#### **Scancell Holdings plc**

# ("Scancell" or the "Company")

### Unaudited interim results for the six month period ended 31 October 2012

Scancell, the developer of therapeutic cancer vaccines based on its patented ImmunoBody® platform, is pleased to announce the interim results for the six month period ended 31 October 2012.

#### **Highlights**

- Encouraging preliminary results from Part 1 of the Phase 1/2 clinical trial for SCIB1 announced in December 2012
- First evidence that the vaccine is producing an immune response in cancer patients which may also be associated with clinical benefit
- Approval received to dose an extra group of patients with a higher, 8mg, dose of SCIB1
- Recruitment and treatment of the final patient in the second part of its Phase 1/2 clinical trial of SCIB1

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#### **CHAIRMAN'S STATEMENT**

As has been previously announced preliminary results from Part 1 of the Phase I/II clinical trials have provided the first evidence that Scancell's ImmunoBody® vaccine approach is producing an immune response in cancer patients. The Company has also announced the development of a new platform technology, Moditope™, which the directors believe could have a profound effect on the way that cancer vaccines are developed.

#### **Financial**

#### **Profit and Loss Account**

The Company made an overall operating loss for the six month period to  $31^{st}$  October 2012 of £989,981 (2011: loss of £(941,674)).

Overall the loss for the six month period was £923,020 (2011: loss £(893,404)).

#### Balance Sheet

The cash at bank at 31 October 2012 was £2,568,359 (30 April 2012: £3,529,007).

#### 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 who received at least four doses of SCIB1, four have shown a vaccine-induced T cell response to treatment. Although the study was not designed primarily to measure tumour response, one patient in the 4mg dose cohort with multiple tumour lesions at study entry had a differential response to treatment including partial or complete regression of all lung metastases. A further two patients who had all their tumours surgically removed prior to SCIB1 treatment have remained disease-free more than a year after first dosing. 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 may also be associated with clinical benefit. In view of the positive results and minimal side effects seen with the 4mg dose the Company intends to evaluate an 8mg dose in parallel with Part 2 of the Phase1/2 study.

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 to be 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

Three of the four patients in the 4mg cohort are still alive and one remains disease-free more than a year after starting treatment. The fourth patient progressed and died too soon after first dosing for any effect to be seen. Two out of the three patients in the 2/4mg cohort are still alive and one remains disease-free more than a year after starting treatment. The third patient died of progressive disease after 63 weeks. 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.

Two further patients on SCIB1 remain disease-free more than one year after treatment started. The first patient had a history of gradual disease progression in the six months prior to study entry, including the development of multiple tumour nodules, which were excised prior to study treatment. This patient was dosed five times with 4mg SCIB1 and had no tumour present at study entry so could not be evaluated for tumour response but is still disease-free 17 months after first dosing and 20 months after the last tumour surgery. The second patient (in the 2/4mg cohort), 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, 19 months after first dosing and 25 months after the last tumour excision. Whilst these results are promising it should be emphasised that they will have to be confirmed in larger, controlled studies in due course.

#### Immune response

All three patients in the 2/4mg dose cohort and one patient in the 4mg dose cohort produced an immune response to the melanoma specific epitopes in SCIB1. Only one of the patients in the lowest dose group showed any immune response to treatment.

Immune response was measured by peptide-specific proliferation that was at least twice the background control at each time point and at least twice the pre-treatment control value on two or more of the six time points measured. The patient with the differential clinical response was also assessed using a cultured enzyme-linked immunosorbent (ELISPOT) assay and made a strong response to the melanoma TRP-2 antigen.

These preliminary results suggest that therapeutic vaccination with SCIB1 induces specific immune responses that may lead to clinical benefit.

In view of the positive results and minimal side effects seen with the 4mg dose, the Company has sought and obtained approval from the Gene Therapy Advisory Committee ('GTAC') and the Medicines and Healthcare products Regulatory Agency ('MHRA') Medicines Division to

dose an additional group of patients with a higher, 8 mg, dose of SCIB1. Scancell's partner Ichor Medical Systems ('Ichor') has also obtained the required parallel approval from the MHRA Devices Division for the use of Ichor's TriGrid™ electroporation delivery device to administer SCIB1 to this additional group of patients."

Assessment of an 8mg dose in a further cohort of three to six patients with evaluable disease 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. This additional cohort will be 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 tumour removed prior to treatment.

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. Two patients are currently receiving long term treatment with SCIB1.

The first patient was recruited to Part 2 of the clinical trials in May 2012 and the final patient started treatment in January 2013. Part 2 of the study is on track to be completed by the end of 2013. A successful outcome, if achieved, would confirm the potential of SCIB1 as a new cancer treatment as well as validating the ImmunoBody® platform technology.

