hardman&co

Scancell Holdings

SCIB development update

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. 2017 will concentrate on raising the necessary funds to enable the commencement of a Phase II SCIB1 trial in combination with a checkpoint inhibitor.

- **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.

- **Interims:** During the first half of fiscal 2017, management has been liaising with consultants to plan the next stage of clinical development of SCIB1. In 1H'17, the cash burn was £2.1m, 63% being spent on R&D, leaving the company with just under £4.5m cash at the end of October, reduced to an estimated £3.0m today.

- **SCIB1:** Scancell reported unprecedented survival data with SCIB1 as a monotherapy in patients with late stage resected malignant melanoma. A Phase II trial in the US using SCIB1 in combination with a checkpoint inhibitor is being prepared in order to study the synergic effects of both cancer therapies.

- **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.

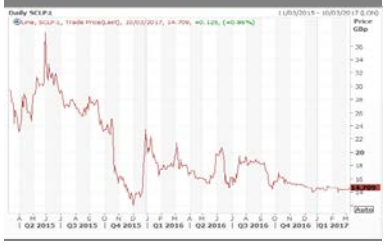
- **Investment summary:** Scancell is trading on an EV of £32m, compared to a cumulative investment of £19m to get the company where it is today, which is extremely low compared to its relevant peers. Scancell's proprietary technologies are in the 'hot' area of immuno-oncology and targeting markets of 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 Apr (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	0.00	0.00	0.00	0.0	0.0	0.0
R&D investment	-1.68	-2.00	-1.85	-2.4	-6.0	-9.7
Underlying EBIT	-2.45	-2.87	-3.00	-4.7	-8.6	-12.5
Reported EBIT	-2.50	-2.96	-3.04	-4.8	-8.6	-12.6
Underlying PBT	-2.42	-2.74	-2.99	-4.7	-8.5	-12.5
Statutory PBT	-2.47	-2.83	-3.03	-4.8	-8.6	-12.5
Underlying EPS (p)	-1.00	-1.03	-1.08	-1.6	-1.8	-2.6
Statutory EPS (p)	-1.03	-1.07	-1.10	-1.6	-1.8	-2.6
Net (debt)/cash	5.57	3.06	6.53	2.3	16.8	5.6
Capital increase	6.16	0.00	5.79	0.0	22.5	0.0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	-	-	-

Source: Hardman & Co Life Sciences Research

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	SCLP
Price (p)	14.6
12m High (p)	21.8
12m Low (p)	12.8
Shares (m)	261.8
Mkt Cap (£m)	38.2
EV (£m)	31.7
Free Float*	75%
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
US Office	+1 858 900 2646
UK HQ	+44 1865 338 069
	www.scancell.co.uk

Key shareholders

Directors	6.6%
Calculus Capital	18.5%
Share Nominees	9.3%
Hargreaves Lansdown	8.0%
Barclayshare Nominees	6.5%
Lynchwood Nominees	4.6%

Diary

Sep-16	Hardman Initiation
2H-17	SCIB1 Phase II

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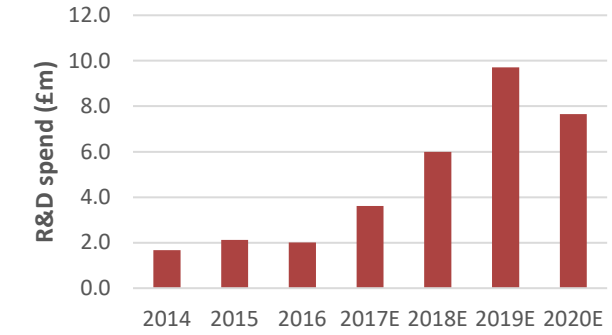
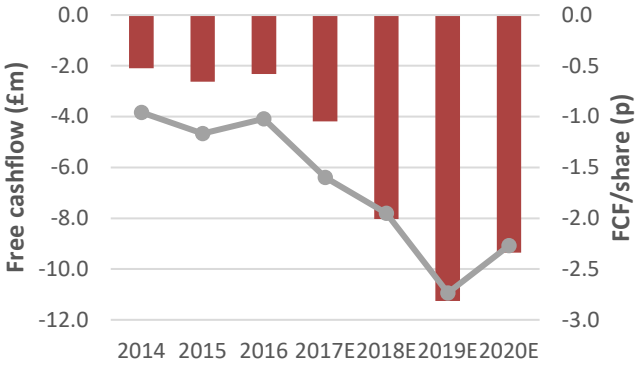
R&D investment



