Scancell Holdings Plc

Final Results for the year ended 30 April 2013

Progress on All Fronts

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer , announces results for the year ended 30 April 2013.

Highlights during the period:

- Successful completion of Part 1 of the SCIB1 Phase 1/2 clinical trial
- Part 2 of the SCIB1 Phase 1/2 clinical trial fully recruited and on track for completion by the end of 2013
- Additional 8mg dose study underway, also expected to be completed by the end of 2013
- Development of new Moditope™ platform
- Strengthened IP with patents awarded in the US and Japan for protein Immunobody® technology platform
- Peter Allen appointed as a Director

Post period highlights:

- Placing and Open offer up to £6.5 million (announced today)

Richard Goodfellow, Joint CEO of Scancell, said:

"We have made excellent progress this year with the successful completion of Part 1 of our Phase 1/2 clinical trial for SCIB1, Part 2 remains on track and our additional 8mg dose study has also commenced. We are delighted that four of the six patients from the 2mg and 4mg dose groups are still alive with one patient remaining disease free two years after initiating treatment.

"We believe our innovative Moditope™ platform has the potential to generate a new class of powerful cancer immunotherapy treatments. We are putting funding in place to identify a lead from this programme and develop it through to the point at which we have secured regulatory approval to start clinical trials, a key value inflexion point. We are confident that such targeted further development of the Immunobody® and Moditope™ platforms will both strengthen Scancell's position as a leading immunotherapy player and allow it to realise an enhanced value for shareholders."

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Chairman's Statement

I am pleased to report on the company's results for the year ended 30th April 2013

Good progress has been made with Part 2 of the Phase 1/2 clinical trial on SCIB1, with the final patient recruited in January 2013. Recruitment of additional patients for the 8mg dose cohort, which is running in parallel with Part 2 of the Phase 1/2 study, has also commenced.

Following a review, the Board has decided that additional value can be delivered to shareholders by the further development of the new platform technology, Moditope™. Whilst currently at an early stage, we believe that the potential of this novel immunotherapy platform could be considerable and as a result plan to identify a lead product to take into pre-clinical and clinical development by the third quarter 2014. Scancell has provisionally selected triple-negative breast cancer (TNBC), ovarian and endometrial cancers as the initial target indications for the first clinical study which is scheduled to start in 2016. The Company has today announced a Placing and Open Offer of up to £6.5million. These additional funds will enable the Company to commence work on the pre-clinical development of the first Moditope™ immunotherapy product and will also give the Company the opportunity to strengthen the clinical data on the 8mg dose of SCIB1, both in terms of number of patients treated and the duration of treatment.

Financial

Profit and Loss

The Group has made a loss for the year from continuing operations of £1,901,944 (2012: loss: (£1,930,064)). The loss for the year was £1,901,944 (2012: profit £557,058).

The increase in development costs in the year reflects the additional costs incurred in the manufacture of the 8mg dose for use in the clinical trials.

The reduced administrative expenses are largely due to the reduction in the charge for share options which has occurred as all of the share options have now reached the end of their vesting period.

Balance Sheet
At the end of the year the Group cash balances amounted to £1,491,320 (2012: £3,529,007). This reduction in cash is attributable to the loss for the year.

The Group's net assets at 30th April 2013 amounted to £5,092,145 (2012: £6,971,337).

The ImmunoBody® Technology Platform

Scancell's mission is to develop medications that fight cancer by spurring the body's immune system. This is a form of treatment that many cancer specialists believe may hold the key to keeping a patient permanently disease-free. Unlike traditional therapies that attack a cancer directly, immunotherapy uses the body's own internal defences to ward off the disease, with the ultimate hope of building up long term resistance to the cancer.

Scancell's ImmunoBody® vaccines generate potent killer T-cells that target and eliminate tumours. Each ImmunoBody® vaccine can be designed to target a particular cancer in a highly specific manner, offering the potential for enhanced efficacy and safety compared with more conventional approaches.

The manipulation and enhancement of human immune systems is also relevant to the treatment of other diseases such as chronic infectious disease. Although Scancell does not intend to venture outside the oncology arena itself, the Company intends to license ImmunoBody® to companies working in other therapeutic areas.

