

16 September 2016

Scancell Holdings Plc
("Scancell" or the "Company")

Final Results for the year ended 30 April 2016

Landmark four year survival achieved in resected SCIB1 patients

Emerging pipeline of three products across five cancer indications

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 2016.

Highlights

- SCIB1 continues to deliver significant survival data from the Phase 1/2 clinical trial in patients with Stage III/IV melanoma
 - Currently 19 of the 20 patients with resected tumours at study entry remain alive
 - Of the 16 patients who received 2-4mg doses of SCIB1
 - Median observation time since entry is 49 months, a landmark survival milestone
 - Only two new incidences of disease progression have been recorded since December 2013
 - Of the four patients who received 8mg doses of SCIB1
 - Median observation time since entry is 18 months
 - None have progressed and none have died
 - As announced on 17 June 2016, treatment for the eight patients in the long-term continued dosing phase has been suspended due to the clinical trial supplies no longer being within the original specification
 - New SCIB1 material being manufactured to support a new study of SCIB1 in combination with a checkpoint inhibitor will also be made available to these continuation patients (subject to regulatory approval)
 - Plans for the US clinical study of SCIB1 in combination with a checkpoint inhibitor remain on track, enrolment expected to commence in Q3 2017
 - The final Clinical Study Report will be issued later this year and will support our US IND submission
- Continued progress made in development of lead product, Modi-1, from Moditope® platform
 - Enrolment for first-in-man clinical study in triple negative breast cancer, ovarian cancer and osteosarcoma expected to commence in early 2018
- Strategic collaboration with Karolinska Institutet to explore the role of citrullination in cancer, a key mechanism underpinning the Moditope® platform
- £6.2m (£5.8m net) raised through a firm placing and open offer involving both existing and new shareholders
- John Chiplin appointed Chairman
- Loss for the year of £2,583,273 (2015: loss £2,414,630)
- Group cash balance at 30 April 2016 was £6,527,435 (30 April 2015: £3,059,001)

Post Period Highlights

- Scancell's executive management team restructured to align expertise with the strategic direction outlined in fundraising
- Dr Alan Lewis appointed to Board as Non-Executive Director
- Opening of new offices in San Diego, US and Oxford, UK to support Company's growth plans

Dr John Chiplin, Executive Chairman of Scancell, said:

“We have continued to make significant progress in the period, both in terms of the maturing clinical data with SCIB1 and further scientific developments on both the ImmunoBody® and Moditope® platforms. We now have a pipeline of three products across five cancer indications and clinical success with any one of these products could transform the value of the business. The Board believes that further clinical studies could add significant value to the Company and is continuing to explore a number of funding options to ensure that the Company has the resources to progress these programmes further.

“Scancell has arrived at an exciting point in its development. We now have the opportunity to transform the business from a small UK-based and largely scientifically-based enterprise into an international force in immuno-oncology. We remain committed to driving this process forward in the US and elsewhere, and to realising the value that has been accumulating over recent years, both for the benefit of our shareholders and cancer patients.”

For Further Information:

Scancell Holdings Plc

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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. Data from the Phase 1/2 clinical trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects. In patients with resected disease there is increasing evidence to suggest that SCIB1 may delay or prevent disease recurrence.

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.

Pre-clinical data on a combination of SCIB1 or SCIB2 and checkpoint inhibition (blockade of the PD-1 or CTLA-4 immune checkpoint pathways) have shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone.

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 the Company's final results for the year ended 30 April, 2016. Over the year, we have continued to make good progress across our two proprietary immuno-oncology platforms, with a pipeline of three products across five cancer indications under development.

SCIB1 continues to deliver compelling survival data in patients with melanoma and plans for our US Phase 2b study of SCIB1 in combination with a checkpoint inhibitor remain on track. Scancell's second ImmunoBody®, SCIB2, will be developed for the treatment of non-small cell lung cancer in combination with a checkpoint inhibitor. Progress has also been made in the pre-clinical development of Modi-1 which is being prepared for clinical trials in three indications, triple negative breast cancer, ovarian cancer and osteosarcoma.

In April 2016, the Company raised £6.2m (£5.8m net proceeds) from a firm placing and open offer; the firm placing raised gross proceeds of £3.4m and the open offer £2.8m. These funds will enable the Company to:

- Secure approval of an Investigational New Drug (IND) application for the SCIB1 checkpoint inhibitor combination study in patients with melanoma;
- Manufacture a new batch of SCIB1 for the SCIB1 checkpoint inhibitor combination study and complete all preparatory work for the trial in the US;
- Prepare and file a Clinical Trial Application (CTA) in the UK for the planned Phase 1/2 clinical trial with Modi-1, manufacture the product and to complete all of the preparatory work for such a trial in the UK; and
- Strengthen the management and infrastructure of the Company from new offices in San Diego and Oxford.

