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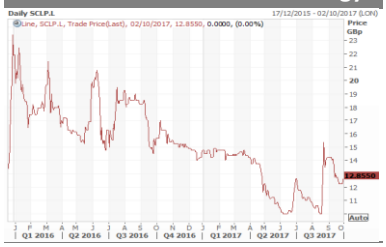
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	SCLP
Price (p)	12.5
12m High (p)	17.9
12m Low (p)	9.7
Shares (m)	312.1
Mkt Cap (£m)	39.0
EV (£m)	31.6
Free Float*	78%
Market	AIM

**As defined by AIM Rule 26*

Description

Scancell is a clinical-stage company focused on the discovery and development of two proprietary immunotherapy platforms with the potential to be used as therapeutic cancer vaccines.

Company information	
Exec Chairman	John Chiplin
CEO	Richard Goodfellow
CSO	Prof. Lindy Durrant
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US Office	+1 858 900 2646
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Key shareholders	
Directors	6.0%
Calculus Capital	16.1%
Share Nominees	7.8%
Hargreaves Lansdown	7.2%
Barclayshare Nominees	5.8%
Legal & General	5.1%

Next event	
10 Oct	AGM
1Q-18	US IND US Ph II SCIB1+CPI
1H-18	SCIB1 Phase II
2018	File CTA Modi-1Phase I/II

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Scancell Holdings

Preparing for next clinical studies

Scancell is a clinical stage pharmaceutical company developing two distinct flexible cancer immunotherapy platforms, each with broad applications. ImmunoBody is a DNA vaccine which stimulates high avidity anti-tumour T-cells for use as a monotherapy or in combination with checkpoint inhibitors. Moditope targets modified antigens and stimulates powerful anti-tumour T-cell responses for use in advanced and hard-to-treat cancers. Both platforms are targeting multi-billion dollar markets. Results provided an update on clinical studies and future plans to progress both platforms to the next development stage.

- **Strategy**: Scancell is developing two proprietary immuno-oncology platforms which target cancer cells directly to produce potent T-cell responses. Both technologies are highly flexible, potentially targeting many types of cancer. The initial aim is to complete proof-of concept trials in five different indications.

- **Results:** During fiscal 2017, management has been preparing for the next stage of clinical development of SCIB1, SCIB2 and Modi-1. In 2017, the cash burn was -£3.84m, mostly related to R&D investments, leaving the company with just under £2.7m cash subsequently boost by the £5m Placing (£4.7m net proceeds).

- **Clinical trials:** Encouraged by the exceptional results from its SCIB1 Phase I/II trial in Stage III/IV melanoma patients, Scancell has been preparing additional clinical studies, using both proprietary platforms. An IND for a Phase II trial using SCIB1 in combination with a checkpoint inhibitor is set to be submitted in 1Q'18.

- **Risks:** Scancell is an early-stage drug development company which carries a high risk that a product might fail in clinical trials. Its focus on cancer immunotherapy is an extremely exciting, but competitive, field. More capital will be required to advance its proprietary assets further along the value chain.

- **Investment summary:** Scancell is trading on an EV of £32m, compared to a cumulative investment of c.£29m to get the company where it is today, which is extremely low compared to its relevant peers. Scancell's proprietary technologies are in the 'hot' area of immuno-oncology and targeting markets of unmet medical need. Given that big pharma is willing to pay handsomely for such validated assets, we foresee considerable upside potential in the shares.

Financial summary and valuation

Year end April (£m)	2015	2016	2017	2018E	2019E	2020E
Sales	0.00	0.00	0.00	0.0	0.0	0.0
R&D investment	-2.12	-2.01	-2.77	-6.0	-9.7	-7.6
Underlying EBIT	-2.87	-3.01	-4.50	-7.9	-11.8	-10.4
Reported EBIT	-2.96	-3.04	-4.55	-8.0	-11.9	-10.4
Underlying PBT	-2.74	-2.99	-4.44	-7.9	-11.7	-10.3
Statutory PBT	-2.83	-3.03	-4.50	-7.9	-11.8	-10.4
Underlying EPS (p)	-1.03	-1.12	-1.34	-1.7	-2.1	-1.9
Statutory EPS (p)	-1.07	-1.14	-1.36	-1.7	-2.1	-1.9
Net (debt)/cash	3.06	6.53	2.67	14.9	4.4	-4.0
Capital increase	0.00	5.79	0.00	19.1	0.0	0.0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	-	-	-