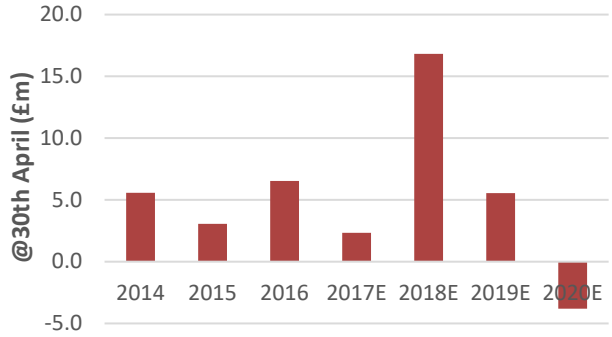
- From 2009-16, the cumulative R&D investment has been ca.£11m
- Future investment is expected to increase significantly to take both platforms further into clinical development
- A Phase II trial for SCIB1 in combination with a checkpoint inhibitor is scheduled to start in 2H 2017
- First-in-Man Modi1 to start in 2018

Free cashflow



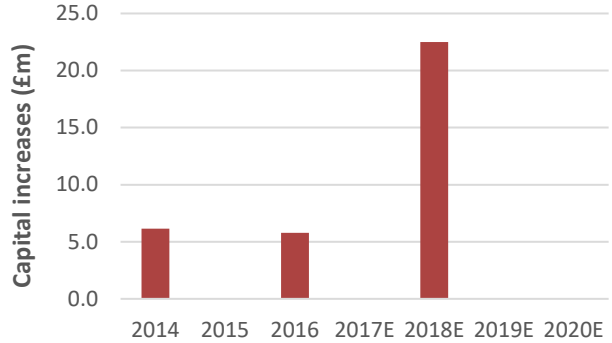
- Given that Scancell is a semi-virtual company outsourcing most of its activities, the cash burn is directly related to R&D investment and administration costs
- There will be a modest increase in costs to prepare for the upcoming clinical trial programme
- The company has opened a US office in San Diego and an office in Oxford to coordinate US and EU clinical trials respectively

Net cash/(debt)



- At 31st October 2016, Scancell had net cash of £4.5m
- Loss over the last 6 months is -£1.72m; net cash position on 30th April forecast at +£2.35m
- Given the planned clinical trial programme, we are assuming that the company raises up to $30m/£24m new capital early in the 2018 financial year

Capital increases



- The company has raised £18.9m through share issues since incorporation to get it where it is today
- The most recent capital increase was £6.2m to fund the preparation needed for the upcoming clinical trial programme for SCIB1, SCIB2 and Modi-1
- Our forecasts assume that Scancell raises ca.$30m/£24m gross new funds early in fiscal 2018

Source: Company data; Hardman & Co Life Sciences Research

2017 interim results

Scancell is developing two distinct proprietary immunotherapy platforms with huge promises in the treatment of certain cancers. The company is undergoing a transition from a single product/indication company to a broader based business developing two platforms, with three products in five cancer indications, thereby having multiple hits on goal. In 2016, unprecedented survival data in patients with late stage malignant melanoma with SCIB1, Scancell's first product derived from the ImmunoBody platform, 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. Scancell also strengthened the Board and its corporate infrastructure during the year. For 2017, the main goals are the implementation and 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, two have now survived for more than five years
- **SCIB1 + Chk1 inhibitor:** Consultation and planning for a combination trial of SCIB1 with a checkpoint inhibitor has progressed, with the study targeted to start later in calendar 2017
- **SCIB2:** Compilation of new data on SCIB2 with plans for a Phase I/II trial in a combination therapy study with a checkpoint inhibitor for non-small cell lung cancer (NSCLC)
- **Modi1:** Scancell demonstrated that Modi1 should be effective in 95% of patients with triple negative breast cancer, ovarian cancer and osteosarcoma; finalising plans for a First-in-Man study in 2018
- **Moditope:** The European Patent Office has indicated that it will grant most of the patent claims, paving the way for strong IP protection for the Moditope platform

