

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

I am pleased to report the Company's interim results for the six-month period ended 31 October 2018. Following the placing of £6.9m (net of costs) at the end of the previous financial year, the Company started the year with further funds being raised from an open offer to shareholders which raised net proceeds of £1.1m, equalling a combined total of £8.0m. Other significant announcements during this period were:

- Confirmation of the European Patent Office granting a European Patent for the Company's Moditope® Immunotherapy platform with effect from 13 June 2018.
- In July 2018 Scancell announced the exercise of its option to licence Ichor Medical Systems' ("Ichor's") proprietary electroporation delivery system which enables Scancell to use the new TriGrid® v2.0 as the delivery system for its planned Phase 2 checkpoint inhibitor combination study with SCIB1 in patients with advanced melanoma. At the same time Ichor exercised its option over 3,184,620 shares at 4.5p each.
- Scancell extended its strategic research collaboration with the Rheumatology Unit at the Karolinska Institute Sweden.
- The Company submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for the proposed Phase 2 clinical study of SCIB1 in combination with Keytruda, in patients with advanced melanoma. Following the submission, the FDA requested additional information. We are working with Ichor to address the device-specific questions and anticipate approval of the IND in H1 2019. Regulatory submissions in the UK and operational activities in both the UK and the US have continued to ensure a rapid start to the study as soon as approvals are obtained.

## 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

In July 2018, Scancell exercised its option to a worldwide commercial licence for the use of Ichor's proprietary TriGrid® 2.0 electroporation delivery system with SCIB1.

Ichor's TriGrid® 2.0 is designed to support eventual commercial deployment and will be used to deliver the SCIB1 vaccine to patients in our planned international Phase 2 clinical study of SCIB1 in combination with a checkpoint inhibitor. Scancell has previously used Ichor's TriGrid® 1.0 delivery system in the SCIB1 Phase 1/2 clinical study in patients with Stage III/IV malignant melanoma. In this study SCIB1 was shown to have a favourable safety profile with no dose-limiting toxicities and no serious adverse events related to study drug or the delivery device. Survival with SCIB1 treatment appears superior to historical survival rates, with 14 of 16 resected patients receiving 2-4 mg doses surviving for more than five years.

An option fee has been paid to Ichor, with further milestone payments due from the start of future Phase 3 clinical trials. The Company also granted an extension of the period for exercise of the Tranche 2 share options (3,184,620 ordinary shares) issued as part payment for the licence option, which were immediately exercised by, subscribed for and allotted to Ichor, as part of the Company's exercise of the commercial licence option. Ichor has agreed to hold these Tranche 2 shares for a period of at least two years from their date of issue.

Following the submission of an IND application for the clinical study to the US FDA, the FDA responded requesting additional information, in particular with respect to Ichor's new TriGrid® 2.0 electroporation delivery system and its use in combination with SCIB1.

Scancell and Ichor are working with the FDA to provide the necessary information to enable timely initiation of the trial. In parallel, Scancell is continuing to work on the operational processes and procedures required to initiate clinical sites in the US and UK to ensure a rapid start to the study once the necessary regulatory



approval is obtained. Scancell anticipates that patient enrolment into this trial will commence in the first half of 2019.

#### SCIB2 vaccine

SCIB2, Scancell's second ImmunoBody® therapy, targets an antigen called NY-ESO-1, which is expressed on a range of solid tumours, including non-small cell lung cancer (NSCLC), oesophageal, ovarian, bladder and prostate cancers, as well as neuroblastoma, melanoma and sarcoma.

In December 2017, Scancell announced a Clinical Development Partnership with Cancer Research UK (CRUK) who will fund and sponsor a UK based Phase 1/2 clinical trial of SCIB2 in combination with a checkpoint inhibitor in patients with solid tumours, focusing on NSCLC in the first instance. The charity's Centre for Drug Development will be responsible for manufacturing the clinical trial supplies of SCIB2, conducting pre-clinical testing, and sponsoring and managing the clinical trial, including the clinical trial timelines.

This collaboration will ensure the continued development of this innovative vaccine and provides an important validation of Scancell's ImmunoBody® platform from one of the world's foremost cancer charities.

