CeNeS reports 2001 Interim Results and Planned Restructuring

Cambridge, UK October 1st 2001 – CeNeS Pharmaceuticals plc (LSE:CEN.L) today announced its unaudited interim financial results for the six months ended 30 June 2001 and a planned restructuring. CeNeS also announced further positive phase II results for its leading pain candidate M6G and an extension to the M6G/Medipad business venture with Elan. At the same time Elan has also agreed to subscribe for a total of 9.1m CeNeS shares at 16.5 pence raising a total of $2.2m.

Planned restructuring

As a result of the difficult market conditions and exceptional global economic circumstances leading to the increased uncertainty over the ability of the company to raise additional capital over the next 12 months, the board has already begun a restructuring programme to preserve shareholder value.

It is planned that in the short term CeNeS will focus efforts on the sales and marketing of pharmaceuticals through its UK hospital sales force and the development and commercialization of its lead development candidate morphine-6-glucuronide (M6G). It is also planned that certain non-core research and development projects will be placed on hold until further funding is available.

Board changes

As part of this restructuring programme is implemented, the board will be reconfigured. Alan Goodman will continue as Chairman, Neil Clark will act as Chief Operating Officer and Finance Director, John Buckle will become Pharmaceutical Marketing and Sales Director and Ron Irwin will remain as non-executive director. Tim Wright, who heads Elan Pharmaceutical's European operation will become Elan's nominated non–executive director. It is planned that the executive directors Daniel Roach (Chief Executive) and Martyn Collett (Commercial Director) will step down as will the remaining non-executive directors namely, David Needham, Mike Redmond, Dan Welch, Harry Wilcox and Paul O'Brien.

Interim results - Operational Update

- Leading pain candidate M6G reports further positive phase II results – it is planned that M6G will enter phase III in 2002.
- Pain portfolio expanded with commencement of business venture with Elan combining M6G with Elan's drug delivery technology. Elan became a 4% shareholder.
- Elan and CeNeS today announce they have agreed to expand scope of business venture and CeNeS agreed to assign additional rights to M6G for the treatment of pain. Elan and CeNeS also agreed to increase funds available for the business venture's clinical development program by $2m to $10m.
- Elan also agrees to subscribe for a second tranche of shares raising $2.2m, which may be used by CeNeS for general corporate purposes. Upon closing, Elan will hold 9.9% of CeNeS shares in issue. Elan will also receive warrants over 914,988 CeNeS ordinary shares at an exercise price of 31.6p.
- Pharmaceutical products division established to timetable – UK hospital sales force recruited and new product Xefo launched as planned in Q3 2001.
- Further progress in clinical development portfolio including :-
  - second phase II sleep trial completed
  - phase II neuropathic pain trial started
  - opioid spray progresses through phase I programme.
- Ion channel and pain research groups integrated with Cambridge NeuroScience:-
  - $0.9m SBIR grant awarded for ion channel research in USA.
- Implementation of restructuring programme.
- Cognition division spin-out strategy initiated in September 2001.

Financial update

- Recurring revenues (excluding out-licensing) increased to £2.7m in H1 2001 (from £1.1m in H1 2000).
- Net loss before licence write-offs and intangible asset amortisation increased to £7.1m in H1 2001 from £2.8m in H1 2000.
- Cash and liquid resources at June 30 2001 of £4.7m.
- Restructuring programme commenced.

Commenting, Chairman Alan Goodman said:

" Under our restructuring programme we are progressing with the implementation of our strategy to build a specialised pharmaceutical company focused on the research, development and sale of CNS and pain pharmaceutical products. The year to date has seen us launch our first new UK product through our new hospital sales force following the successful set up of our pharmaceuticals division in late 2000.

The clinical pipeline that will feed products into the sales division has also made progress and we are excited by the potential of our lead candidate for the treatment of pain, M6G, and our extended collaboration with Elan on this project.

Following the implementation of the restructuring we plan to have sufficient funding to take M6G through phase III trials in 2002/2003 and to have funds until the end of 2003."

About CeNeS
CeNeS is a biopharmaceutical company specialising in the development and commercialisation of drugs for CNS disorders and pain control. The company currently markets four products, and has a research and development pipeline targeting pain, stroke, schizophrenia, addiction, sleep disorders, Parkinson's disease and multiple sclerosis. CeNeS also has a cognitive division, which markets CANTAB, a computerised cognitive test, and a drug delivery division. In addition it has a range of platform technologies including AutoPatch™ its unique automated patch clamping technology. The group has around 130 staff working from modern research and manufacturing facilities in Cambridge (England), Irvine (Scotland) and Boston (USA).

