04 September 2014

Scancell Holdings Plc

Final Results for the year ended 30 April 2014

Emerging data continue to highlight value of ImmunoBody® and Moditope® platforms

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 2014.

Highlights during the period:

- Orphan drug designation granted by FDA for SCIB1 ImmunoBody® for the treatment of metastatic melanoma
- Positive data from Part 2 and an update from Part 1 of the on-going Phase 1/2 clinical trial with SCIB1 ImmunoBody® in patients with Stage III/IV melanoma
    - Melanoma-specific immune response seen in all Part 2 patients
    - Continuing positive survival trend in Part 1 subjects
    - No serious adverse events reported
    - Completion of patient dosing with 8mg of SCIB1 in Part 1 of on-going Phase 1/2 clinical trial in patients with Stage III/IV melanoma
- Planning for preclinical and clinical development of Modi-1, lead vaccine from Moditope® platform underway
    - Provisionally positioned as a novel immunotherapeutic for the treatment of lung, triple-negative breast cancer, ovarian and endometrial cancers
    - Continue to expect first-in-man clinical studies to start in 2016
- Publication of patent application underpinning the Company's Moditope® platform
- Scancell granted an extension of the Option to commercialise Ichor's proprietary Trigrid™ electroporation delivery system with SCIB1
- Loss for the year of £2,222,954 (2013: loss: £1,901,944)
- Group cash balance at 30 April 2014 was £5,566,234 (30 April 2013: £1,491,320). This increase in cash is attributable to the placing and open offer earlier in the financial year which raised £6.1m, net.

Post period highlights:

- New data demonstrates that a combination of SCIB1 and checkpoint inhibition showed enhanced tumour destruction and significantly longer survival times than when either treatment was used alone
- Patent granted in the United States for Scancell's DNA ImmunoBody® platform technology, following the grant of counterparts in Australia, China and Japan
- Further positive results from the on-going Phase 1/2 clinical trial in patients with Stage III/IV melanoma treated with the SCIB1 ImmunoBody®
    - Survival times are highly encouraging in both Part 1 and Part 2 patient groups
    - Melanoma-specific immune responses in 24 of 28 (86%) patients
    - Reduction in the number and size of multiple lung metastases in two patients
    - No serious adverse events reported

Richard Goodfellow, Joint CEO of Scancell, said: *"The cumulative results emerging from our ongoing Phase 1/2 SCIB1 clinical trial, including the destruction of lung metastases in two patients and the apparent prolongation of survival, continues to add to the evidence that SCIB1 has the potential to extend lives without the burden of serious side effects. The rationale for combining SCIB1 and PD-1 blockade, confirmed in recent animal studies, is also compelling.*

"Our ongoing Moditope® research continues to be productive as we continue to prepare Modi-1, our lead vaccine from this platform, for clinical trials which are on schedule to start in 2016.

"Cancer immunotherapy is emerging as one of most exciting areas of pharmaceutical research and development. Scancell now has two innovative technology platforms in this emerging field, both of which are expected to be of substantial interest to the increasing number of pharmaceutical companies establishing R&D programmes in the area. The Board remains dedicated to realising value for our shareholders as we continue to build upon the excellent data garnered to date."

For Further Information:

Scancell Holdings Plc + 44 (0) 74 2323 0 497
Dr Richard Goodfellow, Joint CEO
Professor Lindy Durrant, Joint CEO

Cenkos Securities: +44 (0) 20 7397 8900
Dr Christopher Golden
Stephen Keys

FTI Consulting +44 (0) 20 3727 1000
Simon Conway
Mo Noonan

About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms. Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma and is being evaluated in a Phase 1/2 clinical trial. Data from the trial demonstrate that SCIB1 has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system; the helper cell system where inflammation is stimulated at the tumour site; and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4 T cells that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.

Chairman's Statement

I am pleased to report on the Company's results for the year ended 30th April 2014.

In August 2013 the Company raised £6.1m (net proceeds) in additional investment through a placing and open offer of shares. These funds have enabled the Company to commence work on the pre-clinical development of the first Moditope® cancer immunotherapy product and provided working capital to complete the ongoing SCIB1 clinical trial in patients with melanoma using the higher 8mg dose.

Since the year-end, further results from the clinical trials of our SCIB1 vaccine have been published and as positive and consistent data continue to emerge from this study, our confidence grows that SCIB1 will play an important role in the management of melanoma. Furthermore, the latest animal data showing the powerful synergy between SCIB1 and checkpoint inhibition strongly supports the hypothesis that combining these two therapeutic approaches will be even more effective in the treatment of late stage disease than when either treatment is used alone.