#### Moditope™ vaccine technology platform

The Company has developed a new platform technology, Moditope<sup>TM</sup>, 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. Scancell has identified and patented a series of modified epitopes that overcome this limitation. Not only do these unique epitopes stimulate a CD4 killer T cell response, but *in vitro* tests have shown that cancer patients can produce an immune response to these epitopes.

The Moditope<sup>TM</sup> epitopes can be used to develop both DNA and peptide vaccines and could become an important component of many therapeutic vaccines in the future, both under development at Scancell and other companies.

#### **Board of Directors**

Nigel Evans resigned as a Director and Company Secretary on 11 December 2012 and has made an important contribution to Scancell over many years. In his role as Executive Chairman of the Company from 2000-2007 he played a critical role in the development of the Company at a particularly turbulent time in its history. More recently Nigel has given steadfast support to the Company both as a Board Director and as Company Secretary and the Board wishes him well in his retirement.

#### Outlook

The preliminary results for part 1 of the SCIB1 clinical trials have been extremely encouraging as they provide the first clinical endorsement for our ground breaking cancer vaccine research. During 2013 the assessment of a higher dose in patients with evaluable disease and the future assessment of immune response in part 2 of the clinical trials should provide further evidence to support the use of ImmunoBody® vaccines for the treatment of cancers.

Whilst at an early stage with the new Moditope™ technology platform, the Board is aware that the opportunities could be considerable and, with its existing ImmunoBody® technology is confident that the Company is well placed to create increasing value for shareholders.

David Evans Chairman

## Scancell Holdings plc

# Consolidated Income Statement for the six months to 31<sup>st</sup> October 2012

	Unaudited	Unaudited	Audited
	six months	six months	Year to
	31/10/2012	31/10/2011	30/04/2012
	£	£	£
Continuing operations			
Development expenses	(564,709)	(526,077)	(1,221,339)
Administrative expenses	(425,272)	(415,597)	(740,132)
OPERATING LOSS	(989,981)	(941,674)	(1,961,471)
Interest receivable and similar income	17,904	6,240	31,407
LOSS BEFORE TAXATION	(972,078)	(935,434)	(1,930,064)
Tax on loss on ordinary activities	49,058	42,030	-
LOSS FOR THE PERIOD FROM			
CONTINUING OPERATIONS	(923,020)	(893,404)	(1,930,064)
Discontinued operations			
PROFIT FOR THE PERIOD FROM			
DISCONTINUED OPERATIONS	-	-	2,487,122
PROFIT/(LOSS) FOR THE PERIOD	(923,020)	(893,404)	557,058
EARNINGS PER ORDINARY SHARE (PENCE)			
Continuing and discontinued operations			
Basic	(0.47)	(0.90)	0.30
Diluted	(0.47)	(0.90)	0.27
Continuing operations only			
Basic	(0.47)	(0.90)	(1.04)
Diluted	(0.47)	(0.90)	(1.04)
Consolidated Statement of Comprehensive Income for the period ended 31st October 2012			
Profit/(Loss) for the period	(923,020)	(893,404)	557,058

# Scancell Holdings plc Consolidated Statement of Changes in Equity for the six month period to 31<sup>st</sup> October 2012

	Share capital £	Share premium account £	Share option reserve £	Retained earnings £	Total Equity £
At 1 <sup>st</sup> May 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337
(Loss) for the period				(923,020)	(923,020)
Share option costs			12,200		12,200
At 31st October 2012	194,470	9,904,733	499,362	(4,538,048)	6,060,517
At 1st May 2011 (restated) (Loss) for the period Share issue Share option costs At 31st October 2011 (restated)	159,518 34,575 194,093	8,369,023 1,512,086 9,881,109	279,287 106,450 385,737	(4,172,086) (893,404) - (5,065,490)	4,635,742 (893,404) 1,546,661 106,450 5,395,449
At 1 <sup>st</sup> May 2011 (restated) Profit for the year Share issue Share option costs	159,518 34,952	8,369,023 1,535,710	279,287 207,875	(4,172,086) 557,058	4,635,742 557,058 1,570,662 207,875
At 30 <sup>th</sup> April 2012	194,470	9,904,733	487,162	(3,615,028)	6,971,337