# Moditope® platform

Scancell's Moditope® is an immunotherapy platform targeting tumour associated stress-induced post-translational modifications (siPTMs) to stimulate the production of unprecedented killer T-helper cell (CD4 T-cells) responses that induce anti-tumour activity without toxicity. Moditope® vaccines comprise citrullinated or homocitrulliated tumour-associated peptide epitopes which stimulate the production of cytotoxic CD4 T-cells which identify, target and destroy the tumour cells. Pre-clinical studies have shown unprecedented anti-tumour effects can be delivered without requiring checkpoint inhibition and that enhancement of such responses can be achieved by coupling the Moditope® peptides to an adjuvant molecule, such as Amplivant, which Scancell licensed from ISA Pharmaceuticals in February 2018.

#### Modi-1

Modi-1 consists of two citrullinated vimentin peptides and one citrullinated enolase peptide. Vimentin and enolase peptides are highly expressed in triple negative breast cancer (TNBC), ovarian cancer, sarcoma as well as many other cancers. The Company has completed the key process development work to allow for the Good Manufacturing Practice (GMP) manufacture of the three Modi-1 peptides each conjugated to the Amplivant adjuvant molecule. A defined manufacturing process is a key component for CMC (Chemistry, Manufacturing and Control) regulatory submissions required to support the filing of a clinical trial application (CTA) in the UK, toxicology studies and supply of the Modi-1 vaccine for tThe planned Phase 1/2 clinical study is anticipated to commence in H2 2019.

## Modi-2

Whilst Modi-1 acts by stimulating the production of CD4 T cells using citrullinated tumour-associated peptide epitopes, Modi-2 exploits a new modification, stimulating the production of cytotoxic CD4 T cells using homocitrullinated tumour-associated peptide epitopes. Whereas citrullination involves the conversion of the amino acid arginine to citrulline, the process of homocitrullination involves the conversion of lysine to homocitrulline. Scancell believes this second mechanism of action has the potential to broaden the utilisation of the Moditope® platform.

Modi-2 is currently in pre-clinical development and work is underway to characterise specific homocitrullinated peptides for clinical development that have the potential to address different cancer indications to Modi-1, including tumours with a particularly immunosuppressive environment.

The data generated to date clearly demonstrates the potential of homocitrullinated, as well as citrullinated, tumour-associated peptide epitopes to be developed for the treatment of solid cancers.

#### Collaborations

Scancell was pleased to extend its strategic research collaboration with the Rheumatology Unit at the Karolinska Institute, Sweden. The expanded agreement will explore the potential of the Moditope® platform



to develop multiple immunotherapeutic agents for a range of different cancers. Scancell's research has shown that citrullinated proteins are involved in the control of tumour growth and we believe that this expanded collaboration will help us to further develop Moditope®, not only for use in cancer vaccines, but also other cancer immunotherapy approaches including T-cell receptor (TCR) based therapeutics which is also the subject of Scancell's research collaboration with BioNTech announced in January 2018.

Earlier this month, Cancer Research UK announced the winners of its Grand Challenge award. The Grand Challenge aims to revolutionise how cancer is diagnosed, prevented and/or treated by providing international multi-disciplinary teams the freedom to evaluate novel approaches, at scale, in the pursuit of life changing discoveries. Scancell congratulates the winners of the Award and was delighted that Project Blueprint, "Eradicating Established Tumours with Unique Cancer Vaccines", a proposal submitted by the Company together with BioNTech, Genentech and ISA Pharmaceuticals, was shortlisted.

Project Blueprint was devised to investigate the potential of cancer vaccines, based on treatment with Modi-3, a product generated from Scancell's Moditope® platform, alongside vaccines targeting new mutations within individual patient tumours, for the treatment of virtually all cancers. Notwithstanding the result of the Award, Scancell and its collaboration partners remain committed to the ultimate objective of eliminating tumours by treating patients with such therapeutic vaccine approaches.

#### **Patents**

The European Patent Office granted a European Patent for the Company's Moditope® Immunotherapy platform with effect from 13 June 2018. This patent will provide broad protection for the Company's pipeline of Moditope® vaccines, including any citrullinated epitopes for the treatment of cancer, in all major European territories. This is a key patent for Scancell and endorses our work in identifying a new class of cancer vaccine capable of inducing potent immune responses to stress-induced post-translational modifications (siPTM), in this case, through citrullination of cellular proteins.

#### Corporate

In August, Kate Cornish-Bowden stepped down from her role as Non-Executive Director after seven years on the Board. Kate made an important contribution in guiding Scancell through its formative years and we thank her for her hard work and wish her all the best for the future.