Financial

Profit and Loss

The Group has made a loss for the year of £2,222,954 (2013: loss: £1,901,944).

The increase in development costs in the year reflects the additional costs incurred in commencement of pre-clinical studies on Moditope®.

The increase in administrative expenses is due to the additional patent costs arising in the year.

Balance Sheet

At the end of the year the Group cash balances amounted to £5,566,234 (2013: £1,491,320). This increase in cash is attributable to the placing and open offer earlier in the year.

The Group's net assets at 30th April 2014 amounted to £9,077,264 (2013: £5,092,145).

The ImmunoBody® Technology Platform

Scancell's mission is to develop novel therapeutics 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 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.

SCIB1 melanoma vaccine

At the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2014, Scancell announced further encouraging results from its on-going Phase 1/2 clinical trial in patients with Stage III/IV melanoma treated with the SCIB1 ImmunoBody®. The Phase 1/2 trial is an open label, non-randomised study to determine the safety and tolerability of four dose levels (0.4mg, 2mg, 4mg and 8mg) of SCIB1 administered intramuscularly using the Ichor TriGrid™ electroporation device. Whilst the primary objective of the study is to assess safety and tolerability, the secondary objectives are to evaluate cellular immune responses and to assess any tumour response.

This interim analysis showed that 24 of 28 (86%) of patients developed melanoma-specific immune responses and that the treatment was very well tolerated with no grade 4/5 toxicities observed.

Of particular note was the reduction in the number and size of multiple lung metastases in two patients (one at the 4mg and one at the 8mg dose).

Although this was an open study, the patient survival times were unexpected and highly encouraging. Since the trial commenced in 2010, only two of the 25 patients receiving at least three doses of 2-8mg of SCIB1

had died during the course of the study. Part 1 patients receiving 2mg/4mg doses of SCIB1 had 1-year and 2-year survival rates of 100% and 67%, respectively; none of the five patients receiving 8mg doses of SCIB1 had died.

In Part 2, all 14 patients (with resected tumours) were still alive 16-24 months after study entry (median 21 months) and only three patients had disease progression.

The Company is continuing to recruit additional patients into the extended 8mg dose cohort.

Six patients are currently on long-term treatment with SCIB1.

Whilst this is a Phase 1/2 clinical study and patient numbers are relatively small, there is consistent evidence emerging from this trial that Scancell's SCIB1 ImmunoBody® therapy can produce a reduction in tumour load as well as inducing a powerful immune response in late-stage melanoma patients. When taken together with the apparent delay in disease progression and increasingly extended survival data, these results are highly encouraging and clearly warrant the continued development of SCIB1 ImmunoBody® as an important new therapeutic approach for the treatment of this disease.

SCIB2 vaccine

Our SCIB2 ImmunoBody® vaccine targets tumours expressing the NY-ESO-1 antigen. NY-ESO-1 is expressed by 18% of non-small cell lung cancer patients and by 39% of prostate and 35% of bladder cancer patients. Pre-clinical data is available to support the clinical development of SCIB2 either alone or in combination with a checkpoint inhibitor.

ImmunoBody® Patents awarded

In December 2013, a patent for Scancell's DNA ImmunoBody® platform technology was granted in Japan. Following year-end, a further patent covering the DNA ImmunoBody® platform technology was also granted in the United States. These follow the grant of counterparts in Australia and China.

The patents add to Scancell's growing body of intellectual property for its ImmunoBody® platform and are key to the protection of the Company's pipeline of ImmunoBody® vaccines

The Moditope® Technology Platform

Last year, 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 without toxicity. 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 a series of modified epitopes that overcome this limitation.

The discovery of the highly innovative Moditope® platform opens up a new approach to the development of cancer immunotherapy treatments. Whilst currently at an early stage, we believe that the potential of this novel immunotherapy platform could be considerable. Some the best targets for Moditope® are thought to be the cytoskeletal proteins; one such protein is vimentin, which is the major cytoskeletal protein found in mesenchymal cells. We will identify a lead product (Modi-1) directed against this protein target and any cancer overexpressing vimentin could be of potential therapeutic interest including lung, breast, ovarian and endometrial cancers.

Moditope® Patent published

In February 2014, the Company announced the publication of the patent application underpinning the Company's Moditope® platform. The patent application describes how the Moditope® immunotherapy platform harnesses CD4 positive T-cells to eradicate tumours and overcome self-tolerance, with no requirement for checkpoint blockade. When granted, this patent will protect the platform to at least 2033.