Source: Hardman & Co Life Sciences Research

2017 results

Scancell is developing two distinct proprietary immunotherapy platforms, ImmunoBody and Moditope, with huge promise in the treatment of certain hard-to-treat cancers. During 2017, unprecedented survival data in patients with late stage malignant melanoma with SCIB1 provided the impetus for the next stage of clinical development. Meanwhile, more pre-clinical proof-of-concept studies have enhanced the understanding and positioning of its Moditope platform, which aims to exploit the normal immune response to stressed cells to eradicate tumours. For fiscal year 2018, the main goals are

- To start new clinical trials on SCIB1 in combination with a checkpoint inhibitor,
- Prepare for a clinical trial application (CTA) for a first-in-man study with Modi-1
- Provide funding of the next stage of its development plan.

Development highlights

SCIB1: Unprecedented results in melanoma patients

- **SCIB1:** Continued enhancement of already strong survival data from patients treated with SCIB1 in Stage III/IV melanoma patients. Of the 16 patients treated with a 2-4mg dose, seven have now survived for more than five years
- **SCIB2:** Collaboration with the Addario Lung Cancer Medical Institute (ALCMI) and the Bonnie J Addario Lung Cancer Foundation (ALCF)
- **Moditope:** The European Patent Office has indicated that most of the patent claims will be granted, paving the way for strong IP protection for the platform
- **Modi1:** Progress continues in establishing the effective target population for Modi1 in cancer patients. Scancell identified a powerful adjuvant that allows up to 100-fold lower dose with the same efficacy

Corporate highlights

- **Oxford Office:** Scancell's development and corporate activities are now managed through the Oxford head office, which was opened during the financial year
- **US Office:** Scancell opened an office in San Diego (CA) to support its presence in the US
- **NED:** Appointment of Dr Alan J Lewis as a Non-Executive Director with extensive experience in the US life sciences industry, fund raisings and drug development

Financial highlights

Financials are influenced by the preparation for the Phase II trial

- **R&D spend:** Investment in R&D was higher than forecast at £2.77m (2016: £2.01m) by £0.37m largely due to the current pre-clinical and clinical work, manufacturing of the new batch of SCIB1 and payments to trial advisors
- **Administration:** Overall spend in SG&A was lower than forecast at £1.83m (Forecast: £2.35m), excluding share based payments (non-cash item)
- **Net cash:** The cash balance at 30th April 2017 was £2.67m, £0.32m better than forecast; cash burn for the period was -£3.84m

Scancell Results 2017 – actual vs expectations					
Year ending 30th April (£m)	2016 actual	2017 actual	growth %	2017 forecast	Delta
R&D spend	-2.01	-2.77	+38%	-2.40	+0.37
Administration	-1.00	-1.83	+83%	-2.35	+0.52
EBIT loss	-3.01	-4.60	+53%	-4.75	+0.15
Tax credit	+0.44	+0.75	-	+0.33	-0.42
Net loss	**-2.58**	**-3.54**	**+37%**	**-4.30**	**-0.76**
Net cash/(debt)	6.53	2.67		2.35	+0.32

Figures may not add up exactly due to rounding
Source: Scancell; Hardman & Co Life Sciences Research

Post-period highlights

- **Placing:** Capital increase of £5.0m gross (£4.7m after expenses) realised in May 2017 to support the both platforms and preparation for the next clinical studies

Development update

Scancell has made considerable progress in moving its two proprietary platforms forward during the last 12 months. For fiscal year 2018, the main goal is to start two clinical trials, one on each immunotherapy platform.

Pipeline

Platform	Product candidate	Indication	Pre-clinical	Phase I	Phase II	Phase III	Approved
ImmunoBody	SCIB1	Melanoma	Phase I/II completed				
	SCIB1 + CPI	Melanoma					
	SCIB2	Non-small cell lung cancer					
Moditope	Modi-1	Triple –ve breast cancer Ovarian cancer Osteosarcoma					

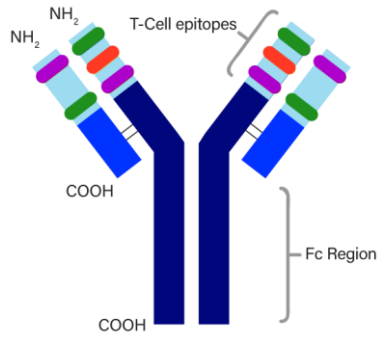
CPI = Checkpoint inhibitor
Source: Hardman & Co Life Sciences Research

To proceed with the planned clinical trial programme, management has been open with the market that further funds would be required. Therefore, upcoming newsflow will be important. For example, an Investigational New Drug (IND) application will be submitted to the FDA in early 2018 for a SCIB1 Phase II combination study with a checkpoint inhibitor.