SCIB1 melanoma vaccine

Clinical Trial
In December 2012, the Company announced preliminary results from Part 1 of the Phase 1/2 clinical trial of its DNA ImmunoBody® vaccine in patients with Stage III/IV malignant melanoma. Of the six patients allocated to the 2mg and 4mg dose cohorts and of those who received at least four doses of SCIB1, four are still alive and four showed a vaccine induced T cell response to treatment. The vaccine produced very few side effects, none of which were serious. These encouraging results provide the first evidence that Scancell's ImmunoBody® vaccine approach is producing an immune response in cancer patients which might also be associated with clinical benefit.

The first part of this Phase 1/2 clinical trial was conducted in five UK centres in eleven patients, ten with stage IV and one with stage III malignant melanoma. Patients were given five doses of 0.4mg, 2mg or 4mg of SCIB1, delivered by Ichor Medical Systems' TriGrid™ electroporation delivery device, over a period of six months. One patient in the 0.4mg dose group and one in the 4mg dose group who received only a single dose of SCIB1 were withdrawn from the study due to progressive disease shortly after study entry and were replaced to ensure that at least three patients in each dose cohort could be fully evaluated for immune response. During the course of the study regulatory approval was granted to increase the SCIB1 dose from 2mg to 4mg in patients in the 2mg cohort, if the vaccine was well tolerated. Two patients in this group received two 4mg doses of SCIB1 and one patient received a single 4mg dose.

Clinical response
Four of the six patients in the 2mg and 4mg cohorts who received at least 4 doses of SCIB1 are still alive and one remains disease-free two years after starting treatment. All four patients in the 0.4mg dose group have now died.

One patient in the 4mg dose group had a long history of metastatic disease and multiple tumour lesions present at the start of treatment (including several in her lungs), all of which decreased in size or disappeared completely following six months of treatment with SCIB1 except for one abdominal tumour nodule which increased in size and which has been resected. This "differential response" pattern is typical of immunotherapeutic agents and is the first signal that SCIB1 may be having an impact on the course of the disease as well as inducing an immune response. Additional studies have suggested that this abdominal tumour may have been largely composed of cells that do not express gp100 and which may therefore not be a suitable target for SCIB1 (which targets tumours that express either gp100 or TRP-2). This finding provides further circumstantial evidence that SCIB1 is successfully targeting tumours that express one of more of these antigens. A second abdominal tumour has since been detected.

One patient on SCIB1 remains disease-free two years after treatment started. This patient (in the 2mg cohort but who also received two 4mg doses at three and six months after the start of dosing) was entered into the study after all recurrent tumour had been resected and remains disease-free 24 months after first dosing and 30 months after the last tumour excision.

Immune response
All three patients in the 2mg/4mg dose cohort and one patient in the 4mg dose cohort produced an increased immune response to the melanoma specific epitopes in SCIB1. The two patients in the 4mg group who did not show an increased immune response to treatment had a strong pre-existing immune response to the target antigens at study entry which could not be increased with SCIB1. Only one of the patients in the lowest dose group showed any immune response to treatment.

Trial Status
The first patient was recruited to Part 2 of the Phase 1/2 clinical trial in May 2012 and the final patient started treatment in January 2013. As expected, the recruitment of patients in the second part of the trial proceeded faster than recruitment for the first part of the trial, as we were not constrained by the cohort study design requiring sequential dose escalation, and there were more patients available with earlier stage disease. Part 2 of the study is on track to be completed by the end of 2013.

GTAC and MHRA have also given their approval to increase the maximum treatment period from six months up to a further five years in these clinical trials. The continuation option will be available for patients with stable disease. This approval provides our investigators with the opportunity to continue dosing patients whose disease has not progressed whilst receiving the SCIB1 vaccine and will allow the Company to gather longer term data on late stage melanoma patients for whom the prognosis is poor. Four patients are currently receiving long term treatment with SCIB1.

8mg Dose
In view of the positive clinical results and minimal side effects seen with the 4mg dose, the Company is currently evaluating an 8mg dose in 3-6 patients with evaluable disease.

This additional cohort will permit an assessment of the safety and immunogenicity of an increased dose of SCIB1 in addition to the effect of this higher dose on tumour burden. The 8mg cohort is being evaluated in parallel with the second part of the Phase 1/2 study which is primarily designed to assess the effect of the 4mg dose on immune response in patients who have had all tumours removed prior to treatment. Three patients have been recruited to the 8mg dose cohort to date. Provided that the 8mg dose is well tolerated, the Company plans to seek approval to recruit an additional 10 patients with evaluable disease to strengthen the data set on the 8mg dose prior to closing the SCIB1 Phase1/2 programme.