Corporate highlights

- **US Office:** New offices in san Diego to support Scancell's presence in the US and to closely follow the US clinical trial programme
- **Oxford:** Scancell has opened an office in Oxford to support the corporate function (financial) and for coordination of all the clinical trials

Financial highlights

Financials are influenced by the preparation for the Phase II trial

- **R&D spend:** Investment in R&D was lower than anticipated largely due variances in the timing of the start of clinical trial planning and payments to trial advisors
- **Administration:** Corporate overheads increased more than expected. There was a full impact of the strengthened management team, coupled with the opening of new offices in San Diego and Oxford
- **Net cash:** The cash balance at 31st October 2016 was £4.5m, about £0.2m better than forecast; cash burn for the period was -£2.1m

Scancell interims 2017 – actual vs expectations					
Half-year to end Oct (£m)	**1H'16 actual**	**1H'17 actual**	**growth %**	**1H'17 forecast**	**Delta**
R&D spend	-0.94	-1.32	+40%	-1.50	+0.18
Administration	-0.40	-0.77	+93%	-0.70	-0.07
EBIT loss	1.34	-2.09	+56%	-2.20	+0.11
Tax credit	+0.18	+0.33	-	+0.35	-0.02
Net loss	**-1.17**	**-1.72**	**+47%**	**-1.80**	**+0.08**
Net cash/(debt)	1.81	4.46		4.30	+0.16

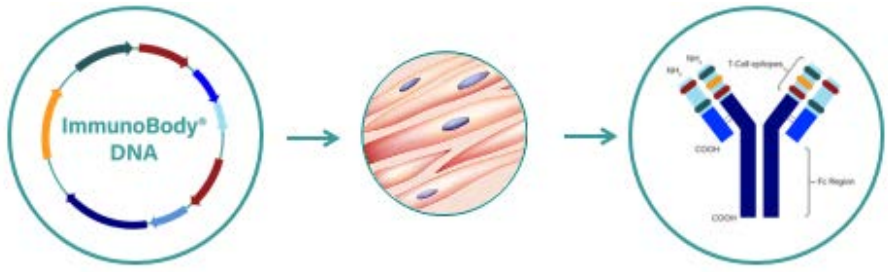
Figures may not add up exactly due to rounding
Source: Scancell; Hardman & Co Life Sciences Research

Post-period highlights

- **Addario partnership:** Scancell is collaborating with the Addario Lung Cancer Medical Institute (ALCMI) and the Bonnie J. Addario Lung Cancer Foundation (ALCF) on the use of SCIB2 from its ImmunoBody platform for the treatment of non-small cell lung cancer (NSCLC)
- **FDA pre-IND meeting:** Scancell met with the FDA on 14th February to discuss its planned Phase II trial of SCIB1 in combination with a checkpoint inhibitor as part of the normal investigational new drug (IND) process
- **TriGrid:** Scancell has extended its licensing agreement with Ichor until July 2018 for access to its proprietary TriGrid electroporation device in support of Scancell's Phase II trial programme

Scancell's immunotherapies are delivered into muscle cells of the body in a small local area of tissue using electroporation (EP) delivery technology. EP uses brief, locally applied, controlled electric pulses to create temporary and reversible permeability, or pores, in the cell membrane. Scancell uses the patented TriGrid electroporation delivery system from Ichor Medical Systems to create an electric field in a reproducible manner.