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Chairman's statement

Overview The first half of 2001 has seen significant progress in developing the core focus of the business that is the research, development and sale of central nervous system (CNS) and pain pharmaceutical products. Significantly there has been progress in the key drivers of the business, namely the establishment and expansion of our pharmaceutical sales division, the successful M6G phase II results and the announcement and start of the M6G business venture with Elan.

We remain committed to establishing a sustainable revenue stream from the pharmaceutical business that will help fund the research and development of new pain and CNS products. However, as a result of the difficult market conditions and exceptional global economic circumstances leading to the increased uncertainty over the ability of the company to raise additional capital over the next 12 months, the board has already begun a restructuring programme to preserve shareholder value.

It is planned that in the short term CeNeS will focus efforts on the sales and marketing of pharmaceuticals through its UK hospital sales force and the development and commercialization of its lead development candidate morphine-6-glucuronide (M6G). It is also planned that certain non-core research and development projects will be placed on hold until further funding is available. The restructuring plan may therefore result in a reduction in headcount.

Pharmaceuticals division We are pleased to report a significant contribution from our new pharmaceutical sales division in the first half of 2001. We acquired our first products from Glaxo Wellcome in late 2000 and have effected a full transfer of all regulatory distribution and manufacturing processes during the year to date. Having established a new supply chain we are looking forward to receiving the benefit of improved margins in the second half of the year.

In September 2001 we announced the launch of our new pain product, Xefo and the recruitment of a hospital sales force that will assist in active promotion of all our current products. We are well placed to take advantage of further product acquisitions as they become available and are intent on growing this division as a major part of our strategy.

We are also pleased by the progress in the clinical development of our lead pain candidate M6G, which is intended to be launched through our own sales force in 2004.

Clinical development and the announcement of clinical trial results in post-operative pain and sleep

Clinical trial results for M6G – for the treatment of post-operative pain

In January we announced results from clinical trials in over 140 post-operative pain patients show that CeNeS' drug has a competitive edge over morphine by reducing by more than 50% the incidence of nausea and vomiting

Today we announce further positive phase II results for our lead candidate M6G (morphine-6-glucuronide) in post-operative pain. The latest results showed that M6G, a metabolite of morphine, has again shown positive results in a Phase II clinical trial comparing M6G with morphine in the relief of post-operative pain. A total of 18 patients undergoing hip-replacement surgery were studied and M6G doses were escalated in three steps, each of which was compared with a standard dose of morphine. Drugs were administered as intravenous bolus injections followed by use of a Patient Controlled Analgesia (PCA) device for 24 hours post-operatively. The data showed that all doses provided effective analgesia during the 24-hour post-operative period and that all doses were well tolerated. A reduction in pain scores over 24 hours was seen in all groups. After 24 hours there did not appear to be any difference between pain relief provided by any of the M6G dose groups and the standard dose of morphine.

A controlled clinical trial in laproscopy patients has already shown M6G to have a competitive edge over morphine by providing comparable pain relief but with a significant reduction in the incidence of nausea, vomiting and sedation. The results of this latest clinical trial support M6G's ability to provide effective analgesia in the post-operative setting.

CeNeS is currently initiating a final phase II study of M6G and morphine to investigate the effect of timing of administration of M6G, in order to optimise pain control during the immediate post-operative period. The extended Elan/CeNeS business venture will now take responsibility for this programme. The latter forms an integral part of the design of the phase III programme planned to commence during 2002, which will be a major milestone in the history of the company.

Clinical trial results from a second sleep study

CEE 03-310 is a dopamine D1 receptor antagonist acquired as part of a licence agreement with Novo Nordisk in 1997. CeNeS is developing the drug candidate for sleep disorders and substance abuse. In the sleep disorders field CeNeS reported data previously describing the significant effect of CEE 03-310 on sleep patterns in young healthy volunteers. We announce today that a second volunteer study has been completed in 24 male subjects. CEE 03-310 again showed a significant alteration in sleep architecture, specifically showing changes in some non-REM stages of light and slow-wave sleep. These effects on sleep patterns, however, did not translate into effects on subjective ratings of sleep quality in the healthy volunteers.

To progress CEE 03-310, the next step in the clinical development programme should be in patients with sleep disorders to explore the effects of this drug in subjects who already have dislocated sleep patterns such as patients experiencing sleep disorders following cardiac surgery. With these results and the increased package of clinical data we will be actively seeking partners for the further development of this potential drug.

