



Intercytex

23<sup>rd</sup> March, 2007

## **Intercytex Group plc Preliminary results for the year ended 31 December 2006**

Intercytex Group plc (LSE: ICX) announces its unaudited preliminary results for the year ended 31 December 2006.

Intercytex is the leading cell therapy company focused on high impact treatments to restore and regenerate skin and hair. Intercytex uses its fully integrated cell technology platform to develop living, human cell-based products, at commercially viable scale in attractive markets.

### **Highlights**

#### Products

- Good recruitment progress in Phase III trial of ICX-PRO for venous leg ulcers
- Commencement of Phase II trial of ICX-PRO in diabetic foot ulcers
- Successful completion of Phase I trial of ICX-RHY for facial rejuvenation
- Commencement of Phase II trial of ICX-TRC for male pattern baldness
- £1.85m grant to automate production of ICX-TRC
- MHRA confirmation that ICX-RHY can currently be sold in the UK without a marketing authorisation

#### Corporate

- Successful listing on AIM in February 2006, raising £13.7 million (net of expenses)
- Successful GCP inspection by MHRA
- Senior management strengthened with appointment of Jan Benschop to Vice President Commercial Development

#### Financial

- Loss before tax for the year ended 31 December 2006 of £9.2m (2005: £7.2m) resulting from an increase in R&D expenditure to advance the product portfolio
- Cash and liquid resources at 31 December 2006 of £11.0 million (2005: £5.7m)

#### Post year end highlights

- Start of Phase II trial of ICX-RHY for facial rejuvenation
- Start of Phase I trial of ICX-SKN for autograft replacement
- Completion of recruitment and biopsies for first cohort in Phase II trial of ICX-TRC
- Data & Safety Monitoring Board recommendation to continue ICX-PRO Phase III trial and increase sample size, based on a review of data from the first 50% of patients

Nick Higgins, CEO commented: *“Over the past 12 months we have completed a considerable amount of commercial and clinical preparatory work. In particular I am pleased to report today that the DSMB has now reviewed the data from over 100 patients in the Phase III trial of our lead product, ICX-PRO for venous leg ulcers, and it has recommended the continuation of the study. The foundations have been laid for a series of value generating events in 2007 as clinical trial data is reported on all four of our products and the first sales of our facial rejuvenation product, Vavelta, are achieved.”*

## Enquiries

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## Notes for Editors

Intercytex is a cell therapy company which bridges aesthetic medicine and tissue repair. It is using its proprietary expertise in cell therapy to develop products that harness the innate ability of human cells to regenerate and repair the body.

Intercytex has four products in development:

- ICX-RHY, a facial rejuvenation product to be launched in the second half of 2007
- ICX-PRO, designed to stimulate active repair in chronic wounds - in a Phase III trial
- ICX-TRC, a hair regeneration product – in a Phase II trial
- ICX-SKN, being developed as a durable and robust skin replacement – in a Phase I trial.

All Intercytex' products are derived from unmodified, human cells.

Intercytex commenced operations in 2000 and currently employs around 75 staff. In addition to its head office in Cambridge, UK, it has a GMP clinical production facility with research and development laboratories in Manchester, UK. Additional laboratories are located in Boston, USA.

Intercytex' shares trade on the Alternative Investment Market of the London Stock Exchange under the ticker symbol ICX.L.

*Statements contained within this press release may contain forward-looking information or statements with respect to the financial condition, results of operations and business achievements/performance of Intercytex and certain of the plans and objectives of management of Intercytex with respect thereto. By their nature, forward-looking statements involve risks and uncertainties that may cause actual results to vary from those contained in the forward-looking statements. In some cases, you can identify such forward-looking statements by terminology such as 'may', 'will', 'could', 'forecasts', 'expects', 'plans', 'anticipates', 'believes', 'estimates', 'predicts', 'potential', 'continue' or similar expressions. A number of factors, including the satisfactory progress of research and development, could cause Intercytex' actual financial condition, results of operations and business achievements/performance to differ materially from the estimates made or implied in such forward-looking statements and, accordingly, reliance should not be placed on such statements. Forward projections reflect management's best estimates based on information available at the time of issue and are not a guarantee of future performance. Other than as required by applicable law, Intercytex does not undertake any obligation to update or revise any forward-looking information or statements to reflect events or circumstances after the date of this release.*

*The term "Intercytex" refers to Intercytex Group plc and its subsidiary undertakings.*

## Chairman's Statement

I am very pleased to report Intercytex' 2006 unaudited preliminary results. This has been a year in which we have laid the foundations for the launch of our first product, ICX-RHY, and our lead clinical candidate, ICX-PRO, has advanced through its Phase III trial. Considerable efforts have been made in preparing the Company's other products for their next stages of development. Thus we are close to a series of value enhancing events in 2007 as our first product sales are achieved and clinical trial data are reported on all four of our products.

