

31 January 2017

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

**Interim Results for the 6 months ended 31 October 2016**

***Strong progress continues across all clinical programmes; planning to start US SCIB1 Phase 2 combination study in H2 2017***

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, announces its interim results for the 6 months ended 31 October 2016.

**Highlights:**

- Planning to commence SCIB1 Phase 2 checkpoint inhibitor combination study in H2 2017
- Continued strong survival data for patients with Stage III/IV malignant melanoma on SCIB1 Phase 1/2 clinical trial
  - 19 of 20 patients with resected disease remain alive, survival well beyond established norms
  - Of the 16 resected patients who received a 2-4mg of SCIB1 only five patients have had recurrence of their disease of whom only one has died; two patients have now survived for 5 years since starting treatment
  - Immune analysis indicates patients may benefit from up to 2 years' continuous treatment to delay or prevent recurrence
- Plans for SCIB2 ImmunoBody® Phase 1/2 clinical trial in non-small cell lung cancer in combination with a checkpoint inhibitor are progressing
- Continued good progress in development of Modi-1, our lead product from the Moditope® platform
  - Identified and validated multiple targets
  - Final phases of selecting best adjuvant to combine with Modi-1
  - First-in-man clinical studies for breast cancer, ovarian cancer and osteosarcoma anticipated to commence in 2018
  - Early feedback from the European Patent Office suggests that broad patent claims for the Moditope® platform may be allowable
- Scancell's licence to Ichor's proprietary TriGrid® electroporation delivery system extended until July 2018
- Opening of new offices in San Diego to support the Company's US growth plans, and in Oxford for its UK corporate and development activities
- Loss for the 6-month period of £1.72 million (2015: loss: £1.17 million)
- Group cash balance at 31 October 2016 was £4.5 million (30 April 2016: £6.5 million)

**Post Period Highlights:**

- Final Clinical Study Report on the SCIB1 Phase 1/2 clinical trial in patients with Stage III/IV malignant melanoma completed in December 2016 which includes safety, immunology and clinical data from patients with Stage III/IV melanoma up to 29 October 2015
- FDA pre-IND meeting scheduled 14 February 2017 for US Phase 2 SCIB1 combination study with a checkpoint inhibitor
- Collaboration with patient advocacy group, the Addario Foundation, to advance SCIB2 non-small cell lung cancer clinical studies

Dr Richard Goodfellow, CEO of Scancell, said: *“We are proud of our achievements over the last few years. Scancell now has established two cancer vaccine platforms from which we have developed three products for use in five cancer indications. In December we completed the Clinical Study Report for our lead product, SCIB1, which will be used to support the US IND submission for a checkpoint inhibitor trial, expected to begin later this year; another major milestone for the Company. We are delighted to be working with the Addario Foundation and this should help to progress our SCIB2 trial in non-small cell lung cancer. Progress continues for our Modi-1 vaccine, with first-in-man studies in breast cancer, ovarian cancer and osteosarcoma due to begin next year. 2017 is set to be an important and busy year for Scancell and the Board remains confident that these planned studies will add significant value to the Company.”*

A full copy of the announcement can be found on the Scancell website: [www.scancell.co.uk](http://www.scancell.co.uk)

#### **For Further Information:**

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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. Experimental data suggests that the high avidity T cells induced by ImmunoBody® vaccines increase expression of PDL-1 on the tumour cell surface, thereby making the tumours more sensitive to checkpoint inhibitor drugs. Re-challenging animals with tumour cells after SCIB1 treatment resulted in 100% survival suggesting that ImmunoBody® induces a powerful memory response. Such an effect has not been observed with checkpoint inhibitors.

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 interim results for the 6-month period ended 31 October 2016. During the period the Company has continued to make excellent progress on both the ImmunoBody® and Moditope® cancer vaccine platforms. The recently completed Clinical Study Report (CSR) on the SCIB1 Phase 1/2 clinical trial will be used to support the US Investigational New Drug (IND) submission for the SCIB1 plus checkpoint inhibitor trial which we are planning to start in the second half of 2017. We have partnered with one of the largest and most highly regarded patient advocacy groups in the US, The Addario Foundation, to accelerate the development of SCIB2 for the treatment of non-small cell lung cancer (NSCLC) and we have made good progress with the Moditope® patent application at the European Patent Office with the examiner indicating that most of the claims will be allowable.

### Financial

#### *Profit and Loss Account*

The Group made an overall operating loss for the 6-month period to 31 October 2016 of £2.11 million (2015: loss of £1.37 million). During the period, development expenditure has increased over the comparative 6-month period as costs of the manufacture of new SCIB1 vaccine have been incurred and additional development work has been carried out on Moditope® and SCIB2. The increase in administrative expenditure reflects increased business development activity in the UK and the USA, together with the costs of the Oxford and La Jolla offices.