Anticipated newsflow	
Date	News
1Q 2018	IND submission in the US for combination study with SCIB1
1H 2018	Start of the Phase II combination study with SCIB1 and a check point inhibitor
2018	File CTA for Modi-1 Phase I/II in sarcoma, breast, ovarian cancers
2019	Modi-1 Phase I/II preliminary results
2020	SCIB1 Phase II preliminary results

Source: Hardman & Co Life Sciences Research

ImmunoBody antibody



Source: Scancell

ImmunoBody

SCIB1 is delivering unprecedented survival data

Scancell continues to deliver exceptional results in patients with advanced melanoma, using its novel immunotherapy treatment SCIB1 based on its proprietary ImmunoBody platform.

Study update

SCIB-001 was a proof of concept Phase I/II trial that enrolled 35 patients with advanced melanoma (Stage III/IV). The main part of the study was completed in October 2015, with the clinical report finalised in December 2016. The excellent safety and tolerability of SCIB1 allowed the trial to be extended.

Unprecedented anti-cancer response in melanoma patients ...

Eight patients have now survived for more than 5 years since starting treatment, and four of them have not had any recurrence of the disease. To put this in context, the 5 year survival rate in stage III and stage IV melanoma patients is ca.50% and 15%, respectively.

... with 18/20 survival in resected melanoma patient since the start of the study in 2010...

- Seven patients with resected disease have reached the 5 years post-treatment survival time point
- Remarkably, one patient with unresected disease is amongst the 5 year survivors despite having had disease progression
- Of the 16 resected patients who received 2mg or 4mg doses, six have had disease recurrence, of whom two have died
- In the 4 patients in the 8mg dose arm, two experienced disease recurrence

... and with excellent safety and tolerability

Overall, of the 20 patients with resected melanoma, 90% remain alive which is well beyond established norms. The data show SCIB1 to be safe and well tolerated at all doses tested (0.4 – 8.0mg) with no serious adverse events related to SCIB1.

Phase II in combination with a checkpoint inhibitor

The US IND for a Phase II trial with SCIB1 in combination with a PD-1 Checkpoint inhibitor is scheduled for 1Q 2018

The IND application for the planned Phase II study using SCIB1 in combination with an anti PD-1 checkpoint inhibitor in the US will be submitted in 1Q 2018. This study will use the new electroporation delivery device, TriGrid 2.0 from Ichor. The FDA recommended in February 2017, that Ichor submits its Master File dossier 30-60 days prior to Scancell's own submission and this is expected to occur in mid-November. We expect that the IND application will be completed in early 2018 and, subject to sufficient funding being available for the trial, patient enrolment will commence in 1H 2018.

SCIB1 GMP manufacture

New batch of SCIB1 manufactured and validated

In June 2016, Scancell announced that the stored batch of SCIB1 was no longer within the original specification, and Scancell suspended dosing with the existing clinical supplies. An agreement was subsequently being signed with a new GMP manufacturer to supply materials and the new batch of SCIB1 has now been manufactured successfully and was release for clinical use in August 2017.

SCIB2

In parallel with the development of SCIB1, Scancell is developing a second ImmunoBody therapeutic vaccine SCIB2, for use in non-small cell lung cancer (NSCLC).

Addario Foundation collaboration

In January, Scancell announced a collaboration with the Addario Lung Cancer Medical Institute ("ALCMI") and the Bonnie J. Addario Lung Cancer Foundation ("ALCF"). To evaluate the use of Scancell's second innovative cancer vaccine SCIB2, from the ImmunoBody platform to treat non-small cell lung cancer (NSCLC).

ImmunoBody European patent granted

The European Patent Office has granted Scancell's DNA ImmunoBody platform technology patent that protects both lead candidates SCIB1 and SCIB2, and subsequent products derived from the platform. This extends global protection for the technology, with patents already granted in the US, Australia and Japan.

Moditope

Moditope represents a completely new class of potent and selective immunotherapy agent which could have a profound effect on the way that cancer immunotherapies are developed. It targets the modified self-antigens induced by cellular stress that also occurs in cancer cells.