Delivery of ImmunoBody platform



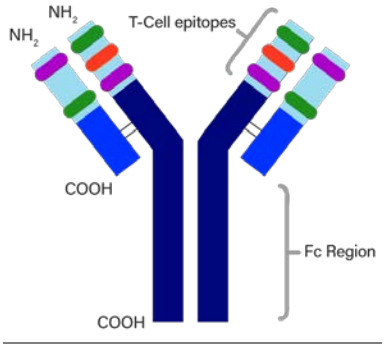
Source: Scancell

Funding

Scancell had just under £4.5m at the end of the reporting period, which we estimate to have been reduced to about £3.0m today. Our initiation report on Scancell – '*New frontiers in T-cell activation and targeting*' dated 26th September 2016 – incorporated a capital increase of $30m/£24m (gross) into our forecasts for fiscal 2017, which may be tranched. It is reasonable to assume that management will be seeking these funds in the coming few months.

SCIB plans

ImmunoBody antibody

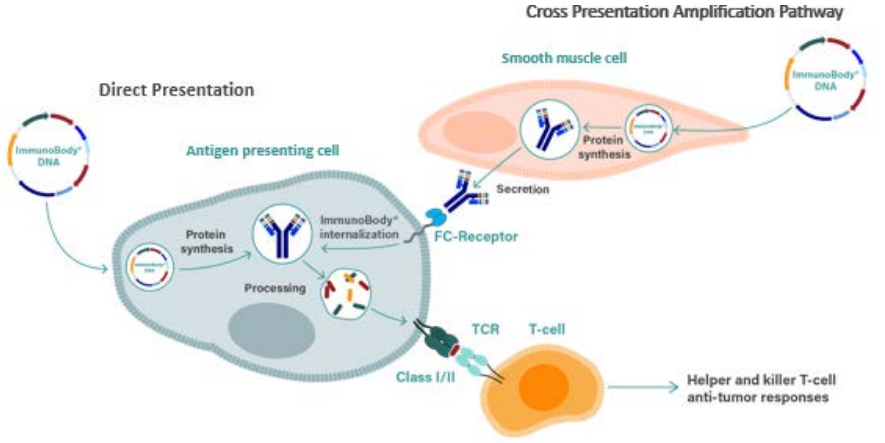


Source: Scancell

Scancell's ImmunoBody technology uses the body's own immune system to generate high avidity tumour killing T-cell responses that target and eliminate tumours. Each ImmunoBody therapeutic vaccine can be designed and customised to target a particular cancer in a highly specific manner, providing the potential for better efficacy and safety compared to more conventional approaches.

Through a combination of direct and cross presentation, the ImmunoBody platform has an exceptional dual mechanism of action. This results in amplification of the immune response, inducing high frequency, high avidity T-cells that deliver a potent anti-tumour effect, which has been shown to produce 100x greater T-cell responses.

ImmunoBody – Dual mechanism of action



Source: Scancell

Two presentation mechanisms work synergistically to produce 100x greater T-cell responses

The ImmunoBody approach positions Scancell very favourably compared to those being adopted by other companies developing cancer vaccine technologies (*details in Hardman initiation note*). For example, Argos Therapeutics[1] recently suspended its Phase III ADAPT clinical trial of Rocapuldencel-T in metastatic renal cancer due to lack of efficacy. This suggests that the vaccine provides too many epitopes resulting in a low avidity response, a key event for efficacy. Additionally, it was used as a monotherapy in addition to standard-of-care with a magnitude superior to that generated by currently approved vaccines.

SCIB1

SCIB1 is Scancell's lead product from the ImmunoBody platform

SCIB1 is Scancell's lead candidate using the ImmunoBody platform. It is a DNA plasmid that encodes just four epitopes within a human IgG1 antibody – one TRP-2 epitope and three gp100 T-cell epitopes – thereby enhancing specificity.

