnology companies. This enables Celltech to pursue a broad portfolio, ensuring that overall pipeline development risks are effectively managed.

Celltech has assembled a strong technology platform underpinning its R&D efforts, including its PEGylated antibody fragment technology, which is now being used in four of its development programmes. This platform has been further strengthened during 2002 with access to Seattle Genetics' novel linker and cytotoxic drug technology. In addition, Celltech has successfully integrated both Abgenix's SLAM technology and Neogenesis' screening capabilities into its own research efforts, and substantial progress is being made in a range of discovery programmes employing these technologies. The productivity of Celltech's discovery efforts is illustrated by the recent advance of a further novel entity, CDP 323, into preclinical development.

Celltech currently has an extensive product portfolio with six products in Phase II or Phase III development and a further four products in earlier stage development. Advances with the key mid- or late-phase products, and their current status, are outlined below.

### CDP 870

CDP 870, a PEGylated humanised anti-TNF $\alpha$  antibody fragment, is being developed as a new treatment for rheumatoid arthritis (RA) and Crohn's disease through a major collaboration with Pharmacia. The market for existing anti-TNF $\alpha$  products is growing substantially, with annualised sales for this drug class currently running at around \$2 billion. Significant further growth is expected, from increased penetration of existing indications, and through the entry of this product class into additional therapeutic areas.

Results from Phase II studies in RA, reported previously, demonstrated a competitive clinical profile for CDP 870, which has been confirmed through further Phase II studies. Pharmacia has now developed a revised formulation of the product which will be

used for the extensive Phase III programme, and subsequently in-market. Following FDA review of this new formulation, and of the Phase III clinical plans, Pharmacia are initiating Phase III studies with patient dosing scheduled to begin in October 2002. Celltech will receive a milestone payment during the second half of 2002 related to the entry of the product into Phase III studies.

In May 2002 Celltech reported that a small Phase II study with CDP 870 administered intravenously in Crohn's disease confirmed earlier efficacy and safety findings obtained from a large subcutaneous dosing study. Planning is ongoing for Phase III studies with CDP 870 in Crohn's disease.

Celltech's collaboration with Pharmacia provides Celltech with co-development and co-marketing rights in the US, EU and Japan. Celltech will earn a share of the profits arising from product sales in RA and Crohn's disease in these territories, along with royalties on sales elsewhere. In July 2002, Pfizer announced that it had signed a definitive agreement to acquire Pharmacia. The terms of Celltech's collaboration agreement are unaffected by this transaction.

### CDP 571

Celltech recently announced the results of two large Phase III studies with its humanised anti-TNF $\alpha$  antibody CDP 571 (previously called Humicade) in Crohn's disease.

The principal study, involving 400 patients, assessed the efficacy and safety of CDP 571 in achieving acute clinical responses, and in maintaining responses over 28 weeks. CDP 571 was administered intravenously, at 8-weekly intervals, at a dose of 10mg/kg. Treatment-related benefit was assessed by the numbers attaining a significant reduction in Crohn's disease activity index (CDAI) or disease remission.

CDP 571 treatment achieved statistically significant efficacy in respect of a range of acute and 28-week clinical endpoints. The 28-week combined primary endpoint (CDAI reduction  $\geq 100$  points and/or remission) was not reached when analysed on an intent to treat basis, but did achieve statistical significance on per protocol data analysis.

Celltech has sought input from gastroenterology clinical opinion leaders with regard to the management of Crohn's disease by anti-TNF $\alpha$  drugs. It has been advised that their acute use, to control

# Operational Review

continued

disease flare, followed by cessation of use until required to treat a further episode of flare, would be a desirable profile. The results obtained with CDP 571 suggest that it is potentially well suited for such episodic treatment, as evidenced by the significant efficacy observed at the 2- and 4-week endpoints, combined with its excellent safety profile. Importantly, very low immunogenicity was observed on repeated dosing.

Celltech has also conducted a pilot open label study in patients who are hypersensitive to infliximab, which showed that CDP 571 is well tolerated and demonstrated encouraging efficacy in relation to acute endpoints in these patients.

Celltech intends to seek guidance from US and European regulatory authorities with regard to the database likely to be required for CDP 571 marketing approval for acute treatment of active Crohn's disease, and for its ongoing clinical management on a periodic, as-needed basis.

CDP 571 is partnered with Biogen, under an equal profit sharing arrangement. Biogen and Celltech intend to review the collaboration following the discussions with regulatory authorities.

## **PDE4 inhibitors**

Phosphodiesterase 4 (PDE4) is a key mediator of underlying inflammation in a number of diseases, including respiratory disorders such as asthma and chronic obstructive pulmonary disorder (COPD). Antagonism of PDE4 by a small molecule orally-active product represents a potentially important therapeutic advance in the treatment of these diseases.

Merck continues to progress a novel, potent once-daily PDE4 inhibitor, which arose from their collaboration with Celltech, in Phase II studies for the treatment of asthma and COPD. Under the terms of the collaboration Celltech will receive progress-related milestone payments, and royalties on worldwide product sales. Celltech also has an option to obtain a share of future profits, through a contribution to Phase III development costs.