Patents Awarded
In a further important step in the development and commercialisation of SCIB1, Scancell has been granted a number of patents during the year. The granting of a composition of matter patent in Europe for SCIB1 protects the unique composition of the vaccine until March 2028. The Company has also had protein ImmunoBody® vaccine patents approved in the United States and Japan. These patents will further strengthen Scancell's IP position and are an important step in the development and commercialisation of the ImmunoBody® platform. The DNA ImmunoBody® patent is expected to be granted in its first jurisdiction in the second half of 2013.

The Moditope™ Technology Platform

On 15 August 2012, the Company announced the development of a new platform technology, Moditope™, which stimulates the production of killer CD4 T cells with powerful anti-tumour activity. CD4 responses to cancer associated antigens have been notoriously difficult to generate whether presented as peptides, proteins or DNA, yet are vital for effective anti-tumour immunity. Scancell has identified and patented a series of modified epitopes that overcome this limitation. Scancell's Moditope™ technology produces killer CD4 T cells that destroy tumours without toxicity.

The discovery of the highly innovative Moditope™ platform opens up a new approach to the development of cancer immunotherapy treatment. Whilst currently at an early stage, we believe that the potential of this novel immunotherapy platform could be considerable and, as a result, plan to identify a lead product to take into clinical trials as soon as possible. Scancell has provisionally selected triple-negative breast cancer (TNBC), ovarian and endometrial cancers as the initial target indications for the first clinical study.

The patent describing the Moditope™ platform was filed in August 2012 and is due to be published in August 2013 after which further details about the technology platform and development plan will be presented to shareholders.

The proposed funding, mentioned below will provide the Company with the financial resources to take Moditope™ to the initial stage of clinical testing which will include the manufacture of material for toxicology, stability and clinical trials, a pre-clinical package, a defined regulatory strategy and clinical plan.

Fundraising

Scancell has today announced a placing of £4.5 million together with an open offer to raise up to £2.0 million.

These additional funds will enable the Company to commence work on the pre-clinical development of the first Moditope™ immunotherapy product and will provide working capital for the completion of the SCIB1 clinical trials.

Board of Directors

Nigel Evans resigned as a Director and Company Secretary on 11 December 2012 and Mike Rippon resigned as a Director on 27 February 2013. Both have given unstinting service and made an important contribution to Scancell over many years and I wish them well in their retirement.

Peter Allen was appointed as a Director on 1 April, 2013. A chartered accountant by profession he has held key senior positions in a number of companies in the life sciences industry, playing a significant role in their development. Peter's strategic oversight and broad experience with innovative life science companies will be invaluable to Scancell.

Staff

The Board recognises that the progress made over the year would not have been possible without the dedication and determination of all our staff and, on behalf of the directors, I offer our warmest thanks to them.

Outlook

The Company is entering an important juncture in its development. We are awaiting the results from Part 2 of our Phase I/II trial on SCIB1, expected at the end of this calendar year, together with the results of the 8mg dose which is being tested in parallel with Part 2 of the clinical trials. In addition, significant development work will be commencing on the Moditope™ platform.

The board of directors is firmly committed to a trade sale and believes that successful results from the clinical trials for SCIB1 together with the development of the Moditope™ platform will make Scancell an even more attractive acquisition opportunity to Pharmaceutical companies and provide a further significant boost to shareholder value.

David Evans
Chairman

SCANCELL
USING IMMUNOLOGY TO FIGHT CANCER

CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 30 APRIL 2013

	2013 £	2012 £
Continuing operations		
Development expenses	(1,452,317)	(1,221,339)
Administrative expenses	(731,672)	(740,132)
OPERATING LOSS	(2,183,989)	(1,961,471)
Interest receivable and similar income	30,037	31,407
LOSS BEFORE TAXATION	(2,153,952)	(1,930,064)
Taxation (note 4)	252,008	-
LOSS FOR THE YEAR FROM CONTINUING OPERATIONS	(1,901,944)	(1,930,064)
Discontinued operations		
PROFIT FOR THE YEAR FROM DISCONTINUED OPERATIONS	-	2,487,122
(LOSS)/PROFIT FOR THE YEAR	(1,901,944)	557,058
EARNINGS PER ORDINARY SHARE (pence) (note 5)		
Continuing and discontinued operations		
Basic	(0.98p)	0.30p
Diluted	(0.98p)	0.27p
Continuing operations only		
Basic	(0.98p)	(1.04)p
Diluted	(0.98p)	(1.04)p