Update on other clinical development programmes

In June 2001 we entered into a collaboration with Elan Corporation plc to develop M6G with their unique Medipad drug delivery device for the treatment of severe pain. It is planned to commence clinical trials with M6G/Medipad in early 2002.

Our candidate for the treatment of neuropathic pain (CNS 5161) commenced a phase II study in early 2001 and we are in early stage discussions with partners to continue the full development of this program

The opioid spray for the novel treatment of pain that we are co-developing with Bioglan Pharma also made progress through phase I studies. Our development partner has announced that the opioid spray is ready to enter its phase II programme. We have also had discussions with potential partners for the European rights to this programme.

CEE 03 - 310 also received an IND to enter a phase II study in substance abuse. The phase II stroke trial of sipatrigine is ongoing and we have increased the recruitment of extra trial centres in Europe.

Following the assignment of European and North American marketing rights of our cancer pain product Moraxen to Bioglan Pharma and Amarin Corporation in 2000, we have been developing the clinical strategy with our partners in 2001. These discussions have been assisted by the transfer of the UK marketing rights from Schwarz Pharma to Bioglan Pharma.

Research

The most notable synergy from the acquisition of Cambridge NeuroScience results from bringing together a focused chemical library of ion channel ligands with CeNeS' world leading ion channel screening technology, "AutoPatch^{TM}".

Pharmaceutical services

Cognition The Cognition division has grown significantly under CeNeS stewardship but the cognitive testing business is not central to the company strategy going forward and the CeNeS board believe that Cambridge Cognition's continued growth and new product development should be funded by new investors in a separate cognition company.
In July 2001, CeNeS announced the acquisition of Management Dynamics Cambridge (a small psychology company), which was combined with the CeNeS cognition division to form Cambridge Cognition Limited. It is intended that this subsidiary is spun out later in 2001 with CeNeS retaining a minority holding.

CeNeS Drug Delivery The drug delivery division has continued to make progress on existing contracts and has signed a marketing agreement with International Processing Corporation (IPC) to co-promote CeNeS oral drug delivery technology. Following the launch in September 2000 the first year of UK sales of Moraxen have been disappointing. However, CeNeS is pleased to report that Bioglan Pharma, who hold the European marketing rights, are now also the UK marketing partner. CeNeS has been actively working with its advisors as part of the restructuring process to realise the potential of the drug delivery business.

Financing CeNeS announced shareholder approval of the CeNeS/Elan business venture on June 25th 2001. The business venture combines CeNeS lead pain candidate, M6G with Elan's Medipad drug delivery technology. At the same time Elan subscribed for 7.8 m shares at 54p raising £4.2m. Elan will also receive warrants over 779,933 CeNeS ordinary shares at an exercise price of 79.26p. To assist in the equity funding of

the business venture, CeNeS issued to Elan a US$12,015,000 convertible exchangeable loan instrument. This instrument can be, in certain circumstances, redeemed in CeNeS shares, repaid in cash or exchanged for shares in the business venture at the option of Elan. There is an additional US$6,408,000 convertible loan instrument that may be drawn down based on CeNeS and Elan's agreement to assist in the funding of the clinical development programme of the business venture. Under the extension of the Elan/CeNeS business venture announced today, the funding available under the convertible loan instrument has increased by a further $1,602,000. Elan also agrees today to subscribe for a second tranche of shares raising $2.2m, which may be used by CeNeS for general corporate purposes. Upon closing, Elan will hold 9.9% of CeNeS shares in issue. Elan will also receive further warrants over 914,988 CeNeS ordinary shares at an exercise price of 31.6p.

In its efforts to obtain financing for the company, a series of fund raising strategies has been reviewed by management but no arrangements have been entered into. As a result of the exceptional global economic circumstances and increased uncertainty over the ability of the company to raise additional capital over the next 12 months, the board has already begun a restructuring programme to preserve shareholder value.

Interim results Net cashflow for the period before financing was £18.4m (H1 2000 £14.3m). Loss for the period was £18.3m (H1 2000 £15.6m). Cash at 30th June 2001 amounted to £4.8m (30th June 2000 £13.8m, 31 December 2000 £10.6m).