Separately, Schering-Plough has notified Celltech that they intend to discontinue development of their PDE4 inhibitor SCH 351591, which was in Phase I studies.

## **SCH 55700**

Schering-Plough has informed Celltech that, following the results of a large Phase II study of SCH 55700, a humanised anti-interleukin 5 antibody, in moderate-severe asthma, they do not intend to pursue development of SCH 55700 in this indication, since the marked and sustained suppression of eosinophils which was observed did not correlate with a clinically useful reduction in asthma symptoms.

## **CDP 860**

CDP 860 is a PEGylated humanised antibody fragment targeted against the beta-receptor for Platelet Derived Growth Factor (PDGF). Recent published research has highlighted the potential for inhibition of the PDGF $\beta$  receptor as a novel approach for the treatment of cancer. CDP 860 will shortly enter an initial Phase II study to determine whether the drug is able to selectively enhance tumour uptake of a standard chemotherapy regimen. The results from this study are expected during 2003.

Celltech retains full commercial rights to CDP 860.

## **BMS 275291**

Bristol-Myers Squibb continues to evaluate this selective matrix metalloproteinase inhibitor in a large Phase II/III trial in

non-small cell lung cancer, which is expected to be completed during 2003.

Celltech will receive further substantial milestone payments and royalties, should the product be successfully commercialised.

## **Early stage pipeline**

There have been continuing advances with novel early-stage development and research programmes. Two PEGylated antibody fragment candidates, CDP 484 for arthritis and CDP 791 for cancer, were entered into preclinical development in late 2001. Both these products are expected to enter Phase I clinical studies in the first half of 2003.

A further product candidate, CDP 323, has recently entered preclinical development. This product is a novel, orally-active small molecule, which exhibits potent activity in anti-inflammatory and immunomodulatory models. It acts as a selective, high affinity antagonist of the integrin VLA4, a validated mechanism which has potential in a number of diseases, including rheumatoid arthritis, inflammatory bowel disease and multiple sclerosis.

Excellent progress is also being made with Celltech's research pipeline, in particular with the anti-sclerostin programme for osteoporosis, recently partnered with Amgen, which possesses considerable expertise in bone biology. Other discovery opportunities, focused in Celltech's core areas of immune/inflammatory disorders and cancer, are continuing to progress well.

## **PHARMACEUTICALS**

Celltech's pharmaceuticals business performs two key strategic roles, firstly to provide sustained operational cashflow to finance the development of key pipeline products, and secondly to provide a platform for the future specialised marketing of some of those products.

Substantial progress has been made in the last six months in refocusing Celltech's pharmaceutical operations. The acquisition from Pharmacia of US and European promotional rights to Dipentum, announced in July 2002, will enable Celltech to accelerate the transformation of the business into one that is able to support marketing of its pipeline products to specialist prescribing audiences. This agreement gives Celltech exclusive sales, marketing and distribution rights for the product in the US, and also provides Celltech with an option to acquire all rights to the product in the US and rest of world excluding Europe in January 2005. Celltech has made an initial payment to Pharmacia of \$6 million in respect of these rights, and may make additional payments of up to \$12 million, should it elect to exercise its option. Celltech has also recently completed the purchase of European rights for Dipentum, involving total payments of \$20 million, to be made during 2002 and 2003. Celltech will establish a gastroenterology sales force in the US, initially with 30 representatives to market Dipentum. In Europe, a part of each sales force will be refocused from their current primary care area to address specialist gastroenterology audiences. The overall size of the European sales organisation will remain broadly similar to its current level. It is intended that these sales forces will in the future market CDP 571 and CDP 870 in Crohn's disease. Celltech will continue to evaluate further small product opportunities that can be marketed by its specialist sales forces.

## Sales of major products and royalty income

	2002 £ million	2001* £ million	% change
Tussionex	24.7	25.2	-2
Zaroxolyn	15.7	14.4	+9
Metadate CD	11.4	5.0	+129
Generic methylphenidate	7.5	9.2	-18
Delsym	4.1	2.3	+79
Ionamin	4.0	2.8	+43
Perenterol	3.9	–	na
Coracten	2.8	2.6	+8
Pediapred	2.3	3.7	-38
Semprex-D	1.7	5.2	-67
Other	38.7	36.3	+7
<b>Total product sales</b>	<b>116.8</b>	<b>106.7</b>	<b>+10</b>
Antibody engineering	26.3	16.4	+60
Pertactin	5.1	3.7	+38
Asacol	4.2	4.9	-14
Mylotarg	1.7	2.1	-19
Other	1.5	0.4	+276
<b>Total royalties</b>	<b>38.8</b>	<b>27.5</b>	<b>+41</b>
<b>Total sales</b>	<b>155.6</b>	<b>134.2</b>	<b>+16</b>
Effect of exchange differences	–	0.4	n/a
<b>As reported</b>	<b>155.6</b>	<b>134.6</b>	<b>+16</b>

\* At constant exchange rates

The Thiemann organisation, now renamed Celltech, which provides the Group with a substantial sales and marketing platform in Germany, has been successfully integrated into the pharmaceutical business, and Celltech is currently exploring a number of options to facilitate sales force coverage of the remaining major European markets.