Post period, Scancell announced the appointment of Dr Samantha Paston as Head of Research and Dr Adrian Parry as Head of Manufacturing. Dr Paston started in her role in mid-January and Dr Parry will start in his role on 01 February 2019. These two appointments are significant for Scancell as we expand our R&D and manufacturing capabilities in order to further advance our ImmunoBody® and Moditope® pipeline products through clinical development.

# Financial

# Profit and Loss Account

The Group made an overall operating loss for the six-month period to 31 October 2018 of £3.68 million (2017: loss of £2.39 million). During the period, development expenditure has increased over the comparative six-month period as the company prepares for the upcoming clinical trials with SCIB1 and Modi-1. The increase in administrative expenditure is largely due to a significant increase in patent costs and licence fees. The increases in patent costs reflects the Company's continued protection and extension of its intellectual property portfolio.

Overall the loss for the six-month period was £3.24 million (2017: loss £2.02 million).

#### Balance Sheet

The cash at bank at 31 October 2018 was £7,576,855 (30 April 2018: £10,303,168) and net assets amounted to £11,926,996 (30 April 2018: £13,940,950).

#### Outlook



The funds raised at the end of the previous financial year and the beginning of this period have enabled Scancell to move towards obtaining regulatory approvals for the initiation of the SCIB1 checkpoint inhibitor combination Phase 2 study in the US and UK, in addition to funding the continuing development of our Moditope® products, Modi-1 and Modi-2, and the underlying platform technology.

Patents awarded with respect to the Moditope® platform and our on-going collaborations mean that we are now well positioned to develop Moditope® based therapeutics, such as vaccines and adoptive T-cell therapies, with the potential to address the unmet need across a broad range of hard to treat cancers.

The Company's recent senior management appointments of Samantha Paston as Head of Research and Adrian Parry as Head of Manufacturing provide additional expertise to enable the transition of our products from the laboratory to the clinic.

Scancell's focus for the immediate future is to initiate the planned Phase 2 clinical study for our lead ImmunoBody®, SCIB1, and to advance our lead Moditope® vaccine, Modi-1, towards the clinic. A positive outcome from both or either of these studies should represent significant value to shareholders.

John Chiplin Chairman



# Scancell Holdings plc Consolidated Profit or Loss and Other Comprehensive Income Statement for the six-month period to 31 October 2018

	Unaudited	Unaudited	Audited
	6 months	6 months	Year to
	31/10/2018	31/10/2017	30/04/2018
	£	£	£
Continuing operations			
Development expenses	(1,842,005)	(1,532,292)	(2,855,264)
Administrative expenses	(1,834,848)	(854,756)	(2,086,536)
OPERATING LOSS	(3,676,853)	(2,387,048)	(4,941,800)
Interest receivable and similar income	7,395	250	2,753
LOSS BEFORE TAXATION	(3,669,458)	(2,386,798)	(4,939,047)
Tax on loss on ordinary activities	424,992	362,819	744,538
LOSS FOR THE PERIOD	(3,244,466)	(2,023,979)	(4,194,509)
Attributable to:			
Equity holders of the parent company	(3,244,466)	(2,023,979)	(4,194,509)
EARNINGS PER ORDINARY SHARE (PENCE) Note 2			
Basic	(0.84)	(0.65)	(1.34)
Diluted	(0.84)	(0.65)	(1.34)



# Scancell Holdings plc Consolidated Statement of Changes in Equity for the six-month period to 31 October 2018

		Share	Share		
	Share	premium	option	Retained	Total
	capital	account	reserve	earnings	Equity
	£	£	£	£	£
	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
At 1 May 2018	374,469	33,374,624	635,569	(20,443,712)	13,940,950
Share issue	10,143	1,206,998			1,217,141
Expenses of issue		(83,057)			(83,057)
Exercise of share options	3,185	140,123			143,308
(Loss) for the period				(3,244,466)	(3,244,466)
Share option costs			(46,880)		(46,880)
At 31 October 2018	387,797	34,638,688	588,689	(23,688,178)	11,926,996
At 1 May 2017	261,558	21,785,295	701,675	(16,249,203)	6,499,325
Share issue	50,500	4,999,500			5,050,000
Expenses of issue		(323,984)			(323,984)
(Loss) for the period				(2,023,979)	(2,023,979)
Share option costs			4,650		4,650
At 31 October 2017	312,058	26,460,811	706,325	(18,273,182)	9,206,012
	Audited	Audited	Audited	Audited	Audited
At 1 May 2017	261,558	21,785,295	701,675	(16,249,203)	6,499,325
Share issue	112,911	12,426,409			12,539,320
Expenses of issue		(837,080)			(837,080)
(Loss) for the period				(4,194,509)	(4,194,509)
Share option costs			(66,106)		(66,106)
At 30 April 2018	374,469	33,374,624	635,569	(20,443,712)	13,940,950