Financial

Profit and Loss Account

The Group made an operating loss for the year to 30 April, 2016 of £3,043,163 (2015: loss of £2,959,995). There has been an increase of 3% in the operating loss over the past two years. The major reasons for this have been an increase in administrative expenses during the year as the Company has incurred additional corporate costs in preparing and developing opportunities within the US. This increase has been partially offset by a reduction in development expenses as a result of expenditure on manufacturing costs being incurred in 2014/15 but not in 2015/16 and reduced clinical trial costs for the current year as the SCIB1 study closed in October 2015.

Overall the loss for the year was £2,583,273 (2015: loss £2,414,630).

Balance Sheet

The cash at bank at 30 April 2016 was £6,527,435 (30 April 2015: £3,059,001) and net assets amounted to £9,992,281 (30 April 2015: £6,754,002).

Two Powerful Proprietary Platforms: ImmunoBody® and Moditope®

Scancell is exploiting the unrivalled potential of the immune system to seek out and destroy cancer using our two proprietary immuno-oncology platforms.

ImmunoBody®

Scancell's potent innovative DNA-based ImmunoBody® therapies generate ultra-high avidity T cell responses that target and eliminate cancerous tumours. Although there have been some successes, therapeutic vaccine development has been hampered by high failure rates that can in large measure be attributed to a failure to trigger the induction of the high avidity multi-targeted anti-tumour T cell responses that are required to control the disease. Pre-clinical studies have confirmed that the ImmunoBody® platform delivers killer T cell responses that are superior in magnitude to those generated by current cancer vaccines. Moreover, different T-cell epitopes can be grafted into the framework allowing for rapid customisation for the targeting of multiple tumour types.

SCIB1 melanoma vaccine

SCIB1 continues to deliver strong survival data. Currently 19 of the 20 Stage III/IV patients with resected tumours remain alive. Despite additional treatment with checkpoint inhibitors and radiation therapy one patient who first experienced disease progression in September 2013 died in April 2016. Of the 16 patients who received 2-4mg doses of SCIB1 the median observation time since entry is now 49 months - a significant survival landmark and one which suggests that SCIB1 may offer curative potential in these difficult to treat patients. Indeed there have only been two new cases of disease progression in this cohort since December 2013. Of the four patients who received 8mg doses of SCIB1, the median observation time since entry is now 18 months. None of these patients have progressed and none have died. As Dr Keith Flaherty, Prof of Medicine at Harvard Medical School commented in July of this year: "The SCIB1 overall survival and progression free survival data to date go well beyond established norms for this group of patients."

The final Clinical Study Report, which will be issued later this year, will provide safety, immunology and clinical data from all patients up to 29 October 2015 (the date of the last patient's dose in the main study) to support our US IND submission.

Following quality control analysis the Company suspended dosing with the current clinical supplies of SCIB1 as the stored drug product was no longer within its original specification. With patient safety of paramount importance, the Company concluded that the clinical supplies were no longer suitable for further use, although no new side effects have emerged. The Company has recently signed a supply agreement with a new GMP manufacturer to supply materials for a planned new study of SCIB1 in combination with a checkpoint inhibitor, which will also be made available to those patients who were receiving long term treatment before their treatment was interrupted.

Plans for the US Phase 2b study of SCIB1 in combination with a checkpoint inhibitor remain on track and enrolment is expected to commence in Q3 2017. The Principal Investigator will be Dr Keith Flaherty who will be joined by leading clinicians across the US. This study is designed to meet the need for enhanced response rates to immune checkpoint therapy which still remain unacceptably low. SCIB1 induced T cell activation provides a means to increase the immunogenicity of cancer cells and subsequently the response rate to immune checkpoint therapy. We have already shown enhanced response rates and survival times using a combination of SCIB1 and checkpoint inhibitor treatment in pre-clinical models of melanoma.

The "second generation" SCIB1 construct, SCIB1 PLUS has now been characterised and will be developed to support future clinical trials in the adjuvant indication. This will eliminate the need for HLA (human leucocyte antigen) testing before treatment and will effectively double the size of the available market for SCIB1.

SCIB2 lung cancer vaccine

SCIB2 contains multiple T cell epitopes derived from the lung cancer associated antigen NY-ESO-1. In a mouse lung cancer model, survival rates with SCIB2 were comparable to that seen with anti-PD-1 checkpoint treatment and moreover, survival rates were boosted to 100% when the checkpoint therapy was combined with SCIB2. At least 80% of patients with non-small cell lung cancer (NSCLC) fail to respond to checkpoint inhibitors as their tumours are insufficiently immunogenic. Targeted T-cell activation with SCIB2 may serve to increase the immunogenicity of lung cancers and subsequently the response rate to checkpoint therapy. We are therefore planning to conduct a US based clinical study on NY-ESO-1 NSCLC patients to assess the safety and efficacy of SCIB2 in combination with a checkpoint inhibitor. The first stages of manufacture will commence in Q4 2016 with the goal of starting enrolment early in 2018.