As part of its overall strategy of refocusing its sales and marketing capabilities towards specialist audiences, Celltech also recently announced a restructuring of its US general sales force. The US sales force was expanded during 2001 in order to support the launch of Metadate CD. Following the conclusion of the immediate post-launch promotional effort, and an appraisal of the in-market performance of Metadate CD, Celltech reduced the US general sales force, from 350 to 170 representatives, during the third quarter of 2002. The restructured sales force will continue to detail Celltech's cough/cold range of products and Zaroxolyn, and will support a more focused marketing campaign with Metadate CD.

The existing pharmaceutical business is providing Celltech with a stable revenue base, with an overall increase of 10% in first half product sales. Excluding the impact of the Thiemann acquisition in September 2001, product sales were slightly lower, at £104.3 million (2001: £106.7 million). This was due mainly to significant US distributor restocking during H1 2001, following planned inventory reductions during 2000. Product sales and royalties are reported in the accompanying table at constant exchange rates (CER), although the effect of exchange differences in the first half of 2002 against the corresponding period in 2001 is immaterial. The performances of major products were as follows:

### Cough/cold products

Sales of Celltech's cough/cold range of products, including Tussionex and Delsym, performed solidly in the first half of 2002, notwithstanding a weak cough/cold season in the US. Tussionex, a prescription-only anti-tussive agent with a 12-hour action, showed

steady sales at £24.7 million for the first half (2001: £25.2 million). Delsym, an over the counter cough medicine, increased sales to £4.1 million (2001: £2.3 million).

Celltech is developing a further product, Codeprex, using its Pennkinetic sustained release technology, which is a 12-hour duration codeine-based product. A US NDA was submitted to the FDA in May 2001, and an approvable letter was received in February 2002. Celltech is currently addressing the points made in the approvable letter and it is anticipated that the product will be launched during 2003.

### Zaroxolyn

This diuretic for the treatment of congestive heart failure increased sales by 9% to £15.7 million (2001: £14.4 million).

### Methylphenidate products

Sales of generic methylphenidate products, for the treatment of attention deficit hyperactivity disorder (ADHD), continue to decline as patients switch to newer once-daily treatments. Celltech's generic methylphenidate products declined in line with the overall market, by 18% to £7.5 million (2001: £9.2 million). This decline is expected to continue in line with the trend towards prescription of once-daily formulations.

Metadate CD, Celltech's once-daily treatment for ADHD, was launched in May 2001 and has achieved over 11% of prescriptions in the once-daily methylphenidate market, and over 3% market share of the overall ADHD market. Sales of Metadate CD for the first half of 2002 were £11.4 million (2001: £5 million). Following the sales force restructuring detailed above, Celltech expects Metadate CD to make a significant positive financial contribution to the business, although it is not anticipated that the product will grow substantially from its current level.

## Financial Results

The financial results for the first half of 2002 reflect a strong underlying performance by the business of the Group, with an increase in operating profit before other income of 36%. The operating expenses for the first half of 2002 incorporate an increase in insurance costs in the period of £2.7 million following the dramatic changes in the insurance market since September 2001. Excluding this charge, operating profit before other income would have shown an increase of 73%.

### Operational profit and loss account for Celltech Group for six months to 30 June 2002

	2002 £ million	2001 £ million	% change
<b>Sales</b>	<b>155.6</b>	134.6	+16
Cost of sales	(48.8)	(41.9)	+16
<b>Gross profit</b>	<b>106.8</b>	92.7	+14
Research and development	(45.1)	(41.7)	+8
Sales, marketing and distribution	(38.8)	(31.0)	+25
Corporate and general administration	(12.8)	(12.6)	+2
<b>Total expenses</b>	<b>(96.7)</b>	(85.3)	+13
<b>Operating profit before other income</b>	<b>10.1</b>	7.4	+36
Other income	0.9	17.8	nm
<b>Operating income: pre goodwill charges</b>	<b>11.0</b>	25.2	nm
Interest	0.9	2.2	
<b>Net profit: pre goodwill charges</b>	<b>11.9</b>	27.4	

Total sales and royalties grew by 16% to £155.6 million, with product sales increasing by 10% to £116.8 million. The performance of key products is detailed in the operational review. Royalty income continued to show strong growth, driven predominately by a 60% increase in antibody engineering revenues, reflecting the strong growth in the underlying products.

Research and development expenses increased to £45.1 million (2001: £41.7 million), net of £2.9 million deferred funding for CDP 870 development in Crohn's disease from Pharmacia (2001: £4.6 million). This investment is expected to increase in the second half of 2002 as Celltech prepares for the entry into clinical development of several new pipeline products.

