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REGEN THERAPEUTICS PLC

PRELIMINARY RESULTS FOR THE YEAR ENDED 31 DECEMBER 2001

London UK, 8th May 2002: **ReGen Therapeutics Plc** ("ReGen") (LSE: RGT), a company developing a potential treatment of Alzheimer's disease, today announces its financial results for the year ended 31 December 2001.

HIGHLIGHTS:

CLINICAL TRIAL

Interim data:

The analysis of interim 15-week data from the clinical trial in Poland showed:

- Statistical significance achieved in ADAS-cog, one of the more significant measurement scales in the assessment of Alzheimer's disease and the Primary Endpoint of the clinical trial
- Consistent clinical trend seen in other exploratory measurement scales
- 28% of patients receiving Colostrinin™ demonstrated stabilisation in progression of the disease
- 11% of patients receiving Colostrinin™ demonstrated an improvement in their disease condition
- A significant number of patients appear to have derived benefit from Colostrinin™ after only 15 weeks of treatment and without experiencing any significant side-effects

Current status:

- Final phase now ongoing where all remaining patients are receiving "open-label" Colostrinin™ for a further 15 week period

- Full 30 week data to be analysed following completion of patient's treatment on 16th May. Analysis of this data is expected to be completed in June

OTHER KEY EVENTS

- Significant progress has been made in developing a large-scale manufacturing process for Colostrinin™ - expectation for full process scale-up during 2003
- Grant of first UK patents – important milestone for the Company's IP portfolio
- Continued progress with scientific research at UTMB

FINANCIAL RESULTS

- Loss of £2.41 million in 2001
- Cash reserves at 31st December 2001 stood at £1.1m
- Autumn of 2001, the Board successfully raised £1.45m by means of a placing of14,446,127 shares
- Further funding necessary for working capital requirements – first stage of fundraising now underway

More/…

Commenting, Percy Lomax, Chairman, said:

"We have continued to make good progress in 2001 and have concentrated on our key objectives; completing the clinical trial in Poland, continuing work on the manufacturing process and researching the scientific background of Colostrinin™. We have been encouraged by the positive data from the first phase of the clinical trial and are delighted that this study demonstrates a statistically significant result in ADAS-cog, the most important parameter being measured in this trial. It is also exciting that a substantial number of patients appear to be benefiting from Colostrinin™ after only 15 weeks of treatment and without unpleasant side-effects. We eagerly await the final results from this clinical trial".

For further information, please contact:

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Further information on ReGen can be found on the Company's website:
www.regentherapeutics.com

The information contained in this press release includes forward-looking statements that involve risks and uncertainties. Any statements that are not statements of historical fact (including without limitation statements to the effect that the Company or its management 'believes', 'expects', 'intends', 'anticipates', 'plans' and similar expressions) should be considered forward-looking statements. Important factors that could cause actual results to differ from those indicated by such forward-looking statements include uncertainties relating to the final results of the current clinical trial, the necessity to conduct further clinical trials and related studies (such as toxicity and bio-equivalence), the ability to develop a scaleable manufacturing process for Colostrinin™, product testing and regulatory approval, efficacy and safety of Colostrinin™ in the treatment of any disease or condition.

CHAIRMAN'S STATEMENT

Our highly focussed development strategy for Colostrinin™ as a potential therapy for Alzheimer's disease continues to progress.

Significant progress has been made in developing a large-scale manufacturing process for Colostrinin™. Pilot-scale development has continued over the last year and as a result the Company currently expects to be in a position to proceed to full process scale-up during 2003 and to have GMP-grade material available in the second half of that year.

Expansion of the intellectual property base continues and 2001 saw the grant of our first patents in the United Kingdom, representing a major achievement in the growth of the Company's IP portfolio.

In April 2001, we were able to report positively on data from the first interim assessment by the International Steering Committee of our ongoing clinical trial in Poland. The Committee's findings confirmed that there were no Colostrinin™ related safety issues of concern in the trial and that there was an encouraging trend towards demonstrating efficacy of Colostrinin™ in those patients receiving it, compared to the placebo group. Based upon these findings, the Committee recommended that the trial be continued.

The Committee also recommended the recruitment of additional patients to improve the statistical validity of the data. The recruitment target of 106 patients was achieved at the end of 2001 and all remaining patients will have completed their medication by 16th May 2002. Analysis of the data from the final phase of the trial and reporting of the results is expected during June.