Revenues in the period were £2.7m (2000 H1 £3.7m). Revenue was higher in the comparable period in 2000 due to £2.6m of out-licensing revenues. The lack of out-licensing revenues is offset by the growth in recurring revenue streams in H1 2001 principally from CeNeS' new pharmaceuticals division. Gross profit percentage is also reduced compared to H1 2000, which again reflects the lumpy licensing revenues in H1 2000 and reduced margins in the pharmaceutical division during the initial transfer of the manufacturing and distribution processes from GlaxoSmithKline to CeNeS.

Research and development costs for the period amount to £16.0m (H1 2000 £16.9m). The six months ended 30th June 2001 costs include £10.7m arising on the consolidation of the write-off of the Medipad licence in the business venture with Elan Corporation. The write-off is consistent with CeNeS policy in respect of licences acquired for early stage development projects. Excluding licence write-offs, research and development costs have increased to £5.4m (H1 2000 £4.6m) reflecting CeNeS' commitment to its research and development portfolio following the acquisition of Cambridge NeuroScience in December 2000. Administration expenses have increased by £3.2m to £5.5m compared to the comparable period in 2000, almost two thirds of this increase is due to an increased amortisation expense in the first half of 2001 of £2.7m, which is some £1.9m higher than the figure for the H1 2000. The amortisation arises from the write down of the goodwill arising on the consolidation of Cambridge NeuroScience in December 2000, CeNeS' merger with Core Group in December 1999 and the amortisation of pharmaceutical product licences acquired in September 2000. The increase in administration expenses also reflects the increased overhead incurred in operating three sites located in Cambridge, UK, Irvine, Scotland and Boston, USA.

The planned restructuring will enable the company to fund the key strategy objectives going forward. To assist in this the level of operating expenses and capital expenditure is to be reduced significantly over the next twelve to eighteen months.

Consolidated Profit and Loss Account

For the six months to 30th June 2001

		Six months ended 30th June 2001 £'000	Six months ended 30th June 2000 £'000	Year ended 31st December 2000 £'000
Turnover		**2,679**	3,729	6,603
Cost of sales		**(1,687)**	(443)	(1,721)
Gross profit		**992**	3,286	4,882
Research and development costs	- continuing	**(5,386)**	(4,657)	(7,785)
	- licences acquired	**(10,664)**	(12,270)	(12,270)
Administrative expenses		**(5,492)**	(2,274)	(6,254)
Operating loss		**(20,550)**	(15,915)	(21,427)
Interest receivable (net)		**100**	332	603
Loss on ordinary activities before and after taxation		**(20,450)**	(15,583)	(20,824)
Minority interest		**2,122**	-	-
Loss for the period		**(18,328)**	(15,583)	(20,824)
Loss per ordinary share		**(12.0p)**	(17.2p)	(20.9p)

Consolidated Balance Sheet
For the six months to 30th June 2001

	Six months ended 30th June 2001 £'000	Six months ended 30th June 2000 £'000	Year ended 31st December 2000 £'000
Fixed assets			
Intangible assets	54,243	22,379	56,917
Tangible assets	5,533	6,237	6,067
	59,776	28,616	62,984
Current assets			
Stocks	634	36	349
Debtors	3,313	4,369	3,986
Cash at bank and in hand	4,749	13,771	10,561
	8,696	18,176	14,896
Creditors			
Creditors - amounts falling due within one year	(4,952)	(6,391)	(7,616)
Net current assets	3,744	11,785	7,280
Total assets less current liabilities	63,520	40,401	70,264
Creditors - amounts falling due after more than one year	(9,869)	(2,922)	(2,668)
Net assets	53,651	37,479	67,596
Capital and reserves			
Called up share capital	16,065	9,977	15,272
Share capital to be issued	5,262	5,262	5,307
Share premium account	84,929	51,454	81,473
Profit and loss account	(63,026)	(39,636)	(44,877)
Other reserves	10,421	10,422	10,421
Equity shareholders' funds	53,651	37,479	67,596
Minority interests	-	-	-
Total capital employed	53,651	37,479	67,596