Overall the loss for the 6-month period was £1.72 million (2015: loss £1.17 million).

#### *Balance Sheet*

The cash at bank at 31 October 2016 was £4,464,928 (30 April 2016: £6,527,435) and net assets amounted to £8,292,755 (30 April 2016: £9,992,281).

### ImmunoBody® platform

Scancell's ImmunoBody® immunotherapy platform uses the body's immune system to identify, attack and destroy tumours. This is achieved by enhancing the uptake and presentation of cancer antigens to harness high avidity T cell responses. 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*

The CSR on the SCIB1 Phase 1/2 clinical trial in patients with Stage III/IV malignant melanoma was completed in December 2016. The CSR includes safety, immunology and clinical data from all patients with Stage III/IV melanoma up to 29 October 2015, the date of the last patient's final dose in the main part of the study.

Currently 19 of the 20 patients with resected tumours at study entry remain alive. Of the 16 resected patients who received 2/4mg doses of SCIB1, only five patients have had a recurrence of their melanoma and only one of these patients has died. Two patients in this group have now reached their 5-year post-treatment survival time point.

Of the four resected patients who received 8mg doses of SCIB1 (recruited after lower dose cohorts), all patients remain alive. Two of these patients experienced recurrence of their melanoma in Q4 2016 following early termination of their treatment in June 2016 pending manufacture of new SCIB1 supplies. One patient had received only one further dose of SCIB1 and the other had received two doses after the end of the main study period. Immune analysis from the patients recruited earlier suggests that patients may benefit from up to two years' continuous treatment to effectively delay or prevent recurrence.

The CSR will support the Company's IND Application for SCIB1 which is anticipated to be filed with the Food and Drug Administration (FDA) as soon as possible after the pre-IND meeting scheduled for 14 February 2017.

Scancell is planning to initiate a Phase 2 checkpoint inhibitor combination study with SCIB1 in melanoma in 2017, led by Principal Investigator Dr Keith Flaherty, Director of the Termeer Center for Targeted Therapy at Massachusetts General Hospital and Associate Professor at Harvard Medical School.

The clinical study will assess the impact of adding SCIB1 to checkpoint inhibitors in patients with late stage melanoma. The aim will be to improve the objective response rates of anti-PD-1 (“checkpoint inhibitor”) monotherapy without adding additional toxicity. The study, which will enrol approximately 80 Stage III/IV metastatic melanoma patients is planned to start in the second part of 2017, with completion approximately 18 months later.

#### *Extension to Ichor commercial option*

Earlier in the year, the Company announced that it has been granted a further extension to its option to licence the commercial use of Ichor Medical Systems' ("Ichor's") proprietary TriGrid® electroporation delivery system with SCIB1, Scancell's ImmunoBody® vaccine for the treatment of melanoma.

Under the terms of the agreed extension, Scancell's licence option, which had been due to expire on 13 July 2016, has been extended until 13 July 2018.

#### *SCIB2 vaccine*

Our second ImmunoBody® vaccine, SCIB2 has been designed to be effective in over 90% of patients that overexpress the cancer antigen NY-ESO-1, including those with lung and other epithelial cancers.

The data we have generated to date with the SCIB2 ImmunoBody® suggest that it should be well tolerated and be an ideal complement to existing and emerging portfolios of checkpoint inhibitor therapies in the treatment of NSCLC. To this end, the Company has announced plans to develop its SCIB2 ImmunoBody® for the treatment of NSCLC in combination with a checkpoint inhibitor. Scancell's Board approved the decision based on the outstanding results from the SCIB1 melanoma clinical trial which extended several years beyond the original completion date due to the unexpectedly long survival times. Planning for Phase 1/2 clinical trials in NSCLC is currently underway. The successful exploitation of novel therapeutic mechanisms, such as that underlying our ImmunoBody® platform, will be critical to further improving the poor mortality rates of patients with lung cancer.

The new collaboration with the Addario Foundation in the US reflects the increasing interest in the role of cancer vaccines in general and is a resounding endorsement for the potential clinical utility of SCIB2 in particular in this difficult to treat group of patients.

#### **Moditope® platform**

Scancell's Moditope® immunotherapy platform is based on exploiting the normal immune response to stressed cells, which is largely mediated by CD4+ T cells, and harnessing this mechanism to eradicate tumours. Scancell's first target for Moditope® was vimentin – a major cytoskeletal protein found in mesenchymal cells. Many epithelial tumours switch from expression of cytokeratin to vimentin during metastasis in a process known as epithelial mesenchymal transition; this change in phenotype enables the cell to become mobile and metastasize to new locations in the body. However, the Company has now identified and validated multiple targets from the Moditope® platform, including enolase, which, together with vimentin, will form the basis for Modi-1, Scancell's first product derived from the Moditope® platform.