Share Capital – Placing and Open Offer

On 1st August 2013, the shareholders of the Company approved resolutions for; (i) the placing of 20,000,000 ordinary 0.1p shares at a price of 22.5p and (ii) an open offer to qualifying shareholders, who had not taken part in the placing, to subscribe for 8,888,888 ordinary 0.1p shares at a price of 22.5p. Following the approval of these resolutions the Company raised £6.1m, net of costs.

Ichor

Scancell signed an agreement with Ichor in July 2009 for the supply and use of the TriGrid™ device for Scancell's pre-clinical and clinical studies with SCIB1 and gives Scancell an option ('The Option') to licence TriGrid™ for commercial use on payment of certain undisclosed milestones and royalties. The Option could be exercised at any time up to July 2014. In return, Ichor was granted share options to subscribe for Scancell shares at a subscription price of 4.5p as follows: on regulatory approval to start clinical trials in the UK, 1,592,310 share options ('Tranche 1'); on starting the first Phase II clinical trial, 3,184,620 share options ('Tranche 2'); and on completing the first Phase II clinical trial, 3,184,620 share options ('Tranche 3'). Tranches 1 and 2 have already vested.

During the year, Scancell announced that it had been granted an extension of its Option to commercialise Ichor's proprietary TriGrid™ electroporation delivery system with SCIB1. Under the terms of the extension, Scancell's Option, which had been due to expire in July 2014, will be extended until July 2016. In exchange, Scancell agreed in November 2013 to waive the two year lock in period following the exercise of Tranche 1 share options (over 1,592,310 shares) that Ichor exercised.

Regulatory

In February 2014, the United States Food and Drug Administration ('FDA') granted orphan drug designation to Scancell's SCIB1 ImmunoBody® for the treatment of metastatic melanoma. Orphan drug status in the United States qualifies the development of SCIB1 for a 50% tax credit for clinical trials, a waiver of the prescription drug user fee for the drug approval procedure and a period of seven years of market exclusivity following drug approval by the FDA. During the orphan market exclusivity period, the FDA cannot approve a NDA (new drug application) or a generic drug application for the same product including the principal molecular structure features of the drug and for the same rare disease indication. This status together with our patent portfolio provides further protection for SCIB1 in our key US market.

Board of Directors

Mr Peter Allen stepped down as a Non-Executive Director on 9th May, 2014 and the Board would like to thank Peter for his work during his time on the Board. I am pleased to announce the appointment of Dr Sally Adams to the Board as Development Director from 1st May, 2014. Sally has already been working closely with the Scancell team for several years and will play an important role in the development of our ImmunoBody® and Moditope® platforms.

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

Whilst recognising the relatively early stage of the SCIB1 clinical trial, the most recent results announced at ASCO in June 2014 confirm the strength and frequency of immune response in late stage melanoma patients. The destruction of lung metastases and the apparent prolongation of survival further adds to the evidence that SCIB1 has the potential to extend lives without the burden of serious side effects. The rationale for combining SCIB1 and PD-1 blockade, confirmed in recent animal studies, is also compelling.

Our ongoing Moditope® research continues to be productive as we continue to prepare Modi-1, our lead vaccine from this platform, for clinical trials which are on schedule to start in 2016.

Cancer immunotherapy has recently become one of the most exciting areas of pharmaceutical research and development. Scancell now has two innovative technology platforms in this emerging field, both of which are expected to be of substantial interest to the increasing number of pharmaceutical companies establishing R&D programmes in the area. The Board remains dedicated to realising value for our shareholders as we continue to build upon the excellent data garnered to date.

David Evans
Chairman

CONSOLIDATED PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME STATEMENT
for the year ended 30 April 2014

	2014 £	2013 £
Development expenses	(1,677,115)	(1,452,317)
Administrative expenses	(820,105)	(731,672)
OPERATING LOSS (note 2)	(2,497,220)	(2,183,989)
Interest receivable and similar income	29,186	30,037
LOSS BEFORE TAXATION	(2,468,034)	(2,153,952)
Taxation (note 3)	245,080	-
LOSS AND TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(2,222,954)	(1,901,944)
EARNINGS PER ORDINARY SHARE (pence) (note 4)		
Continuing operations		
Basic	(1.03)p	(0.98)p
Diluted	(1.03)p	(0.98)p

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
for the year ended 30 April 2014