# Scancell Holdings plc Consolidated Statement of Financial Position as at 31 October 2018

	Unaudited	Unaudited	Audited
	31/10/2018 £	31/10/2017 £	30/04/2018 £
ASSETS			
Non-current assets			
Plant and equipment	63,837	80,966	76,910
Goodwill	3,415,120	3,415,120	3,415,120
	3,478,957	3,496,086	3,492,030
Current assets			
Trade and other receivables	164,723	107,620	97,304
Income tax assets	1,169,530	1,111,656	744,538
Cash and cash equivalents	7,576,855	4,961,865	10,303,168
	8,911,108	6,181,141	11,145,010
TOTAL ASSETS	12,390,065	9,677,227	14,637,040
LIABILITIES			
Current liabilities			
Trade and other payables	(463,069)	(471,215)	(696,090)
TOTAL LIABILITIES	(463,069)	(471,215)	(696,090)
NET CURRENT ASSETS	8,448,039	5,709,926	10,448,920
NET ASSETS	11,926,996	9,206,012	13,940,950
TOTAL EQUITY			
Called up share capital	387,797	312,058	374,469
Share premium account	34,638,688	26,460,811	33,374,624
Share option reserve	588,689	706,325	635,569
Retained earnings	(23,688,178)	(18,273,182)	(20,443,712)
	11,926,996	9,206,012	13,940,950



# Scancell Holdings plc Consolidated Cash Flow Statement for the six-month period to 31 October 2018

	Unaudited	Unaudited	Audited
	6 months	6 months	Year to
	31/10/2018	31/10/2017	30/04/2018
	£	£	£
Cash flows from operating activities			
Operating (loss) for the period	(3,676,853)	(2,387,048)	(4,941,800)
Depreciation	13,072	12,143	27,612
Share based payment expense	(46,880)	4,650	(66,106)
Operating (loss) for the period before changes			
in working capital	(3,710,661)	(2,370,255)	(4,980,294)
(Increase)/decrease in trade and other receivables	(67,419)	(5,817)	4,499
(Decrease)/increase in trade and other payables	(233,020)	(60,664)	164,211
Cash generated from operations	(4,011,100)	(2,436,736)	(4,811,584)
Income taxes received		-	748,837
Net cash from operating activities	(4,011,100)	(2,436,736)	(4,062,747)
Cash flows from investing activities			
Asset acquisition			(11,413)
Other income	-	-	(11,413)
Finance income	7,395	250	2,753
Net cash used by investing activities	7,395	250	(8,660)
Net cash used by investing activities	1,595	250	(0,000)
Financing activities			
Proceeds from issue of share capital	1,360,449	5,050,000	12,539,320
Expenses of share issue	(83,057)	(323,984)	(837,080)
	1,277,392	4,726,016	11,702,240
Net increase/(decrease) in cash and cash	(2.726.212)	2 200 520	7 620 922
equivalents	(2,726,313)	2,289,530	7,630,833
Cash and cash equivalents at beginning of the year	10,303,168	2,672,335	2,672,335
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Cash and cash equivalents at end of the period	7,576,855	4.961,865	10,303,168



# Scancell Holdings plc Notes to the Interim Financial Statements for the six-month period to 31 October 2018

# 1 Basis of preparation

This interim statement for the six-month period to 31 October 2018 is unaudited and was approved by the Directors on 30 January 2019. 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 2018.

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 2018, 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 2018 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 31/10/2018	6 months to 31/10/2017	Year ended 30/04/2018
Loss after taxation	(3,244,466)	(2,023,979)	(4,194,509)
Weighted average number of shares	385,822,703	310,115,790	312,726,405
Basic earnings per share	(0.84)p	(0.65)p	(1.34)p

At 31 October 2018 the Company had 387,796,556 Ordinary Shares of 0.1p in issue.

#### 3 Taxation

Taxation for the six months ended 31 October 2018 is based on the effective rates of taxation which are estimated to apply for the year ended 30 April 2019.

#### 4 Interim results

These results were approved by the Board of Directors on 30 January 2019. Copies of the interim report are available to the public from the Group's registered office and the Group's website, <a href="https://www.scancell.co.uk">www.scancell.co.uk</a>.