### Commercial Development

In March we received confirmation from the MHRA that ICX-RHY is outside the scope of the current legislation covering the marketing of medicines and devices in the UK; since it therefore does not need a marketing authorisation we are able to launch the product in the UK. We are also reviewing the opportunities in certain other European markets.

Since receiving the letter from the MHRA we have been evaluating the market opportunity and preparing for launch. Until recently the only cell therapy approach to facial rejuvenation on the UK market was the autologous product, Isolagen. This was withdrawn in November 2006 because, despite good sales, being an autologous product with high manufacturing costs it was reported to be unprofitable. Our market research has shown that there remains a strong appetite amongst aesthetic doctors for the natural outcomes which a cell therapy approach to facial rejuvenation could achieve. We are therefore confident that ICX-RHY will be well received and that, as an allogeneic product with a much simpler manufacturing process, it will achieve satisfactory margins.

The branding process was completed earlier this year and the product has been named Vavelta. We intend to launch the product in the second half of this year, when we have obtained early data from our Phase II trials, through our own sales and marketing organisation. Initially we will target a niche of high-end aesthetic doctors who are particularly interested in cell therapy. In 2008, with an increasing clinical data package, we will escalate promotional efforts and broaden the customer base.

We are investigating whether there are opportunities to initiate the small scale commercialisation of ICX-TRC in 2008. This will depend on the outcome of the ongoing Phase II trial and further regulatory review.

In anticipation of filing for a marketing licence around the end of the year and in conjunction with the branding of ICX-RHY we will shortly finalise a brand for ICX-PRO. We have developed an elegant transport/delivery system for the product which will enhance its ease of use characteristics.

In consultation with a panel of clinicians we have identified removal of basal cell carcinomas as an interesting early application of ICX-SKN. Assuming a successful Phase I trial we will examine the use of ICX-SKN in patients undergoing this procedure in the first Phase II trial of the product.

### Clinical Development

#### *ICX-PRO*

Our lead clinical product, ICX-PRO for the treatment of chronic ulcers, is currently being used in two clinical trials. The first is a multi-centre Phase III trial in the US, UK and Canada evaluating efficacy in venous leg ulcers. The trial is designed to demonstrate improved wound healing compared with the standard of care – four layer compression bandaging. Patient recruitment accelerated during the year and we anticipate reaching the initial recruitment target of 216 patients later this month.

The Data and Safety Monitoring Board (DSMB) has conducted a sample size re-estimation based on a review of the data from the first 108 patients randomised to the trial. The DSMB has stated its belief that the response rate from the standard-of-care control arm assumed in the original trial design was too low. We are pleased to report today that the DSMB has recommended continuation of the trial with an increase in patient numbers in order to ensure a statistically significant result. The Company is

currently discussing with the FDA the exact number of additional patients to be recruited, but based on an initial discussion our expectation is that this will be around 135. Recruitment is now expected to be completed in Q4/2007 and data from the trial announced in mid-2008.

Recruitment is also ongoing for a Phase II trial in the UK in diabetic foot ulcers to assess proof of concept in this indication. Data from this trial will be announced in H2/2007.

#### *ICX-TRC*

We started a Phase II trial of ICX-TRC, our cell therapy product for hair regeneration in male-pattern baldness, in September. The process involves taking a biopsy from the subject, separating out the relevant cells, and growing them in our facility using our proprietary process. All biopsies from the first cohort of 9 patients have been taken and most of these patients have been treated. Further cohorts will follow investigating variations in delivery technique. We expect to report preliminary data from this trial around the middle of the year.