Moditope®

Scancell's Moditope® platform technology overcomes the immune suppression induced by tumours themselves, allowing activated T cells to seek out and kill tumour cells that would otherwise be hidden from the immune system. This is achieved by stimulating the production of CD4+ T cells using citrullinated tumour-associated peptide epitopes which overcome self-tolerance and destroy tumour cells. Pre-clinical studies have shown unprecedented anti-tumour effects that can be delivered even in the absence of checkpoint therapy.

Publication of the scientific data supporting the Moditope® platform in *Cancer Research* in December 2015 provided further endorsement of the quality of Scancell's innovative research and earlier this year we were pleased to announce a strategic collaboration with Karolinska Institutet to explore the role of citrullination in cancer, a key mechanism underpinning the Moditope® platform

Modi-1

Modi-1 is comprised of two citrullinated vimentin peptides and one citrullinated enolase peptide. Vimentin and enolase peptides are highly expressed in triple negative breast cancer, ovarian cancer and osteosarcoma. In animal models a single immunisation of Modi-1 resulted in a 100% survival rate. We are now actively planning a first-in-man clinical study to assess the safety and objective response rate of Modi-1 in all three target cancers which is expected to commence enrolment in early 2018.

Management and infrastructure changes

In May 2016, the Company made changes to the structure of Scancell's executive management team to align expertise with the strategic direction outlined in the fundraising, completed in April 2016. I have assumed the role of Executive Chairman and will be directly involved in raising the profile of the Company in the US. Dr Richard Goodfellow became CEO and Professor Lindy Durrant became Chief Scientific Officer, allowing her to focus fully on her innovative work that underpins the Company's novel technology platforms. In order to support the Company's ambitious US growth plans, an office has been opened in San Diego and Dr Alan Lewis, who is based in the US has recently joined the Board as a non-executive director. Alan brings a wealth of industry experience, both commercially and financially and has extensive experience in drug discovery and development. In addition, we have opened an office on the Oxford Science Park from which all UK development activities will henceforth be coordinated.

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

Outlook

The Company has made significant progress during the course of the past year, both in terms of the maturing clinical data with SCIB1 and further scientific developments on both the ImmunoBody® and Moditope® platforms. We now have a pipeline of three products (SCIB1, SCIB2, Modi-1) across five cancer indications (melanoma, lung, breast, ovarian cancer and osteosarcoma) and clinical success with any one of these products could transform the value of the business. The Board therefore believes that further clinical studies could add significant value to the Company and is continuing to explore with its advisors a number of funding options to ensure that the Company has the resources to progress these programmes further.

Scancell has arrived at an exciting point in its development. We now have the opportunity to transform the business from a small UK based and largely scientifically based enterprise into an international force in immuno-oncology. I remain committed to driving this process forward in the US and elsewhere, and to realising the value that has been accumulating over recent years, both for the benefit of our shareholders and cancer patients.

John Chiplin
Chairman

**CONSOLIDATED PROFIT OR LOSS AND OTHER
COMPREHENSIVE INCOME STATEMENT
FOR THE YEAR ENDED 30 APRIL 2016**

	2016 £	2015 £
Development expenses	(2,009,046)	(2,118,366)
Administrative expenses	(1,034,117)	(841,629)
OPERATING LOSS (note 2)	(3,043,163)	(2,959,995)
Interest receivable and similar income	13,552	131,513
LOSS BEFORE TAXATION	(3,029,611)	(2,828,482)
Taxation (note 3)	446,338	413,852
LOSS AND TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(2,583,273)	(2,414,630)
EARNINGS PER ORDINARY SHARE (pence) (note 4)		
<i>Continuing operations</i>		
Basic	(1.14)p	(1.07)p
Diluted	(1.14)p	(1.07)p

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
for the year ended 30th April 2016**

	Share Capital £	Share Premium £	Share Option £	Retained Earnings £	Total £
Balance 1st May 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264
Loss for the year				(2,414,630)	(2,414,630)
Share option charge			91,368		91,368
Balance 30 April 2015	224,951	16,036,276	613,726	(10,120,951)	6,754,002
Share issue	36,607	6,186,653			6,223,260
Expenses of issue		(437,634)			(437,634)
Loss for the year				(2,583,273)	(2,583,273)
Share option charge			35,926		35,926
Balance at 30 April 2016	261,558	21,785,295	649,652	(12,704,224)	9,992,281