Sales and marketing expenses of £38.8 million (2001: £31 million) reflected the full effect of the US sales force expansion undertaken during 2001, in addition to the impact of the Thiemann acquisition. Following the reduction in the US general sales force announced in July 2002, these expenses will reduce significantly in the second half of 2002, partly offset by a charge related to the restructuring, which will be included within operating expenses.

Celltech, like many other companies, has been significantly impacted by the global increase in insurance premiums, which was exacerbated by the events of 11 September 2001. Premiums in the insurance year to September 2002 have increased by 57% to £6.1 million. This situation would have been considerably more adverse had a three year agreement not been in place for certain layers of product liability insurance. It is estimated that this agreement will have saved Celltech some £4 million of premiums for each of the years 2002 and 2003.

As a consequence of these onerous changes in the insurance market, which has continued to harden for the annual renewal of cover to September 2003, and in anticipation of significant further increases in liability premiums in 2003/4, Celltech has formed a subsidiary captive insurance company to underwrite certain areas of risk. An initial charge of £1.5 million has been recorded in the six months to June 2002 and it is anticipated that a similar charge will be required in the second half. A further charge is likely to be required in 2003 to reflect the risks underwritten by this captive insurance company based on estimates of future incidence. It will initially cover certain product liability risks, but from September 2003 will underwrite broader liability risks, thereby allowing Celltech to reduce the level of premiums paid to external insurers. The charge in 2002 and any charge required in 2003 will impact profits in those years; in the six months to 30 June 2002 insurance costs, which are predominantly included in cost of sales, have consequently increased by £2.7 million compared to the equivalent period last year. The effect of this charge for the captive insurance subsidiary will be to decrease earnings per share for the year from previous market expectations by approximately 1.0p.

Corporate and general administration expenses were tightly controlled during 2002, with a 2% increase from the first half of 2001.

Notwithstanding the increase in operating expenses detailed above, operating profit, excluding other operating income, increased by 36% to £10.1 million. Overall operating profit was £11 million (2001: £25.2 million, including a £17.5 million up front payment from Pharmacia in respect of the CDP 870 collaboration), with net profit before tax and goodwill

amortisation amounting to £11.9 million. Earnings per share before goodwill amortisation were 3.6p.

Other operating income includes milestone income of £1.6 million relating predominately to Celltech's collaborations with Biogen, Abbott and Amgen, less a £0.7 million write down required in respect of the Group's small portfolio of equity investments.

The cash position of the Group remains strong, with a gross cash position of £98.8 million as at 30 June 2002, partially offset by \$50 million (£32.6 million) senior loan notes repayable December 2003. In addition, the Group has committed undrawn borrowing facilities of £80 million. The Group believes its finances will be adequate for currently envisaged operational requirements and small technology or infrastructure acquisitions.

Interest income for the six months to June 2002 was lower than the equivalent period in 2001. This was attributable to lower interest rates during the period on cash balances, particularly in the US, in addition to a lower average cash balance.

The effective tax rate for the six months to June 2002 was 16% (2001: 17%). Due to the availability of tax losses, Celltech expects to maintain a tax rate of not more than 20% for at least three years, based upon the current fiscal environment in the US and UK.

# Consolidated Profit and Loss Account

for the six months ended 30 June 2002

	Notes	Six months ended 30 June			6 months ended 30 June 2001 Total £ million*	Year ended 31 December 2001 Total £ million
		2002 Before goodwill £ million	2002 Goodwill £ million	2002 Total £ million		
<b>Turnover</b>		<b>155.6</b>	–	<b>155.6</b>	134.6	303.1
Cost of sales		<b>(48.8)</b>	–	<b>(48.8)</b>	(41.9)	(83.5)
<b>Gross profit</b>		<b>106.8</b>	–	<b>106.8</b>	92.7	219.6
<b>Expenses:</b>						
Research and development		<b>(45.1)</b>	–	<b>(45.1)</b>	(41.7)	(90.7)
Selling, marketing and distribution expenses		<b>(38.8)</b>	–	<b>(38.8)</b>	(31.0)	(78.6)
General administrative expenses excluding integration items and goodwill charges		<b>(12.8)</b>	–	<b>(12.8)</b>	(12.6)	(24.9)
Integration costs		–	–	–	–	(7.8)
Goodwill amortisation		–	<b>(46.8)</b>	<b>(46.8)</b>	(43.1)	(92.6)
<b>Total expenses</b>		<b>(96.7)</b>	<b>(46.8)</b>	<b>(143.5)</b>	(128.4)	(294.6)
<b>Operating profit/(loss) before other income</b>		<b>10.1</b>	<b>(46.8)</b>	<b>(36.7)</b>	(35.7)	(75.0)
Other operating income	2	<b>0.9</b>	–	<b>0.9</b>	17.8	18.8
<b>Operating profit/(loss)</b>		<b>11.0</b>	<b>(46.8)</b>	<b>(35.8)</b>	(17.9)	(56.2)
Net interest receivable		<b>0.9</b>	–	<b>0.9</b>	2.2	3.6
<b>Profit/(loss) on ordinary activities before taxation</b>		<b>11.9</b>	<b>(46.8)</b>	<b>(34.9)</b>	(15.7)	(52.6)
Tax on profit/(loss) on ordinary activities	3	<b>(1.9)</b>	<b>2.5</b>	<b>0.6</b>	(2.0)	(2.9)
<b>Profit/(loss) on ordinary activities after taxation</b>		<b>10.0</b>	<b>(44.3)</b>	<b>(34.3)</b>	(17.7)	(55.5)
Accrual for unpaid preference share dividend		<b>(0.1)</b>	–	<b>(0.1)</b>	(0.1)	(0.2)
<b>Transfer to/(from) profit and loss reserve</b>		<b>9.9</b>	<b>(44.3)</b>	<b>(34.4)</b>	(17.8)	(55.7)
<b>Basic earnings per share</b>	4	<b>3.6p</b>		<b>(12.5)p</b>	(6.5)p	(20.3)p
<b>Diluted earnings per share</b>	4	<b>3.6p</b>		<b>(12.5)p</b>	(6.5)p	(20.3)p