Modi-1

Proof-of-concept trial expected to start recruiting in 2018

Scancell's lead candidate is Modi-1, a therapeutic peptide vaccine which contains a combination of two citrullinated vimentin epitopes and one citrullinated α-enolase epitope. These epitope targets are known to be highly expressed in triple negative breast cancer (90%), ovarian cancer (95%) and sarcoma (100%).

Modi-1 is expected to enter proof-of-concept trials in advanced sarcoma, triple negative breast cancer and ovarian cancer in 4Q 2018, with first data expected in 4Q 2019.

Improvement

A new adjuvant reduces the effective dose of Modi-1 by 10x to -100x

A novel adjuvant has been identified that allows the dose of Modi-1 to be reduced by 10 to 100-fold, which will allow clinically relevant doses to be administered to patients and, ultimately, have a significant positive impact on cost of product.

Clinical trial application for a Phase I/II trial by end 2018

Scancell is currently working on process development, with the aim of bringing the new version of Modi-1 into clinic trials, with a clinical trial application expected to be submitted for a proof-of-concept Phase I/II in 2018.

Financial Summary

- **SG&A** – Administrative costs increased 73% to £1.73m (2016: £1.00m) due to changes in management structure, the opening of offices in Oxford (UK) and San Diego (CA) plus a significant increase in patent costs for both platforms
- **R&D** – The increase is due to multiple factors, including planning/monitoring and GMP manufacture of the new batch of SCIB1. Our forecasts only show planned R&D based on a £16m capital raise. In reality, R&D investment is likely to continue rising in 2020, once more capital is raised
- **Cash** – Scancell has cash in the bank of £2.67m (£6.53m) on the 30th April 2017, subsequently boosted £4.7m (net) by the Placing funds in May 2017
- **Capital increases** – In addition to the Placing of £4.7m net, a subsequent £16m capital raise has been allocated in FY18

Profit & Loss account

Year end April (£m)	2015	2016	2017	2018E	2019E	2020E
Profit & Loss						
Sales	0.00	0.00	0.00	0.00	0.00	0.00
SG&A	-0.75	-1.00	-1.73	-1.90	-2.09	-2.72
R&D	-2.12	-2.01	-2.77	-6.00	-9.70	-7.65
Licensing/Royalties	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-2.87**	**-3.01**	**-4.50**	**-7.90**	**-11.80**	**-10.37**
Share based costs	-0.09	-0.04	-0.05	-0.06	-0.07	-0.08
Statutory EBIT	-2.96	-3.04	-4.55	-7.97	-11.87	-10.45
Net financials	0.13	0.01	0.05	0.05	0.06	0.03
U/l Pre-tax profit	**-2.74**	**-2.99**	**-4.44**	**-7.85**	**-11.74**	**-10.34**
Tax payable/credit	0.41	0.45	0.95	1.20	1.94	1.53
Underlying net income	-2.32	-2.55	-3.49	-6.65	-9.80	-8.81
Underlying Basic EPS (p)	**-1.03**	**-1.12**	**-1.34**	**-1.72**	**-2.10**	**-1.89**
Statutory Basic EPS (p)	-1.07	-1.14	-1.36	-1.74	-2.12	-1.91
Balance sheet						
Share capital	0.22	0.26	0.26	0.26	0.26	0.26
Reserves	6.53	9.73	6.24	18.65	8.78	-0.11
Short-term loans	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash & deposits	3.06	6.53	2.67	14.91	4.38	-4.01
Invested capital	**3.70**	**3.46**	**3.83**	**4.00**	**4.66**	**4.16**
Cashflow						
Underlying EBIT	-2.87	-3.01	-4.50	-7.90	-11.80	-10.37
Working capital	0.08	-0.01	-0.02	-0.02	-0.02	-0.02
Company op cashflow	**-2.76**	**-3.00**	**-4.49**	**-7.89**	**-11.78**	**-10.36**
Capital expenditure	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-2.62**	**-2.33**	**-3.84**	**-6.89**	**-10.53**	**-8.39**
Capital increases	0.00	5.79	0.00	19.12	0.00	0.00
Change in net debt	**-2.51**	**3.47**	**-3.86**	**12.24**	**-10.53**	**-8.39**
Opening net cash	5.57	3.06	6.53	2.67	14.91	4.38
Closing net cash	**3.06**	**6.53**	**2.67**	**14.91**	**4.38**	**-4.01**

Source: Hardman & Co Life Sciences Research

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