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION
as at 30 April 2016**

	2016 £	2015 £
ASSETS		
<u>Non-current assets</u>		
Plant and machinery	64,611	86,504
Goodwill	3,415,120	3,415,120
	<u>3,479,731</u>	<u>3,501,624</u>
<u>Current assets</u>		
Trade and other receivables	120,765	136,785
Tax receivables	440,001	660,504
Cash and cash equivalents	6,527,435	3,059,001
	<u>7,088,201</u>	<u>3,856,290</u>
TOTAL ASSETS	<u>10,567,932</u>	<u>7,357,914</u>
LIABILITIES		
<u>Current Liabilities</u>		
Trade and other payables	(575,651)	(603,912)
TOTAL LIABILITIES	<u>(575,651)</u>	<u>(603,912)</u>
NET ASSETS	<u>9,992,281</u>	<u>6,754,002</u>
SHAREHOLDERS' EQUITY		
Called up share capital	261,558	224,951
Share premium	21,785,295	16,036,276
Share option reserve	649,652	613,726
Profit and loss account	(12,704,224)	(10,120,951)
TOTAL SHAREHOLDERS' EQUITY	<u>9,992,281</u>	<u>6,754,002</u>

**CONSOLIDATED CASH FLOW STATEMENT
for the year ended 30 April 2016**

	2016 £	2015 £
Operating activities		
Cash generated from operations	(2,997,585)	(2,763,460)
Income taxes received	666,841	124,713
Net cash from operating activities	(2,330,744)	(2,638,747)
Investing activities		
Grant monies	9,776	64,668
Loan repayment	-	49,725
Finance income	3,776	17,121
Net cash used by investing activities	13,552	131,514
Financing activities		
Proceeds from issue of share capital	6,223,260	-
Expenses of share issue	(437,634)	-
Net cash generated from financing activities	5,785,626	-
Net increase in cash and cash equivalents	3,468,434	(2,507,233)
Cash and cash equivalents at beginning of the year	3,059,001	5,566,234
Cash and cash equivalents at end of the year	6,527,435	3,059,001

NOTES TO THE FINANCIAL INFORMATION
For the year ended 30 April 2016

1 BASIS OF PREPARATION

These financial results do not comprise statutory accounts for the year ended 30 April 2016 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 2016.

The financial statements have been prepared on the going concern basis on the grounds that the directors have reviewed the funding available and the group's cash flow forecast and are content that sufficient resources are available to enable the group to continue in operation for at least twelve months from the date of approval of these accounts.

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

	2016 £	2015 £
Operating Loss is stated after charging/(crediting):		
Depreciation on tangible fixed assets	21,893	29,117
Operating lease rentals	12,500	14,523
Research and development	2,009,046	2,118,366
Auditors' remuneration – fee payable for audit of the company	8,250	7,250
Auditors' remuneration – fee payable for audit of the subsidiary company	10,775	7,250
Auditors' remuneration for non-audit services	1,500	1,260
Directors' remuneration	330,448	150,413
	<u>446,338</u>	<u>413,852</u>

3 TAXATION

Analysis of the tax credit

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

	2016 £	2015 £
Current tax		
UK corporation tax credits due on R&D expenditure	440,001	422,976
Adjustment to prior year	6,337	(9,124)
	<u>446,338</u>	<u>413,852</u>

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:

	2016 £	2015 £
Loss on ordinary activities before tax	<u>(3,029,611)</u>	<u>(2,828,482)</u>
Loss on ordinary activities multiplied by the small company rate of tax in the UK (20%)	(605,922)	(565,696)
Effects of:		
Disallowed expenditure	8,733	20,028
Timing differences	7,777	9,010

Enhanced tax relief on R&D expenditure	(343,593)	(327,849)
Reduced tax relief for losses surrendered for R&D tax credits	166,897	160,439
Prior year over provision	(6,337)	9,124
Unrelieved losses carried forward	326,107	281,092
Current tax (credit)	<u>(446,338)</u>	<u>(413,852)</u>

The Group has tax losses to carry forward against future profits of approximately £11,180,000 (2014: £9,575,000)

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 the prevailing rate of tax when the timing differences are expected to reverse is £1,888,000 (2015: £1,894,300).

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:

	2016 £	2015 £
Earnings used in the calculation of basic earnings per share	(2,583,273)	(2,414,630)
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	<u>(2,583,273)</u>	<u>(2,414,630)</u>
Weighted average number of ordinary shares of 0.1p each for the calculation of basic earnings per share	<u>227,558,335</u>	<u>224,950,683</u>

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 2015 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.

6 AVAILABILITY OF ACCOUNTS

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