#### *ICX-RHY (Vavelta)*

During the period we completed a Phase I clinical trial of ICX-RHY, our innovative product for facial rejuvenation. The study, conducted in collaboration with Professor Nicholas Lowe MD FRCP at the Cranley Clinic, London, consisted of a placebo-controlled safety and tolerability study in 10 healthy volunteers. Each subject received a course of three injections given into the skin of the upper arm. ICX-RHY was shown to be very well tolerated; no serious adverse events were reported and all adverse events were transient and resolved without treatment.

On the basis of these very encouraging data we have designed two Phase II studies. The first, to examine the effect of the product on naso-labial folds, commenced in March 2007 again with Professor Lowe. A second study should commence in the second quarter in Birmingham with Dr David Eccleston to assess the impact of ICX-RHY on facial imperfections caused by acne. Data will become available from these trials from the middle of 2007 onwards that will support both the launch of the product in the UK and the continuation of the clinical development programme.

#### *ICX-SKN*

ICX-SKN is our fourth product candidate which has been designed as a living skin replacement for use as an 'off the shelf' skin graft. A Phase I trial in volunteers to assess safety and persistence of the product commenced in February 2007; the patient treatment phase is complete and early observations are encouraging.

### **Regulatory developments**

#### Advanced Therapies Medicinal Products (ATMP) Regulation (2005/0227/COD)

Although currently ICX-RHY is not regulated in the UK as either a device or a medicine we believe that in time it will become regulated by pending European legislation covering ATMPs. This legislation is currently in draft form and we do not anticipate that it will become law in the UK until sometime in 2008. The legislation will contain 'grandfather' provisions allowing for the continued sale of products which were available prior to the legislation coming into force.

The new legislation will also probably regulate ICX-TRC and ICX-SKN as ATMPs which are both currently regulated as medicines in the UK. We do not expect the new regulation to have any significant effect on the development path of either of these products.

#### Regulatory Authority for Tissue and Embryos

Being based upon human cells our product candidates are also regulated by the Human Tissue Authority (HTA). The government has announced plans to merge HTA with the Human Fertilisation and Embryology Authority (HFEA) to form the new Regulatory Authority for Tissue and Embryos

(RATE). RATE will combine the statutory functions that are currently the responsibility of HTA and HFEA. We do not anticipate that this change will affect the development of our product candidates.

## **Management**

One key appointment was made to our senior management team when Jan Benschop joined us as VP Commercial Development in July. Jan has over 25 years experience in the sales and marketing of pharmaceutical, healthcare and biological products. In particular he brings highly relevant experience in aesthetic medicine having been a Director of Allergan responsible for the European marketing of BOTOX®.

## **Facilities**

Our R&D and production operations are conducted from our premises in Manchester. During the year we leased an additional 2,228 square foot in Manchester immediately adjoining our Good Manufacturing Practice (GMP) suite to provide additional QC laboratories and GMP raw material storage. We also took out an option over a further 12,454 square feet on the ground floor of our building to provide the in-market production capacity we will need following the launches of ICX-RHY and ICX- PRO.

Following the successful GMP inspection of our facility in Manchester last year the MHRA conducted a Good Clinical Practice (GCP) inspection which I am pleased to say we passed.

## **Fundraising and Financial Results**

£13.7m of net proceeds were received in February 2006 from the IPO in which 13.9m new ordinary shares were issued at a price per share of 108p.

The operating cash outflow for the year was £9.2m (2005: £6.3m). The net cash inflow after financing was £5.3m (2005: £3.9m) resulting in year end cash and liquid resources of £11.0m (2005: £5.7m).

Turnover in the year relates to receipt of the second milestone from Bosley under the ICX-TRC option agreement and other operating income comprises funding under the DTI grant for ICX-TRC. The pre-tax loss for the year was £9.2m (2005: £7.2m). The increase reflects higher R&D costs due to the increase in clinical trial programme activity, in particular the costs of the multi-centre ICX-PRO Phase III trial, and the additional staff hired to support this activity. The reduction in general and administrative costs reflects lower fundraising costs. The charge for share-based payments resulting from implementation of FRS 20 (IFRS 2) was £252k.

## **Prospects**

In recent months a number of well qualified observers have commented that the field of regenerative medicine is beginning to fulfil its early promise. With its late stage pipeline and strong commercial prospects Intercytex is a significant force in this sector. In 2007 continued clinical progress and the launch of Vavelta will emphasise the attractiveness of our business and our prospects.