The value of the Moditope® platform has recently received a significant boost following notification from the European Patent Office that the examiner had indicated that most of the claims will be allowable. We therefore anticipate that the patent application will be approved with broad claims later this year.

#### *Modi-1*

The pre-clinical development of Modi-1, the lead candidate from our Moditope® platform technology is continuing to progress. Pre-clinical data suggests that Modi-1 should be effective in up to 95% of patients with triple negative breast and ovarian cancers and up to 100% of patients with osteosarcoma. The Company is in the final phases of selecting the best adjuvant to combine with Modi-1 before commencing manufacture of the vaccine for first-in-man trials which are scheduled to start in 2018.

#### **Outlook**

We are very proud of our achievements over the last few years. We now have two established cancer vaccine platforms from which we have developed three products for use in five cancer indications. Scancell's most developed cancer vaccine is its melanoma vaccine, SCIB1, for which the CSR has now been completed and we are planning to start the Phase 2 study of SCIB1, in combination with a checkpoint inhibitor in the US in the second half of 2017.

The Company is also planning a clinical study on its lung cancer vaccine, SCIB2. We believe that the importance and role of SCIB2 in the treatment of lung cancer will be considerably enhanced by the collaboration with the Addario Foundation, one of the leading lung cancer advocacy groups in the US.

A first-in-man clinical study to assess the Company's innovative Modi-1 cancer vaccine in breast cancer, ovarian cancer and osteosarcoma, is expected to commence in 2018.

The increasing attractiveness of Scancell's products and technologies to pharmaceutical companies has to a large extent occurred as a result of the renewed interest in cancer vaccines as ideal partners for the checkpoint inhibitors, which although a major advance, only work in a minority of patients. Scancell is now in the enviable position of having not one, but two disruptive technologies in immuno-oncology and the Company is currently engaged in active discussions with several companies on both platforms. Closing a significant commercial arrangement with one or more of these companies would go a long way to underpin the value of these assets.

The Board 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 Scancell has the resources to progress these programmes further.

John Chiplin  
Chairman

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

**Scancell Holdings plc**  
**Consolidated Profit or Loss and Other Comprehensive Income Statement**  
**for the 6-month period to 31 October 2016**

	Unaudited 6 months 31/10/2016 £	Unaudited 6 months 31/10/2015 £	Audited Year to 30/04/2016 £
<b>Continuing operations</b>			
Development expenses	(1,315,190)	(938,211)	(2,009,046)
Administrative expenses	(795,607)	(429,563)	(1,034,117)
<b>OPERATING LOSS</b>	<b>(2,110,797)</b>	<b>(1,367,774)</b>	<b>(3,043,163)</b>
Interest receivable and similar income	56,138	12,011	13,552
<b>LOSS BEFORE TAXATION</b>	<b>(2,054,659)</b>	<b>(1,355,763)</b>	<b>(3,029,611)</b>
Tax on loss on ordinary activities	334,095	180,800	446,338
<b>LOSS FOR THE PERIOD</b>	<b>(1,720,564)</b>	<b>(1,174,963)</b>	<b>(2,583,273)</b>
Attributable to:			
Equity holders of the parent company	<b>(1,720,564)</b>	<b>(1,174,963)</b>	<b>(2,583,273)</b>
<b>EARNINGS PER ORDINARY SHARE (PENCE)</b> Note 2			
Basic	(0.66)	(0.52)	(1.14)
Diluted	(0.66)	(0.52)	(1.14)

**Scancell Holdings plc**  
**Consolidated Statement of Changes in Equity**  
**for the 6-month period to 31 October 2016**

	Share capital £	Share premium account £	Share option reserve £	Retained earnings £	Total Equity £
	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>
At 1 May 2016	261,558	21,785,295	649,652	(12,704,224)	9,992,281
(Loss) for the period				(1,720,564)	(1,720,564)
Share option costs			21,038		21,038
At 31 October 2016	261,558	21,785,295	670,690	(14,424,788)	8,292,755
At 1 May 2015	224,951	16,036,276	613,726	(10,120,951)	6,754,002
(Loss) for the period				(1,174,963)	(1,174,963)
Share option costs			27,902		27,902
At 31 October 2015	224,951	16,036,276	641,628	(11,295,914)	5,606,941
	<i>Audited</i>	<i>Audited</i>	<i>Audited</i>	<i>Audited</i>	<i>Audited</i>
At 1 May 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 costs			35,926		35,926
At 30 April 2016	261,558	21,785,295	649,652	(12,704,224)	9,992,281