SCIB1 Phase I/II monotherapy

A proof-of-principle Phase I/II trial (SCIB-001) enrolled 35 patients with Stage III/IV melanoma has produced unprecedented results, which provide the foundation and stimulus to move it to the next stage of development. The main study period for this trial was completed in October 2015, with the clinical report being finalised in December 2016.

[1] http://ir.argostherapeutics.com/releasedetail.cfm?ReleaseID=1013884

Trial outcome

Unprecedented anti-cancer response in melanoma patients …

Overall, the immune responses induced were more consistent in patients with fully-resected disease, suggesting that SCIB1 may confer protection from recurrence which commonly occurs in resected melanoma patients. The data also support the view that SCIB1 would be effective in early stage melanoma patients. The excellent safety and tolerability of SCIB1 allowed the trial to be extended, with treatment for some patients for up to 5 years.

… with 19/20 survival in resected melanoma patient since the start of the study in 2010…

- In the 20 patients with resected melanoma, 19 remain alive, which is an unprecedented outcome. The patient that has died was from the 4mg dose cohort
- Of the 16 resected patients who received 2mg or 4mg doses, five have had a recurrence of their melanoma, including the patient that has died
- The median observation time of 4 years for the 16 patients with resected disease receiving 2/4mg of SCIB1 is beyond the expected norm for patients affected by melanoma
- Two patients have reached the 5 years post-treatment survival time point
- SCIB1 was safe and well tolerated in all dose regimen, from 0.4mg to 8mg with no serious adverse events recorded related to SCIB1

… and with excellent safety and tolerability at the higher dose

- In the 8mg SCIB1 cohort (recruited after lower dose cohorts), two resected patients had recurrence of their melanoma. This might be due to the temporary suspension of treatment, pending the manufacture of a new batch of SCIB1
- A dose-dependent immune response was observed, with 8mg being selected as the appropriate dose for subsequent studies
- Stronger immune responses were observed in resected patients compared to responses in patients with tumour, in addition to the high disease-free survival rate
- Clinical efficacy of SCIB1 at higher dose (4mg and 8mg) in patients with inoperable melanoma with partial response by RECIST
- Continued and broader responses were seen for up to 2 years of treatment with SCIB1, suggesting that patients may derive benefit from long term administration

Phase II study of SCIB1 with a PD-1 checkpoint inhibitor

IND application

Scancell is in active discussion with the FDA for its Phase II trial…

Results from the first study will be used to support an IND application in the US and Scancell met with the FDA on 14th February for a standard pre-IND meeting ahead of submitting its application in 2017.

…in combination with a checkpoint inhibitor

Although the SCIB1 trial showed that patients with aggressive but low tumour burden responded well to this therapy, patients with more advanced disease may benefit from using this drug in combination with a checkpoint inhibitor. Checkpoint blockade has demonstrated anti-tumour responses in approximately 20-40% of melanoma patients. However, the majority of patients are non-responders and do not stimulate a suitable immune response. These patients may benefit from an effective vaccine that stimulates high avidity T-cell responses in addition to checkpoint blockade.

Phase II clinical study

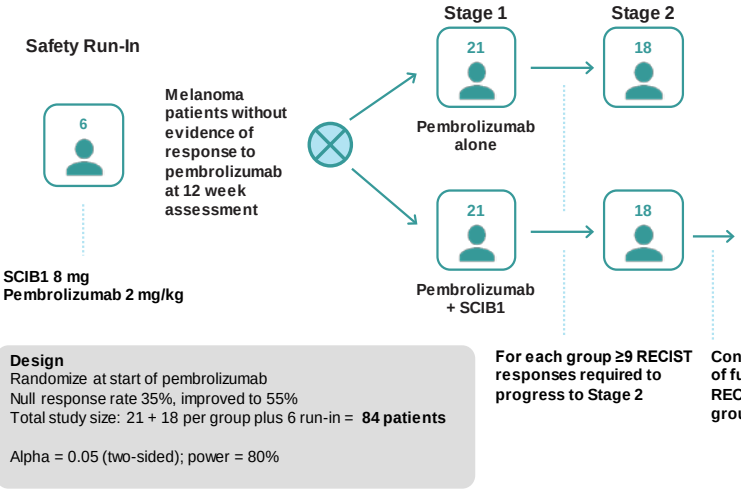
The IND application is mandatory for the Phase II study using SCIB1 in combination with a PD-1 checkpoint inhibitor (Keytruda) in the US. The study is targeted to start recruiting during the second half of 2017 and is scheduled to take about 18 months, suggesting early read-out at the end of 2018.