Throughout the year, we have maintained our long-term relationships with academia, particularly our scientific collaboration with the University of Texas, Medical Branch in the USA. This collaboration is aimed at building up our knowledge of the structure and physiological properties of Colostrinin™ and its component peptides and is helping us to better understand its mode of action. Such knowledge and understanding is important to any future drug development programme and is expected to enable the Company to add to its intellectual property portfolio.

The above developments can only be continued from a realistic funding base. During the Autumn of 2001, the Board successfully raised £1.45m by means of a placing of shares, which was accomplished in spite of turbulent conditions in the financial markets following the events of September 11th. Further funding is necessary to continue the development of Colostrinin™ and the Company's other activities. The Company is currently seeking to raise the first stage of this funding requirement.

During the year, Dr Friedrich Rentschler resigned from the Board and we thank him and his colleagues for their support during the Company's formative years. Notwithstanding this resignation, the Rentschler group is still involved with the Colostrinin™ project through its biotechnology division's continued responsibility for monitoring the clinical trial in Poland.

Following the introduction of Financial Reporting Standard 18, Accounting Policies, which requires the directors to regularly review the group's accounting policies, the directors have considered the groups' policy for accounting for Research and Development. Whilst it is acceptable under UK Accounting Standards to either capitalise or write off immediately research and development costs it is usual practice within the pharmaceutical industry to write off such expenditure. Therefore the board has decided to change its accounting policy within these accounts to write off expenditure on Research and Development each year as incurred. A prior year adjustment has been made to reflect this change.

This change of policy had the effect of increasing our losses before tax and we have restated those for the year to December 2000 to give a comparison with year 2001. The effect of the change in 2000 was to increase the loss by £1.28 million to £2.35 million. In 2001 a further loss of £2.41 million was incurred. Cash reserves at the year-end stood at £1.1m.

POST YEAR END EVENTS

Wieland Wolf resigned from the Board in January 2002. He played a major part in the start up and early years of the Company and we thank him for his services.

The most important event since the 2001 year end was our announcement of further interim data from the first phase of the current clinical trial of Colostrinin™. This data showed an encouraging trend towards efficacy and was described by Dr Mervyn Busson, former Director of Medical Sciences at The Boots Company plc, Fellow of the Faculty of Pharmaceutical Physicians and our independent medical advisor, as clinically significant.

The trial involved 106 patients at six clinical centres in Poland. The first phase of the trial was double-blind, placebo-controlled, where half of the patients received Colostrinin™ for 15 weeks and the other half received a placebo. Neither the patients nor the clinicians treating them were aware of whether the active material or the placebo was being administered. Following completion of the first phase, a final phase is now ongoing where all remaining patients are receiving "open-label" Colostrinin™ for a further 15 week period.

Full Sample Analysis of Overall Response (being the analysis of all patients who have fulfilled the inclusion criteria of the trial) after the first 15-week phase shows that:

- **28% of patients receiving Colostrinin™ demonstrated disease-stabilisation and a further 11% in the same group showed an actual improvement in their condition. Thus, a total of 39% of patients in the Colostrinin™ group appear to have derived a real benefit from receiving the drug.**

- **The benefits observed in the Colostrinin™ treated group far outweigh those seen in the placebo group, where the data showed that 13% of the patients stabilised and 8% showed some improvement, a total of 21%.**

These results supplement the initial analysis of the data from the first phase of the trial, which showed that:

- **The results achieved statistical significance at the interim stage in ADAS-cog, one of the more commonly used measurement scales of Alzheimer's disease. ADAS-cog measures cognitive function and is this clinical trial's Primary Endpoint (the parameter that the trial was primarily designed to investigate).**

- **Statistical significance was achieved in one of the six secondary measurement scales (IADL, which measures the ability of older people to perform normal every day activities). By definition, these evaluations are exploratory for the purposes of this trial.**

- **Results across all seven measurement scales used in the trial showed that progression of disease amongst those patients being treated with Colostrinin™ was consistently slower than in those receiving the placebo.**

- **When measured specifically according to their ADAS-cog scores, almost half of the patients receiving Colostrinin™ showed no deterioration at 15 weeks (the median change in score for the treated group was 0.3 ADAS-cog points, compared with a median score change of 4.67 ADAS-cog points for the placebo group).**

The particularly exciting element to arise from the data received to date is that those patients who appear to have derived benefit from Colostrinin™ have done so after only 15 weeks of treatment and without experiencing any significant side-effects. This data is therefore considered by the Company to be of significant clinical importance, given that Alzheimer's disease is invariably progressive and degenerative if left untreated.