# Scancell Holdings plc Consolidated Statement of Financial Position as at 31<sup>st</sup> October 2012

	Unaudited	Unaudited	Audited
	31/10/2012	31/10/2011	30/04/2012
ASSETS	£	£	£
Non-current assets			
Plant and equipment	140,092	109,157	106,267
Goodwill	3,415,120	3,415,120	3,415,120
doddwiii	3,555,212	3,524,277	3,521,387
	3,333,212	3,324,277	3,321,367
Current assets			
Trade and other receivables	152,152	144,024	131,106
Income tax assets	49,058	116,250	74,220
Cash and cash equivalents	2,568,359	1,915,276	3,529,007
	2,769,569	2,175,550	3,734,333
TOTAL ASSETS	6,324,781	5,699,827	7,255,720
LIABILITIES			
Current liabilities			
Trade and other payables	264,264	304,378	284,383
NET CURRENT ASSETS	2,505,305	1,871,172	3,449,950
NET ASSETS	6,060,517	5,395,449	6,971,337
TOTAL EQUITY			
Called up share capital	194,470	194,093	194,470
Share premium account	9,904,733	9,881,109	9,904,733
Share option reserve	499,362	385,737	487,162
Retained earnings	(4,538,048)	(5,065,490)	(3,615,028)
	6,060,517	5,395,449	6,971,337

# Scancell Holdings plc Consolidated Cash Flow Statement for the six month period to 31<sup>st</sup> October 2012

	Unaudited six months 31/10/2012	Unaudited six months 31/10/2011	Audited Year to 30/04/2012
Cook flours from an austing activities	£	£	£
Cash flows from operating activities	(000 001)	(041.674)	F2F 6F1
Operating (loss) profit for the period	(989,981) 16,559	(941,674)	525,651
Depreciation Share based payment expense	-	12,365 106,450	35,978 207.875
	12,200	100,430	207,875
Operating (loss) profit for the year before changes in working capital	(961,222)	(822,859)	769,504
(Increase) in trade and other receivables	(21,046)	(85,398)	(72,480)
(Decrease) in trade and other payables	(20,119)	182,591	162,596
Cash generated from operations	(1,002,387)	(725,666)	859,620
Income taxes received	74,220		<u>-</u>
Net cash from operating activities	(928,167)	(725,666)	859,620
Cash flows from investing activities			
Asset acquisition	(50,385)	(22,590)	(43,312)
Finance income	17,904	6,240	31,407
Net cash used by investing activities	(32,481)	(16,350)	(11,905)
Cash flows from financing activities			
Proceeds from issue of share capital	-	1,728,771	1,752,771
Expenses of share issue	-	(182,109)	(182,109)
Net cash generated from financing activities	0	1,546,662	1,570,662
Net increase/(decrease) in cash and cash equivalents	(960,648)	804,646	2,418,377
Cash and cash equivalents at beginning of the year	3,529,007	1,110,630	1,110,630
Cash and cash equivalents at end of the period	2,568,359	1,915,276	3,529,007

Scancell Holdings plc
Notes to the Interim Financial Statements
for the period to 31<sup>st</sup> October 2012

#### 1 Basis of preparation

This interim statement for the six month period to  $31^{st}$  October 2012 is unaudited and was approved by the Directors on 30th January, 2013. The financial information contained in the interim report has been prepared in accordance with the accounting policies set out in the annual report and accounts for the year ended  $30^{th}$  April 2012.

The financial information contained in the interim report does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. The financial information for the full preceding year is based on the statutory accounts for the year ended 30<sup>th</sup> April 2012, upon which the auditors, Champion Accountants LLP, issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006. The audited statutory accounts for the year ended 30 April 2012 have been lodged with the Registrar of Companies.

As permitted, this interim report has been prepared in accordance with AIM Rule 18 and not in accordance with IAS 34 "Interim Financial Reporting" therefore it is not fully in compliance with IFRS as adopted by the European Union.

#### 2 Earnings per share

Basic earnings per share, from continuing operations, is calculated by dividing the earnings attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year.

The calculations of earnings per share are based on the following losses and numbers of shares.

	6 months to 31/10/2012	6 months to 31/10/2011	Year ended 30/04/2012
Loss after taxation	(923,020)	(893,404)	(1,930,064)
Weighted average number of shares	194,469,485	101,921,210	186,184,758
Basic earnings per share	(0.47)p	(0.9)p	(1.04)p

At 31<sup>st</sup> October 2012 the Company had 194,469,485 Ordinary Shares of 0.1p in issue.

#### 3 Taxation

Taxation for the six months ended 31<sup>st</sup> October 2012 is based on the effective rates of taxation which are estimated to apply for the year ended 30<sup>th</sup> April 2013.

#### 4 Interim results

These results were approved by the Board of Directors on 30th January, 2013-. Copies of the interim report are available to the public from the Group's registered office and the Group's website, www.scancell.co.uk.