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 30th APRIL 2013

(Loss)/Profit for the year	(1,901,944)	557,058
Attributable to:		
Equity holders of the owners of the company	(1,901,944)	557,058

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
for the year ended 30th April 2013

	Share capital £	Share Premium Account £	Share Option Reserve £	Retained earnings £	Total Equity £
At 1st May 2011	159,518	8,369,023	279,287	(4,172,086)	4,635,742
Profit for the year				557,058	557,058
Share issue	34,952	1,535,710			1,570,662
Share option costs			207,875		207,875
At 30th April 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337
At 1st May 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337
(Loss) for the year	-	-	-	(1,901,944)	(1,901,944)
Share option costs			22,752		22,752
At 30th April 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
as at 30 April 2013

	2013 £	2012 £
Non-current assets		
Plant and machinery	131,655	106,267
Goodwill	3,415,120	3,415,120
	3,546,775	3,521,387
Current assets		
Trade and other receivables	117,164	131,106
Tax receivables	252,000	74,220
Cash and cash equivalents	1,491,320	3,529,007
	1,860,484	3,734,333
TOTAL ASSETS	5,407,259	7,255,720
LIABILITIES		
Current Liabilities		
Trade and other payables	(315,114)	(284,383)
TOTAL LIABILITIES	(315,114)	(284,383)
NET ASSETS	5,092,145	6,971,337

SHAREHOLDERS' EQUITY		
Called up share capital	194,470	194,470
Share premium	9,904,733	9,904,733
Share option reserve	509,914	487,162
Profit and loss account	(5,516,972)	(3,615,028)
TOTAL SHAREHOLDERS' EQUITY	5,092,145	6,971,337

CONSOLIDATED CASH FLOW STATEMENT
for the year ended 30 April 2013

	2013 £	2012 £
Operating activities		
Cash generated from operations	(2,072,557)	859,620
Income taxes received	74,226	-
Net cash from operating activities	**(1,998,331)**	**859,620**
Investing activities		
Asset acquisition	(69,393)	(43,312)
Finance income	30,037	31,407
Net cash used by investing activities	**(39,356)**	**(11,905)**
Financing activities		
Proceeds from issue of share capital	-	1,752,771
Expenses of share issue	-	(182,109)
Net cash generated from financing activities	-	**1,570,662**
Net increase in cash and cash equivalents	**(2,037,687)**	**2,418,377**
Cash and cash equivalents at beginning of the year	**3,529,007**	**1,110,630**
Cash and cash equivalents at end of the year	**1,491,320**	**3,529,007**

1 BASIS OF PREPARATION

These financial results do not comprise statutory accounts for the year ended 30 April 2013 within the meaning of Section 434 of the Companies act 2006. The financial information in this announcement has been extracted from the audited financial statements for the year ended 30 April 2013.

The financial information has been prepared in accordance with International Financial Reporting Standards ('IFRS'), as adopted by the European Union, and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The financial statements have been prepared under the historical cost convention and in accordance with applicable accounting standards.

2 GOING CONCERN

Having regard to the Principal Risks set out in the Directors' Report, the Directors have reviewed the funding position for the forward period and considered the viability of business plans and budgets. These show that currently available cash resources will be sufficient to enable the group to meet its commitments until around December 2013 based on budgeted expenditure.

Scancell Holdings plc is planning to raise additional funds of approximately £6.1m, net of costs, by means of a placing of shares and open offer on the AIM market. The Directors consider that these funds will provide sufficient working capital to complete the clinical trials for SCIB1 and commence the pre-clinical studies for the Moditope Platform. The placing of shares and open offer is subject to receiving approval from Scancell Holdings plc members. It is anticipated that, subject to shareholder approval, the placing will take place at the beginning of August 2013.