The Company believes that if the trends demonstrated by the interim data are shown to continue by the data from the final phase of the trial, Colostrinin™ has the potential to become one of the first therapies for Alzheimer's disease that modifies the disease process, and therefore offers long term benefits to Alzheimer's sufferers. This would be in contrast to the symptomatic short-term relief and, in some cases, unpleasant side effects currently offered by some drugs already on the market.

The Board of Directors is now evaluating the options open to it for taking the Company forward into its next stage of development.

Percy Lomax
Executive Chairman
8th May 2002

CONSOLIDATED PROFIT AND LOSS ACCOUNT
for the year ended 31 December 2001 (Unaudited)

	2001	2000 (restated)
	£	£
Administrative expenses	**1,573,387**	1,227,369
Development costs	**916,114**	1,280,657
Operating loss	**(2,489,501)**	(2,508,026)
Interest receivable	**78,817**	156,587
Interest payable	**(3,668)**	-
Loss on ordinary activities before taxation	**(2,414,352)**	(2,351,439)
Taxation on loss from ordinary activities	**(88,741)**	83,455
Loss on ordinary activities after taxation	**(2,325,611)**	(2,267,984)
Loss per share	**(4.64)p**	(4.71)p

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES
for the year ended 31 December 2001 (Unaudited)

	2001	2000 (restated)
	£	£
Loss for the financial year and total recognised gains and losses relating to the year	**(2,325,611)**	(2,267,984)
Prior year adjustment (as explained in note 4)	**(1,716,906)**	
Total gains and losses recognised since last annual report	**(4,042,517)**	

CONSOLIDATED BALANCE SHEET
at 31 December 2001 (Unaudited)

	2001		2000 (restated)	
	£	£	£	£
Fixed assets				
Intangible assets		**1,863,315**		1,819,652
Tangible assets		**38,459**		73,055
		1,901,774		1,892,707
Current assets				
Investments	-		200,000	
Debtors	**324,948**		230,493	
Cash at bank and in hand	**1,098,911**		2,177,662	
	1,423,859		2,608,155	
Creditors: amounts falling due within one year	**363,431**		493,632	
Net current assets/(liabilities)		**1,060,428**		(2,114,523)
Total assets less current liabilities		**2,962,202**		4,007,230
Capital and reserves				
Called up share capital		**3,349,229**		2,626,922
Share premium		**5,469,163**		4,910,642
Profit and loss account		**(5,856,366)**		(3,530,754)
Equity shareholders' funds		**2,962,026**		4,006,810
Non-equity minority interests		**176**		420
		2,962,202		4,007,230

CONSOLIDATED CASH FLOW STATEMENT
for the year ended 31 December 2001 (Unaudited)

	2001		2000 (restated)	
	£	£	£	£
Net cash outflow from operating activities		**(2,531,149)**		(2,348,019)
Returns on investments and servicing of finance				
Interest received	**78,817**		156,587	
Interest paid	**(3,668)**		-	
		75,149		156,587
Taxation		**(34)**		(1,736)
Capital expenditure and financial investment				
Payments to acquire tangible fixed assets	**(11,711)**		(94,789)	
Payments to acquire intangible fixed assets	**(119,914)**		(218,801)	
Proceeds from sales of fixed assets	**28,080**		-	
		(103,545)		(313,590)
Net cash outflow before management of liquid resources and financing		**(2,559,579)**		(2,506,758)
Management of liquid resources				
Decrease/(Increase) in short term deposits	**900,000**		(1,850,000)	
Sales/(Purchase) of short-term investments	**200,000**		(200,000)	
		1,100,000		(2,050,000)
Financing				
Proceeds of shares issued for cash	**1,444,614**		5,279,997	
Expenses paid on share issue	**(163,786)**		(553,108)	
		1,280,828		4,726,889
(Decrease)/Increase in cash		**(178,751)**		170,131

NOTES

1. The financial information contained in this announcement does not constitute statutory financial statements within the meaning of Section 240 of the Companies Act 1985. The financial information for the year ended 31 December 2000 has been extracted from the statutory financial statements for that year which have been filed with the Registrar of Companies. The audit report on those financial statements was unqualified but contained an explanatory paragraph dealing with a fundamental uncertainty relating to going concern. The financial information for the year ended 31 December 2001 has been extracted from the draft statutory financial statements for that year upon which the auditors have yet to report. The auditors have indicated that their final audit report will contain an explanatory paragraph dealing with the fundamental uncertainty referred to in the next paragraph.