The pro-forma results of the Group for the comparative periods are presented on page 16 to this interim statement

\* Restated for FRS 19, see note 3.

# Consolidated Balance Sheet

as at 30 June 2002

	Notes	As at 30 June 2002 £ million	As at 30 June 2001 £ million*	As at 31 December 2001 £ million
<b>Fixed assets</b>				
Intangible assets		<b>452.8</b>	500.5	498.3
Tangible assets		<b>98.8</b>	99.3	103.5
Investments	6	<b>38.3</b>	31.1	38.3
		<b>589.9</b>	630.9	640.1
<b>Current assets</b>				
Stocks		<b>48.3</b>	41.1	45.7
Debtors		<b>56.5</b>	72.1	82.7
Equity investments	7	<b>0.5</b>	12.0	2.0
Cash and liquid resources		<b>98.8</b>	123.3	90.4
		<b>204.1</b>	248.5	220.8
<b>Creditors: amounts due within one year</b>	8	<b>(96.8)</b>	(107.9)	(119.2)
Net current assets		<b>107.3</b>	140.6	101.6
<b>Total assets less current liabilities</b>		<b>697.2</b>	771.5	741.7
<b>Creditors: amounts due after more than one year</b>	8	<b>(43.7)</b>	(43.8)	(45.6)
<b>Provisions for liabilities and charges</b>	9	<b>(71.3)</b>	(69.7)	(76.9)
<b>Net assets</b>		<b>582.2</b>	658.0	619.2
<b>Capital and reserves</b>				
Called up share capital	10	<b>141.2</b>	140.8	141.0
Share premium account		<b>83.0</b>	80.5	81.6
Other reserves		<b>621.3</b>	621.0	621.2
Profit and loss account		<b>(263.3)</b>	(184.3)	(224.6)
<b>Shareholders' funds</b>		<b>582.2</b>	658.0	619.2

\* Restated for FRS 19, see note 3.

# Consolidated Cash Flow Statement

for the six months ended 30 June 2002

	Notes	6 months ended 30 June 2002 £ million	6 months ended 30 June 2001 £ million	Year ended 31 December 2001 £ million
<b>Cash inflow from operating activities</b>	a	<b>16.5</b>	19.7	38.7
<b>Returns on investments and servicing of finance</b>				
Net interest received		–	1.7	2.5
		<b>16.5</b>	21.4	41.2
<b>Taxation paid</b>		<b>(0.9)</b>	(3.0)	(4.3)
<b>Taxation refunded</b>		<b>0.2</b>	13.0	13.0
<b>Taxation (outflow)/inflow</b>		<b>(0.7)</b>	10.0	8.7
<b>Capital expenditure and financial investment</b>				
Payments made to acquire fixed assets		<b>(6.2)</b>	(5.4)	(16.1)
Proceeds from sale of fixed assets		<b>0.2</b>	0.4	1.1
Proceeds from disposal of investments		<b>0.8</b>	3.0	11.5
Payments made to acquire intangible fixed assets		<b>(1.3)</b>	–	(11.8)
Payments made to acquire fixed asset investments		–	–	(7.0)
Other		–	0.2	–
<b>Net cash outflow from capital expenditure and financial investment</b>		<b>(6.5)</b>	(1.8)	(22.3)
<b>Disposals and acquisitions of businesses</b>				
Deferred consideration		–	(1.5)	(1.5)
Acquisition of Thiemann, less cash acquired		–	–	(26.2)
Net proceeds from European asset sales		–	1.5	3.0
Cash funding in respect of businesses held for resale		–	(3.4)	(4.1)
Proceeds from sale of business held for resale		–	15.3	15.3
<b>Net cash inflow/(outflow) from disposals and acquisitions of businesses</b>		–	11.9	(13.5)
<b>Net cash inflow before management of liquid resources and financing</b>		<b>9.3</b>	41.5	14.1
<b>Management of liquid resources</b>		<b>11.7</b>	(14.6)	(7.0)
<b>Financing</b>				
Receipts from issuing shares		<b>1.6</b>	3.7	5.0
Capital element of finance lease rental payments		<b>(0.2)</b>	(0.2)	(1.3)
Repayment of loan of acquired subsidiaries		–	–	(5.4)
<b>Net cash inflow/(outflow) from financing</b>		<b>1.4</b>	3.5	(1.7)
<b>Increase in cash in the period</b>	b	<b>22.4</b>	30.4	5.4