	Share capital £	Share Premium Account £	Share Option Reserve £	Retained earnings £	Total Equity £
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
At 1st May 2013	194,470	9,904,733	509,914	(5,516,972)	5,092,145
(Loss) for the year	-	-	-	(2,222,954)	(2,222,954)
Exercise of options	1,592	70,062	(33,605)	33,605	71,654
Share issue	28,889	6,061,481	-	-	6,090,370
Share option costs	-	-	46,049	-	46,049
At 30th April 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
as at 30 April 2014

	2014 £	2013 £
Non-current assets		
Plant and machinery	115,621	131,655
Goodwill	3,415,120	3,415,120
	3,530,741	3,546,775
Current assets		
Trade and other receivables	146,514	117,164
Tax receivables	371,366	252,000
Cash and cash equivalents	5,566,234	1,491,320
	6,084,114	1,860,484
TOTAL ASSETS	9,614,855	5,407,259
LIABILITIES		
Current Liabilities		
Trade and other payables	(537,591)	(315,114)
TOTAL LIABILITIES	(537,591)	(315,114)
NET ASSETS	9,077,264	5,092,145
SHAREHOLDERS' EQUITY		
Called up share capital	224,951	194,470
Share premium	16,036,276	9,904,733
Share option reserve	522,358	509,914
Profit and loss account	(7,706,321)	(5,516,972)
TOTAL SHAREHOLDERS' EQUITY	9,077,264	5,092,145

CONSOLIDATED CASH FLOW STATEMENT
for the year ended 30 April 2014

	2014 £	2013 £
Operating activities		
Cash generated from operations	(2,219,082)	(2,072,557)
Income taxes received	125,715	74,226
Net cash from operating activities	**(2,093,367)**	**(1,998,331)**
Investing activities		
Asset acquisition	(22,930)	(69,393)
Grant monies	5,557	-
Loan repayment	6,236	-
Finance income	17,393	30,037
Net cash used by investing activities	**6,256**	**(39,356)**

Financing activities		
Proceeds from issue of share capital	6,571,654	-
Expenses of share issue	(409,629)	-
Net cash generated from financing activities	6,162,025	-
Net increase in cash and cash equivalents	**4,074,914**	**(2,037,687)**
Cash and cash equivalents at beginning of the year	**1,491,320**	**3,529,007**
Cash and cash equivalents at end of the year	**5,566,234**	**1,491,320**

1 BASIS OF PREPARATION

These financial results do not comprise statutory accounts for the year ended 30 April 2014 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 2014.

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 OPERATING LOSS

	2014	2013
	£	£
Operating Loss is stated after charging/(crediting):		
Depreciation on tangible fixed assets	38,962	44,006
Operating lease rentals	14,056	14,056
Research and development	1,677,115	1,452,317
Auditors' remuneration – fee payable for audit of the company	6,900	6,500
Auditors' remuneration – fee payable for audit of the subsidiary company	6,900	6,500
Auditors' remuneration for non-audit services	1,200	1,350
Directors' remuneration	95,417	63,168

3 TAXATION

Analysis of the tax credit

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

	2014	2013
Current tax	£	£
UK corporation tax credits due on R&D expenditure	245,652	252,000
Adjustment to prior year	(572)	8
	245,080	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:

	2014 £	2013 £
Loss on ordinary activities before tax	(2,468,034)	(2,153,952)
Loss on ordinary activities multiplied by the small company rate of tax in the UK (20%)	(493,607)	(430,790)
Effects of:		
Disallowed expenditure	11,853	4,600
Timing differences	6,135	(2,464)
Enhanced tax relief on R&D expenditure	(248,466)	(254,731)
Reduced tax relief for losses surrendered for R&D tax credits	200,988	206,517
Prior year over provision	572	(8)
Unrelieved losses carried forward	277,445	224,868
Current tax charge/(credit)	(245,080)	(252,008)

The Group has tax losses to carry forward against future profits of approximately £8,134,000 (2013: £6,744,000).

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 £1,597,000 (2013: £1,312,000).

4 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:

	2014 £	2013 £
Earnings used in the calculation of basic earnings per share	(2,222,954)	(1,901,944)
Profit for the year from discontinued operations included in the calculation of basic earnings per share	-	-
Earnings used in calculation of basic earnings per share from continuing operations	(2,222,954)	(1,901,944)
Weighted average number of ordinary shares of 0.1p each for the calculation of basic earnings per share	216,700,004	194,469,485

Diluted earnings per share

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.

5 DELIVERY OF ACCOUNTS

The audited statutory accounts in respect of the prior year ended 30 April 2013 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.

6 AVAILABILITY OF ACCOUNTS

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