Ian Kent  
Chairman  
22nd March 2007

**Intercytex Group plc**  
**Consolidated profit and loss account**

	<i>Unaudited</i> Year ended 31 Dec 2006 £	<i>Audited</i> Year ended 31 Dec 2005 £
Operating income	82,586	-
	<hr/>	<hr/>
	82,586	-
Research and development costs	(8,565,931)	(5,604,736)
General and administrative expenses	(1,259,644)	(1,590,068)
Other operating income: grants receivable	50,585	-
	<hr/>	<hr/>
Total expenses	(9,774,990)	(7,194,804)
<b>Operating loss</b>	<b>(9,692,404)</b>	<b>(7,194,804)</b>
	<hr/>	<hr/>
Interest receivable	525,321	88,454
Interest payable and similar charges	(66,584)	(129,229)
	<hr/>	<hr/>
	458,737	(40,775)
	<hr/>	<hr/>
<b>Loss on ordinary activities before taxation</b>	<b>(9,233,667)</b>	<b>(7,235,579)</b>
<b>Tax on loss on ordinary activities</b>	<b>1,028,888</b>	<b>727,657</b>
	<hr/>	<hr/>
<b>Loss on ordinary activities after taxation</b>	<b>(8,204,779)</b>	<b>(6,507,922)</b>
	<hr/>	<hr/>
<b>Loss per share:</b>		
Basic and diluted *	(15.0p)	(20.6p)
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\* Continuing activities and in total.

**Consolidated statement of total recognised gains and losses**  
**for the year ended 31 December 2006**

There are no recognised gains or losses other than the loss of £8,204,779 attributable to the shareholders for the year ended 31 December 2006 (2005: loss of £6,507,922).

**Intercytex Group plc**  
**Consolidated balance sheet**

	<i>Unaudited</i> <i>Group</i> <i>2006</i> £	<i>Audited</i> <i>Group</i> <i>2005</i> £
<b>Fixed assets</b>		
Tangible assets	671,900	587,306
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<b>Current assets</b>		
Stocks	27,322	49,771
Debtors	1,542,474	1,156,693
Short term investments	8,681,021	1,000,000
Cash at bank and in hand	2,305,725	4,686,613
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<b>Creditors:</b> amounts falling due within one year	12,556,542 (1,659,496)	6,893,077 (1,867,131)
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<b>Net current assets</b>	10,897,046	5,025,946
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<b>Total assets less current liabilities</b>	11,568,946	5,613,252
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<b>Creditors:</b> amounts falling due after more than one year	(165,328)	(108,199)
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<b>Net assets</b>	11,403,618	5,505,053
	=====	=====
<b>Capital and reserves</b>		
Called up share capital	560,481	418,250
Share premium account	21,289,089	7,580,362
Capital redemption reserve	229,065	229,065
Merger reserve	18,902,411	18,902,411
Profit and loss account	(29,577,428)	(21,625,035)
	-----	-----
Shareholders' funds	11,403,618	5,505,053
	=====	=====

The financial statements were approved by the Board on 22nd March 2007 and signed on its behalf by

I F Kent  
 Director

**Intercytex Group plc**  
**Consolidated cash flow statement**

	<i>Unaudited</i>	<i>Audited</i>
	<i>Year ended</i>	<i>Year ended</i>
	<i>31 Dec</i>	<i>31 Dec</i>
	<i>2006</i>	<i>2005</i>
	<i>£</i>	<i>£</i>
<b>Net cash outflow from operating activities</b>	<i>Note 3</i> (9,172,464)	(6,259,625)
<b>Returns on investments and servicing of finance</b>		
Interest received and similar income	445,924	88,454
Interest element of finance lease rental payments	(66,584)	(63,884)
	<hr/>	<hr/>
	379,340	24,570
	<hr/>	<hr/>
<b>Taxation</b>		
R&D tax credits received	722,817	589,099
	<hr/>	<hr/>
<b>Capital expenditure and financial investment</b>		
Purchase of tangible fixed assets	(213,144)	(22,202)
	<hr/>	<hr/>
<b>Net cash outflow before management of liquid resources</b>	(8,283,451)	(5,668,158)
	<hr/>	<hr/>
<b>Management of liquid resources</b>		
(Increase) / decrease in short term deposits	(7,681,021)	500,000
	<hr/>	<hr/>
<b>Financing</b>		
Issue of ordinary share capital *	13,850,958	7,868,408
Issue of unsecured convertible loan notes	-	1,939,091
Repayments of capital element of finance leases	(267,374)	(252,249)
	<hr/>	<hr/>
	13,583,584	9,555,250
	<hr/>	<hr/>
<b>(Decrease)/increase in cash</b>	(2,380,888)	4,387,092
	<hr/> <hr/>	<hr/> <hr/>
<b>Net cash inflow after financing</b>		
Net cash outflow before management of liquid resources	(8,283,451)	(5,668,158)
Financing	13,583,584	9,555,250
	<hr/>	<hr/>
<b>Net cash inflow</b>	5,300,133	3,887,092
	<hr/> <hr/>	<hr/> <hr/>