2. Following the initial results of the Clinical trials, the Directors have reviewed and amended the company's plans for utilising its existing resources and identified a need for additional funding during the next financial year. The Directors anticipate that this will be addressed by a further placing of shares.

   On this basis the Directors consider it appropriate to prepare the financial statements on the going concern basis.

   If the fundraising and ongoing drug development programme are not successful then adjustments may be necessary to write down assets to their recoverable amounts, reclassify fixed assets and long term liabilities as current and provide for additional liabilities.

3 Expenditure on pure and applied research and development costs are charged to the profit and loss account in the year in which it is incurred. This policy differs from that used in prior years and further details of this change are outlined in note 4. All other accounting policies used to prepare the financial information contained in this statement are consistent with those set out in the statutory financial statements for the year ended 31 December 2000. All accounting policies are in accordance with applicable accounting standards.

4 Prior year adjustment

   The accounting policy for research and development expenditure for the year ended 31 December 2001 differs from that used in prior years in that the company are now charging research and development expenditure to the profit and loss account in the year that it is incurred.

   Previously the policy was to charge pure and applied research expenditure to the profit and loss account. Development costs were also charged to the profit and loss account unless individual projects satisfied the following criteria.

   - The project is clearly defined and related expenditure is separately identifiable;
   - The project is technically feasible and commercially viable;
   - Current and future costs are expected to be exceeded by future sales; and
   - Adequate resources exist for the project to be completed.

In such circumstances the costs were carried forward and amortised over the expected useful life of products commencing in the year the group starts to benefit from the expenditure.

The directors consider the revised policy to be more in line with other companies in the industry and therefore enable the financial statements to be more comparable with others.
The effect of this change in policy is to increase the reported loss in the year to 31 December 2000 by £1,280,657. Had the policy not been revised, the reported loss in the year to 31 December 2001 would have been £916,114 less.

5. Intangible fixed assets

Costs amounting to £119,914 relating to patent rights have been capitalised in the year in accordance with the Group's stated accounting policy.

6. Share capital

During the year the company issued 14,446,127 ordinary shares of 5p each at a premium of 5p per share.

The issued shares rank pari passu with existing shares.

7. Losses per share

The basic loss per ordinary share has been calculated using the weighted average number of shares in issue during the relevant financial year. The weighted average number of equity shares in issue are 50,141,506 and the loss is £2,325,611 (2000 - 48,174,663 shares and the loss restated £2,267,984).

The effect of all potential ordinary shares is anti-dilutive.

8. Reconciliation of movements in equity shareholders' funds

	2001		**2000 (restated)**	
	£	**£**	**£**	**£**
Loss for the financial year		**(2,325,611)**		(2,267,984)
New share issue		**722,307**		942,857
Premium on new share issue net of issue costs		**558,521**		3,784,031
Increase/(decrease) to equity shareholders' funds		**(1,044,783)**		2,458,904
Opening equity shareholders' funds	**5,723,715**		1,984,154	
Prior year adjustment	**(1,716,906)**		(436,248)	
		4,006,809		1,547,906
Closing equity shareholders' funds		**2,962,026**		4,006,810

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

	2001	2000 (restated)
	£	£
Operating loss	**(2,489,501)**	(2,508,026)
Amortisation	**76,006**	74,490
Depreciation	**18,227**	24,612
(Increase) in debtors	**(5,680)**	(66,433)
(Decrease)/increases in creditors	**(130,201)**	127,338
Net cash outflow from operating activities	**(2,531,149)**	(2,348,019)

10. Reconciliation of net cash flow to movement in net funds

	2001	2000 (restated)
	£	£
Increase/(decrease) in cash in the year	**(178,751)**	170,131
(Decrease)/Increase in liquid resources	**(1,100,000)**	2,050,000
Movement in net funds in the year	**(1,278,751)**	2,220,131
Net funds at start of year	**2,377,662**	157,531
Net funds at end of year	**1,098,911**	2,377,662

11. The annual report and financial statements for the year ended 31 December 2001 will be sent to all shareholders in due course and copies will be available from the company's business address at Suite 406, Langham House, 29-30 Margaret Street, London, W1W 8SA.