**Scancell Holdings plc**  
**Consolidated Statement of Financial Position**  
**as at 31 October 2016**

	Unaudited	Unaudited	Audited
	31/10/2016	31/10/2015	30/04/2016
	£	£	£
<b>ASSETS</b>			
<b>Non-current assets</b>			
Plant and equipment	107,473	73,250	64,611
Goodwill	3,415,120	3,415,120	3,415,120
	<u>3,522,593</u>	<u>3,488,370</u>	<u>3,479,731</u>
<b>Current assets</b>			
Trade and other receivables	111,057	103,615	120,765
Income tax assets	774,096	590,339	440,001
Cash and cash equivalents	4,464,928	1,813,718	6,527,435
	<u>5,350,081</u>	<u>2,507,672</u>	<u>7,088,201</u>
<b>TOTAL ASSETS</b>	<u>8,872,674</u>	<u>5,996,042</u>	<u>10,567,932</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	(579,919)	(389,101)	(575,651)
<b>TOTAL LIABILITIES</b>	<u>(579,919)</u>	<u>(389,101)</u>	<u>(575,651)</u>
<b>NET CURRENT ASSETS</b>	4,770,162	2,118,571	6,512,550
<b>NET ASSETS</b>	<u>8,292,755</u>	<u>5,606,941</u>	<u>9,992,281</u>
<b>TOTAL EQUITY</b>			
Called up share capital	261,558	224,951	261,558
Share premium account	21,785,295	16,036,276	21,785,295
Share option reserve	670,690	641,628	649,652
Retained earnings	(14,424,788)	(11,295,914)	(12,704,224)
	<u>8,292,755</u>	<u>5,606,941</u>	<u>9,992,281</u>



**Scancell Holdings plc**  
**Consolidated Cash Flow Statement**  
**for the 6-month period to**  
**31 October 2016**

	Unaudited 6 months 31/10/2016 £	Unaudited 6 months 31/10/2015 £	Audited Year to 30/04/2016 £
<b>Cash flows from operating activities</b>			
Operating (loss) for the period	(2,110,797)	(1,367,775)	(3,043,163)
Depreciation	11,991	13,254	21,893
Share based payment expense	21,038	27,902	35,926
Operating (loss) for the period before changes in working capital	(2,077,768)	(1,326,619)	(2,985,344)
(Increase)/decrease in trade and other receivables	9,708	33,170	16,020
(Decrease)/increase in trade and other payables	4,268	(214,810)	(28,261)
Cash generated from operations	(2,063,792)	(1,508,259)	(2,997,585)
Income taxes received	-	250,965	666,841
<b>Net cash from operating activities</b>	<b>(2,063,792)</b>	<b>(1,257,294)</b>	<b>(2,330,744)</b>
<b>Cash flows from investing activities</b>			
Asset acquisition	(54,853)	-	-
Grant monies	-	9,776	9,776
Other income	50,041	-	-
Finance income	6,097	2,235	3,776
<b>Net cash used by investing activities</b>	<b>1,285</b>	<b>12,011</b>	<b>13,552</b>
<b>Financing activities</b>			
Proceeds from issue of share capital	-	-	6,223,260
Expenses of share issue	-	-	(437,634)
	-	-	5,785,626
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(2,062,507)</b>	<b>(1,245,283)</b>	<b>3,468,434</b>
<b>Cash and cash equivalents at beginning of the year</b>	<b>6,527,435</b>	<b>3,059,001</b>	<b>3,059,001</b>
<b>Cash and cash equivalents at end of the period</b>	<b>4,464,928</b>	<b>1,813,718</b>	<b>6,527,435</b>

**Scancell Holdings plc**  
**Notes to the Interim Financial Statements**  
**for the period to 31 October 2016**

**1 Basis of preparation**

This interim statement for the 6-month period to 31 October 2016 is unaudited and was approved by the Directors on 30 January 2017. 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 April 2016.

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 April 2016, 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 2016 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 31/10/2016	6 months to 31/10/2015	Year ended 30/04/2016
Loss after taxation	(1,720,564)	(1,174,963)	(2,583,273)
Weighted average number of shares	261,558,099	224,950,683	227,558,335
Basic earnings per share	(0.66)p	(0.52)p	(1.14)p

At 31 October 2016 the Company had 261,558,099 Ordinary Shares of 0.1p in issue.

**3 Taxation**

Taxation for the 6 months ended 31 October 2016 is based on the effective rates of taxation which are estimated to apply for the year ended 30 April 2017.

**4 Interim results**

These results were approved by the Board of Directors on 30 January 2017. 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](http://www.scancell.co.uk).