# Notes to the Consolidated Cash Flow Statement

for the six months ended 30 June 2002

## (a) Net cash inflow from operating activities

	6 months ended 30 June 2002 £ million	6 months ended 30 June 2001 £ million	Year ended 31 December 2001 £ million
Operating loss	(35.8)	(17.9)	(56.2)
Integration	–	–	7.8
Operating loss before integration costs	(35.8)	(17.9)	(48.4)
Amortisation	46.8	43.1	92.6
Depreciation	7.0	6.6	12.6
Increase in stocks	(4.0)	(2.3)	(5.5)
Decrease/(increase) in debtors	25.7	(7.9)	(26.2)
(Decrease)/increase in creditors	(21.0)	1.7	20.5
<b>Net cash inflow from operating activities before integration costs</b>	<b>18.7</b>	<b>23.3</b>	<b>45.6</b>
Outflow relating to integration costs	(2.2)	(3.6)	(6.9)
<b>Net cash inflow from operating activities</b>	<b>16.5</b>	<b>19.7</b>	<b>38.7</b>

## (b) Reconciliation of net cash flow to movement in net funds

	6 months ended 30 June 2002 £ million	6 months ended 30 June 2001 £ million	Year ended 31 December 2001 £ million
Increase in cash in the period	22.4	30.4	5.4
Management of liquid resources	(11.7)	14.6	7.0
Loans and finance leases acquired with subsidiaries	–	–	(5.4)
Loans and finance leases disposed with businesses sold	–	0.3	0.3
Decrease in long term debt and finance leases	0.2	0.2	6.7
Change in net funds	10.9	45.5	14.0
Exchange differences	(0.4)	0.1	0.5
Movements in the period	10.5	45.6	14.5
Opening net funds	53.1	38.6	38.6
<b>Closing net funds</b>	<b>63.6</b>	<b>84.2</b>	<b>53.1</b>

## (c) Analysis of net funds

	At 31 December 2001 £ million	Cash flow £ million	Exchange Movements £ million	At 30 June 2002 £ million
Cash	36.3	22.4	(2.3)	56.4
Liquid resources	54.1	(11.7)	–	42.4
Finance leases	(2.8)	0.2	–	(2.6)
Loans	(34.5)	–	1.9	(32.6)
	53.1	10.9	(0.4)	63.6

# Consolidated Statement of Total Recognised Gains and Losses

for the six months ended 30 June 2002

	<b>6 months ended 30 June 2002 £ million</b>	6 months ended 30 June 2001 £ million*	Year ended 31 December 2001 £ million
Consolidated loss for the period/year	<b>(34.3)</b>	(17.7)	(55.5)
Exchange adjustments on retranslation of net assets of subsidiary undertaking	<b>(4.4)</b>	2.6	0.3
Total recognised losses for the period/year	<b>(38.7)</b>	(15.1)	(55.2)
Prior year tax adjustment	–	5.0	5.0
<b>Total losses recognised since previous annual report</b>	<b>(38.7)</b>	(10.1)	(50.2)

\* Restated for FRS 19, see note 3

## Reconciliation of Movements in Shareholders' Funds

for the six months ended 30 June 2002

	<b>6 months ended 30 June 2002 £ million</b>	6 months ended 30 June 2001 £ million	Year ended 31 December 2001 £ million
Shareholders' funds at start of period	<b>619.2</b>	669.4*	669.4*
Total recognised losses for the period	<b>(38.7)</b>	(15.1)	(55.2)
Share capital issued (net of expenses)	<b>1.7</b>	3.7	5.0
Net movement in shareholders' funds	<b>(37.0)</b>	(11.4)	(50.2)
<b>Shareholders' funds at end of period</b>	<b>582.2</b>	658.0	619.2

\* Originally £664.4 million before prior year adjustment of £5 million

# Notes to the Financial Statements

for the six months ended 30 June 2002

## 1 Basis of preparation

- (a) The financial information contained in this half year report has been prepared on the basis of the accounting policies set out in the Group's audited accounts for the year ended 31 December 2001.
- (b) The half year report was approved by the Board of Directors on 16 September 2002. The financial information for the six months ended 30 June 2002 is unaudited, but has been reviewed in accordance with Auditing Practices Board guidance by KPMG Audit Plc whose report is included on page 15.
- (c) The comparative figures for the financial year ended 31 December 2001 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Company's auditors and delivered to the registrar of companies. The report of the auditors was unqualified and did not contain a statement under section 237(2) or (3) of the Companies Act 1985.
- (d) The Group does not publish financial information for its half year results under US generally accepted accounting principles.