Consolidated Cash Flow Statement

For the six months to 30th June 2001

	Six months ended 30th June 2001 £'000	Six months ended 30th June 2000 £'000	Year ended 31st December 2000 £'000
Net cash outflow from operating activities	(9,820)	(14,629)	(17,760)
Returns on investments and servicing of finance			
Interest received	156	416	743
Interest paid	(12)	(16)	(29)
Interest element of finance lease rental payments	(30)	(68)	(121)
Net cash inflow from returns on investment and servicing of finance	114	332	593
Capital expenditure and financial investments			
Payment to acquire tangible fixed assets	(154)	(162)	(298)
Payment to acquire product licences	(8,542)	-	(10,252)
Receipts from sale of tangible fixed assets	13	82	69
Net cash outflow from capital expenditure and financial investment	(8,683)	(80)	(10,481)
Acquisitions			
Purchase of subsidiary undertakings	-	-	(1,234)
Net cash acquired with subsidiary	-	123	4,685
Net cash inflow from acquisitions	-	123	3,451
Net cash outflow before financing	(18,389)	(14,254)	(24,197)
Financing			
Issue of ordinary share capital	4,225	13,118	21,242
Costs associated with issue of shares	-	-	(1,084)
Issue of convertible loan note (net)	8,502	-	-
Grant receipts	-	56	-
Repayment of loans	(32)	(13)	(45)
Capital element of finance lease rentals	(257)	(288)	(507)
Net cash inflow from financing	12,438	12,873	19,606
Decrease in cash	(5,951)	(1,381)	(4,591)

Reconciliation of Net Cash Flow to Movement in Net Funds

For the six months to 30th June 2001

	Six months ended 30th June 2001 £'000	Six months ended 30th June 2000 £'000	Year ended 31st December 2000 £'000
Decrease in cash in the period	(5,951)	(1,381)	(4,591)
Cash (inflow)/outflow due to changes in debt and lease finance	(8,213)	301	552
Change in net funds resulting from cash flows	(14,164)	(1,080)	(4,039)
New finance leases	-	(60)	(175)
Exchange adjustments	139	-	-
Movement in net funds	(14,025)	(1,140)	(4,214)
Net funds brought forward	9,481	13,695	13,695
Net funds carried forward	(4,544)	12,555	9,481

Notes to the Interim Financial Statements

1. Accounting policies

a) Basis of preparation

These interim statements do not constitute statutory financial statements within the meaning of Section 240 of the Companies Act 1985. Results for the six month periods ended 30th June 2001 and 30th June 2000 have not been audited. The results for the year ended 31st December 2000 have been extracted from the statutory financial statements that have been filed with the Registrar of Companies and upon which the auditors reported without qualification.

b) Intangible fixed assets

Intangible assets include goodwill arising on the acquisition of CeNeS Limited by Core Group, the acquisition of Cambridge NeuroScience and the acquisition of product licences.

2. Debtors

Debtors include Bioglan Pharma drug development costs invoiced in advance relating to the opioid spray project. The collaboration costs are being expensed in the profit and loss account over the timeline of the relevant development project.

3. Creditors

Creditors due after one year include £8.5m relating to a convertible unsecured loan note. The note has a fixed term of 8 years and bears an interest rate of 5%

4. Loss per share

The loss per share is based on losses of £18.3m (June 2000 £15.6m) and the average number of shares in issue during the half year of 152,969,449 shares (June 2000 90,826,434).

5. Reconciliation of operating loss to net cash outflow from operating activities

	Six months ended 30 June 2001 £'000	Six months ended 30 June 2000 £'000	Year ended 31 December 2000 £'000
Operating loss	(20,550)	(15,915)	(21,427)
Depreciation	695	645	1,266
Amortisation of grant	(21)	(81)	(51)
Amortisation of goodwill	2,673	816	2,017
Amortisation of licence acquired	10,664	-	-
Loss on sale of tangible fixed assets	2	19	6
(Increase)/decrease in stocks	(285)	40	(273)
(Increase)/decrease in debtors	659	(3,703)	(2,970)
Increase/(decrease) in creditors	(3,657)	3,550	3,672
Net cash outflow from operating activities	(9,820)	(14,629)	(17,760)

Independent review report to CeNeS Pharmaceuticals plc

Introduction

We have been instructed by the company to review the financial information for the six months ended 30 June 2001 which comprises the Consolidated Profit & loss account, Consolidated Balance sheet, Consolidated Cash Flow Statement, Reconciliation of net cash flow to movement in net funds and Reconciliation of operating loss to net cash outflow from operating activities. 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 directors are responsible for preparing the interim report in accordance with the Listing Rules of the Financial Services Authority which 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 any changes, and the reasons for them, are disclosed.

Review work performed

We conducted our review in accordance with guidance contained in Bulletin 1999/4 issued by the Auditing Practices Board for use in the United Kingdom. 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 excludes audit procedures such as tests of controls and verification of assets, liabilities and transactions. It is substantially less in scope than an audit performed in accordance with United Kingdom 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 2001.

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Date
October 1 2001