\* net of issue costs of £1,326,762 (2005:£82,756)

## Notes to the financial information

### 1. Basis of preparation

The financial information disclosed in this announcement does not constitute the Group's statutory financial statements. The financial information for the year ended 31 December 2005 has been extracted from the statutory accounts of Intercytex Limited for that year, which have been delivered to the Registrar of Companies. The auditors' report on those accounts was unqualified and did not contain any statement under sections 237(2) or (3) of the Companies Act 1985.

The financial statements in respect of the year end 31 December 2006 will be delivered to the Registrar of Companies in due course and will also be sent to shareholders. The auditors' opinion is yet to be issued. However an unmodified audit opinion is expected to be issued. This preliminary statement was approved by the Board on 22nd March 2006.

The 2006 financial year is the first year in which the Group has adopted FRS 20 – 'Share-based payment'. In accordance with this standard, the cost of share-based payments awarded to employees under the Group's share option schemes and Long Term Incentive Plan is measured by reference to their fair value at the date of award. This cost is recognised over the vesting period of the awards based on the number of options and/or shares which in the opinion of the directors will ultimately vest. The impact in 2006 is a charge of £252,386. The charges for prior periods are insignificant and accordingly the comparatives for those periods have not been restated.

This is the first year of the DTI grant. The capital element of the grant is deferred and released to profit and loss over the expected useful life of the robotic system. The revenue element of the grant has been credited to income so as to match it with the related expenditure.

### 2. Loss per share

The calculation of loss per ordinary share is based on the loss of £8,204,779 (2005: £6,507,922) and on 54,594,161 (2005: 31,634,872) ordinary shares, being the weighted average number of ordinary shares in issue during the year.

The exercise of share options in existence during the year would have the effect of reducing the loss per ordinary share, and are not therefore dilutive under the terms of FRS 22.

### 3. Reconciliation of group operating loss to net cash outflow from operating activities:

	Unaudited <i>Year ended</i> 31 Dec 2006 £	Audited <i>Year ended</i> 31 Dec 2005 £
Total operating loss	(9,692,404)	(7,194,804)
Depreciation and amortisation charges	376,985	350,466
Share-based compensation	252,386	-
(Increase)/decrease in stock	22,449	(45,335)
Increase in debtors	(313)	(243,490)
Increase/(decrease) in creditors	(131,567)	873,538
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Net cash outflow from operating activities	(9,172,464)	(6,259,625)
	=====	=====

4. Reconciliation of net cash flow to movement in net funds:

	Unaudited <i>Year ended</i> 31 Dec 2006 £	Audited <i>Year ended</i> 31 Dec 2005 £
<b><i>Increase/(decrease) in cash</i></b>	(2,380,888)	4,387,092
Capital element of finance lease repayments	267,374	252,249
New finance leases	(248,435)	(183,096)
Increase/(decrease) in short term deposits	7,681,021	(500,000)
Issue of unsecured convertible loan notes	-	(1,939,091)
Conversion of unsecured convertible loan notes	-	1,939,091
<b><i>Movement in net funds</i></b>	<u>5,319,072</u>	<u>3,956,245</u>
<b><i>Net funds at start of year</i></b>	5,330,103	1,373,858
<b><i>Net funds at end of year</i></b>	<u><u>10,649,175</u></u>	<u><u>5,330,103</u></u>