## 2 Other operating income

Other operating income is in respect of milestones of £1.6 million less a £0.7 million write off required in respect of the Group's equity investments (see note 7). The 30 June 2001 income of £17.8 million included £17.5 million of a non-refundable, non creditable payment from Pharmacia in respect of CDP 870.

## 3 Taxation

Taxation has been provided at a rate approximate to that estimated to apply for the 12 months to 31 December 2002. The charge includes federal and state taxes payable in the US and other overseas territories.

The Group adopted FRS 19 'Deferred Taxation' for the year ended 31 December 2001. The standard requires that a full provision is recognised for deferred tax liabilities including those in respect of goodwill on which tax benefits are obtained.

The adoption of this standard resulted in the recognition of an additional £15.3 million deferred tax liability on the acquisition of Medeva along with a £15.3 million goodwill asset.

The deferred tax liability will reverse over a three year period from the date Medeva was acquired, 26 January 2000. Consequently £5 million has now been taken as a credit in 2000 and the half year tax charge as presented last year has been credited with £2.6 million. The tax credit for the six months ended 30 June 2002 is £2.5 million.

## 4 Earnings per share

### Basic

The calculation of earnings per share is based on the loss after taxation for the six months of £34.4 million (2001: loss £17.8 million) and the weighted average number of ordinary shares in issue of 275.2 million (2001: 274.3 million). In addition the basic earnings per share before goodwill amortisation, based upon a profit of £9.9 million, is provided.

### Diluted

The diluted EPS for the six months ended 30 June 2002, before goodwill amortisation, calculated in accordance with FRS 14, is 3.6p. The numerator is £10 million which excludes the goodwill charge and related tax of £44.3 million. The weighted average number of shares used for the dilution calculation is 278.2 million. No other diluted EPS numbers have been calculated, since the effect of an increase in ordinary shares would be anti-dilutive.

## 5 Exchange rates

The Group uses the average exchange rates prevailing during the period to translate the results of overseas subsidiary undertakings and the period-end rates to translate the net assets of those undertakings. The currency which most influences the Group's results is the US dollar and the relevant exchange rates are as follows:

US\$/Sterling	30 June 2002	30 June 2001
Period average	1.45	1.44
Period end	1.53	1.42

## 6 Fixed asset investments

Investments include two five year convertible loan notes issued by PowderJect Pharmaceuticals plc, one for £25 million issued on 2 October 2000 and a second for £6 million issued on 30 March 2001. These were issued at par, pay interest half yearly at 4% per annum and have a cash yield to maturity of 7%. Interest is being accrued and credited in the profit and loss account at the 7% rate. Alternatively the loan notes convert into PowderJect ordinary shares at a price of £7.19.

# Notes to the Financial Statements

continued

## 7 Equity investments

Equity investments are valued at the lower of cost and net realisable value. As at 30 June 2002 equity investments comprised an investment in Targeted Genetics Corporation of 692,500 shares with a market value of £0.5 million.

207,500 shares in Matrix Pharmaceuticals Inc. and 244,500 shares in Targeted Genetics Corporation were disposed of in the six months to 30 June 2002. This disposal generated cash of £0.8 million. In total a £0.7 million charge has been recorded within Other income to take account of the disposals made and to write down the remaining holding to market value.

## 8 Creditors

At 30 June 2002, the Group had recorded the following liabilities:

	Current As at 30 June 2002 £ million	Long-term As at 30 June 2002 £ million	Current As at 31 December 2001 £ million	Long-term As at 31 December 2001 £ million
Loan	–	32.6	–	34.5
Trade creditors, accruals and other	92.2	3.8	116.0	4.0
Corporation taxes	3.5	–	1.7	–
Deferred consideration	–	5.8	–	5.8
Finance leases	1.1	1.5	1.5	1.3
	<b>96.8</b>	<b>43.7</b>	119.2	45.6

## 9 Provisions for liabilities and charges

	Deferred tax £ million	Integration £ million	Non-Insured Claims £ million	Total £ million
Balance at 1 January 2002	65.5	11.4	–	76.9
(Utilisation)/movement in period	(4.9)	(2.2)	1.5	(5.6)
<b>At 30 June 2002</b>	<b>60.6</b>	<b>9.2</b>	<b>1.5</b>	<b>71.3</b>

## 10 Called up share capital

There were 275.4 million Ordinary shares of 50p each and 3.5 million convertible redeemable cumulative preference shares of £1 each in issue at 30 June 2002.