The Directors consider that on the basis of the assessment of risks set out in the Directors' Report and with planned funding being received, the Group will be able to meet all of its obligations until at least 31st December, 2015 Accordingly the directors consider that the going concern basis is appropriate for the preparation of these financial statements.

3 OPERATING LOSS

	2013 £	2012 £
Operating profit is stated after charging/(crediting):		
Depreciation on tangible fixed assets	44,006	35,978
Operating lease rentals	14,056	14,056
Research and development	1,452,317	1,221,339
Auditors' remuneration – fee payable for audit of the company	6,500	6,250
Auditors' remuneration – fee payable for audit of the subsidiary company	6,500	6,250
Auditors' remuneration for non-audit services	1,350	2,850
Directors' remuneration	63,168	50,950

4 TAXATION

Analysis of the tax credit

The tax credit on the loss on ordinary activities for the year was as follows:

	2013 £	2012 £
Current tax		
UK corporation tax credits due on R&D expenditure	252,000	-
Adjustment to prior year	8	-
	252,008	-

Factors affecting the tax charge

The tax assessed for the years is lower than the applicable rate of corporation tax in the UK. The difference is explained below:

	2013 £	2012 £
Profit/(Loss) on ordinary activities before tax	(2,153,952)	557,058
Profit/(Loss) on ordinary activities multiplied by the standard rate of tax in the UK (20%)	(430,790)	111,412
Effects of:		
Disallowed expenditure	4,600	42,217
Timing differences	(2,464)	(21,706)
Enhanced tax relief on R&D expenditure	(254,731)	(159,642)
Reduced tax relief for losses surrendered for R&D tax credits	206,517	-
Prior period refund	(8)	-
Unrelieved losses carried forward	224,868	27,719
Current tax charge/(credit)	(252,008)	-

The Group has tax losses to carry forward against future profits of approximately £6,744,000 (2012: £5,850,000)

A deferred tax asset has not been recognised in respect of these losses as the Group does not anticipate sufficient taxable profits to arise in the foreseeable future to fully utilise them.

The estimated value of the deferred tax asset not recognised measured at a standard rate of 20% is £1,312,000 (2012: £1,090,000)

5 EARNINGS PER SHARE

Basic earnings per share

The earnings and weighted average number of ordinary shares used in the calculation of basic earnings per share is as follows:

	2013 £	2012 £
Earnings used in the calculation of basic earnings per share	(1,901,944)	557,058
Profit for the year from discontinued operations included in the calculation of basic earnings per share	-	(2,487,122)
Earnings used in calculation of basic earnings per share from continuing operations	(1,901,944)	(1,930,064)
Weighted average number of ordinary shares of 0.1p (2011) 1p each for the calculation of basic earnings per share	194,469,485	186,184,758

Diluted earnings per share

The earnings used in the calculation of diluted earnings per share are as follows:

	2013	2012
	£	£
Earnings used in the calculation of basic earnings per share	(1,901,944)	557,058
Profit for the year from discontinued operations included in the calculation of basic earnings per share	-	(2,487,122)
Earnings used in calculation of diluted earnings per share from continuing operations	(1,901,944)	(1,930,064)

The weighted average number of ordinary shares for the purposes of diluted earnings per share reconciles to the weighted average number of ordinary shares used in the calculation of basic earnings per share as follows.

Weighted average number of ordinary shares of 0.1p each for the calculation of basic earnings per share	194,469,485	186,184,758
Shares deemed to be issued for no consideration in respect of share options	18,374,520	18,374,520
Weighted average number of ordinary shares of 0.1p each for the calculation of diluted earnings per share	212,844,005	204,559,278

As the Group is reporting a loss from continuing operations for both years then, in accordance with IAS33, the share options are not considered dilutive because the exercise of the share options would have the effect of reducing the loss per share.

6 DELIVERY OF ACCOUNTS

The audited statutory accounts in respect of the prior year ended 30 April 2012 have been delivered to the Registrar of Companies. The auditors issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006. Without qualifying that opinion, the auditors drew attention to the fact that the Company's plan to raise additional funds by the placing of shares was subject to shareholder approval.

7 AVAILABILITY OF ACCOUNTS

This announcement is not being posted to shareholders. The Report and Accounts will be posted to shareholders later today. Copies of this announcement and further copies of the Report and Accounts can be downloaded from the Company's website: www.scancell.co.uk.