## 11 Contingent liabilities

Group contingent liabilities in relation to litigation concerning lonamin and self insurance in relation to methylphenidate were disclosed in the financial statements for the year ended 31 December 2001. Since the publication of the financial statements for the year ended 31 December 2001, the significant changes to these matters have been as follows:

### (a) Lonamin

Although a small number of additional cases have been brought since the publication of the financial statements on 11 March 2002, the number of cases dismissed and pending dismissal has increased at a higher rate. The significant changes in this litigation since March 2002 have been as follows (all numbers approximate): an additional 2,750 have been dismissed without payment of any sums by way of damages or costs to third parties (bringing the total dismissed without liability to 5,500) and dismissals of approximately 200 are pending. This leaves a total of approximately 300 cases that have neither been dismissed nor are pending dismissal as of August 2002 (compared to 650 such cases at 11 March 2002).

### (b) Self Insurance

Since 20 September 2001 the Group has been required to increase its levels of self insurance in respect of methylphenidate. Accordingly the Group has decided to retain a level of self insurance of up to £10 million, to establish its own captive insurer and to enter into alternative financing arrangements in respect of an additional £40 million. No methylphenidate claims have been received since 20 September 2001.

In respect of the captive insurer the Group has recognised a provision of £1.5 million for exposures on potential non-insured claims in existence as at 30 June 2002.

# Independent Review Report by KPMG Audit plc to Celltech Group plc

## **Introduction**

We have been instructed by the company to review the financial information set out on pages 8 to 14 and we have read the other information contained in the interim report and considered whether it contains any apparent misstatements or material inconsistencies with the financial information.

## **Directors' responsibilities**

The interim report, including the financial information contained therein, is the responsibility of, and has been approved by, the directors. The Listing Rules of the Financial Services Authority require that the accounting policies and presentation applied to the interim figures should be consistent with those applied in preparing the preceding annual accounts except where they are to be changed in the next annual accounts in which case any changes, and the reasons for them, are to be disclosed.

## **Review work performed**

We conducted our review in accordance with guidance contained in Bulletin 1999/4: Review of interim financial information issued by the Auditing Practices Board. A review consists principally of making enquiries of group management and applying analytical procedures to the financial information and underlying financial data and, based thereon, assessing whether the accounting policies and presentation have been consistently applied unless otherwise disclosed. A review is substantially less in scope than an audit performed in accordance with Auditing Standards and therefore provides a lower level of assurance than an audit. Accordingly we do not express an audit opinion on the financial information.

## **Review conclusion**

On the basis of our review we are not aware of any material modifications that should be made to the financial information as presented for the six months ended 30 June 2002.

KPMG Audit Plc  
Chartered Accountants  
London  
16 September 2002

## Pro-forma Financial Statements for Celltech Group

Celltech acquired Medeva on 26 January 2000. The pro-forma financial statements of Celltech Group set out below detail the performance as though the entities had been merged for the entire period, excluding restructuring costs and goodwill amortisation.

	6 months ended 30 June 2002 £ million	6 months ended 30 June 2001 £ million	6 months ended 30 June 2000 £ million	Year ended 31 December 2001 £ million
<b>Turnover</b>	<b>155.6</b>	134.6	114.5	303.1
Cost of sales	<b>(48.8)</b>	(41.9)	(33.7)	(83.5)
<b>Gross profit</b>	<b>106.8</b>	92.7	80.8	219.6
Investment in research and development	<b>(45.1)</b>	(41.7)	(35.9)	(90.7)
Sales, marketing and distribution	<b>(38.8)</b>	(31.0)	(25.0)	(78.6)
Corporate and general administrative	<b>(12.8)</b>	(12.6)	(14.6)	(24.9)
<b>Total expenses</b>	<b>(96.7)</b>	(85.3)	(75.5)	(194.2)
<b>Operating profit before other income</b>	<b>10.1</b>	7.4	5.3	25.4
Other operating income	<b>0.9</b>	17.8	4.1	18.8
<b>Operating profit</b>	<b>11.0</b>	25.2	9.4	44.2
Net interest receivable	<b>0.9</b>	2.2	0.7	3.6
<b>Profit before tax</b>	<b>11.9</b>	27.4	10.1	47.8
Taxation	<b>(1.9)</b>	(4.6)	(1.4)	(8.1)
<b>Profit after tax</b>	<b>10.0</b>	22.8	8.7	39.7
<b>Basic Earnings per share</b>	<b>3.6p</b>	8.3p	3.4p	14.4p

# Company Information

## **Celltech Group plc**

208 Bath Road  
Slough  
Berkshire SL1 3WE  
United Kingdom

Telephone: (44) (0) 1753 534655

Fax: (44) (0) 1753 536632

Website: [www.celltechgroup.com](http://www.celltechgroup.com)

Registered Number: 2159282

Celltech's shares are listed on the London Stock Exchange under symbol "CCH" and, in the form of ADS's, on the New York Stock Exchange under the symbol "CLL". There are two ordinary shares to one ADS.

## **Company Advisors**

Auditor:	KPMG Audit Plc
Corporate Relations:	Brunswick
Financial Advisors:	J P Morgan
Solicitors:	Allen & Overy
Stockbrokers:	Cazenove