Targeted to start in 2H 2017…

…and aiming to recruit 80 patients with advanced metastatic melanoma

A key objective of the study will be to evaluate safety and response rates in melanoma patients administered with SCIB1 in addition to a checkpoint inhibitor. Initially, the safety and tolerability of the combination will be evaluated in a small cohort of patients and followed up at 12 weeks. The proposed parallel group study design will then evaluate the response rates to the checkpoint inhibitor with or without SCIB1 and would require approximatively 80 stage III/IV metastatic melanoma patients.

SCIB1 ± PD-1 phase IIb trial protocol



Source: Scancell

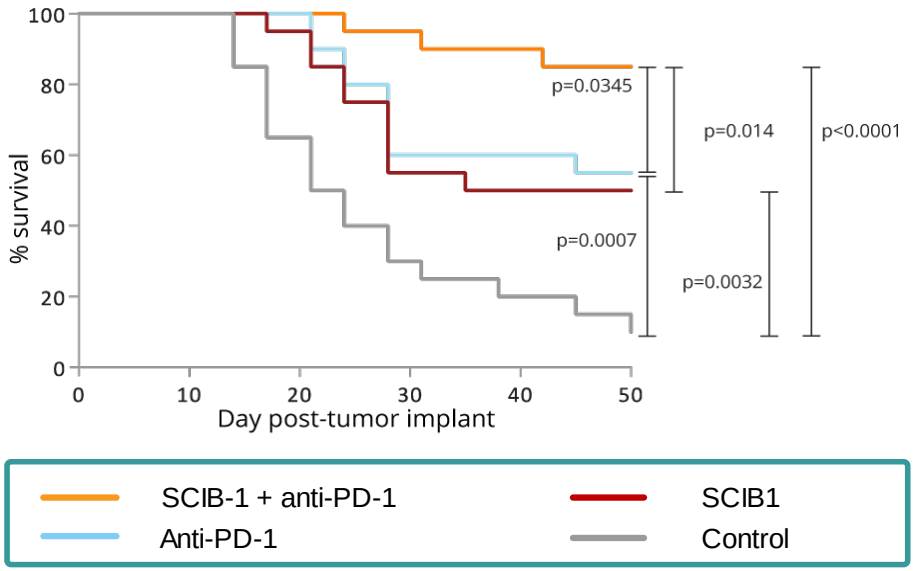
This trial will be led by Dr Flaherty, Director of the Termeer Center for Targeted Therapy at Massachusetts General Hospital and Associate Professor at Harvard Medical School. The primary end-point will be immune-related response rate; with secondary end-points including overall response rate, duration of response and progression-free survival at 6 months.

Rationale

SCIB1 enhances anti-tumour response when combined with a checkpoint inhibitor

In an *in vivo* study, vaccination of HLA-DR4 transgenic mice with SCIB1, high frequency and avidity T-cell responses were induced which resulted in survival (45%) of mice with poorly immunogenic B16F1-DR4 tumours. PD-1 blockade also resulted in increased CD8 T-cell infiltration and an anti-tumour response with 50% of mice showing long term survival.

Comparison of SCIB1 alone or with PD-1 antibody



Source: Scancell

In line with the hypothesis that PD-1/PD-L1 signalling results in inhibition of proliferation of high avidity T-cells at the tumour site, the combination of PD-1 blockade with SCIB1 vaccination enhanced the number and proliferation of the CD8 tumour infiltrate. This resulted in a potent anti-tumour response with 85% survival of the mice.

Conclusion

Checkpoint inhibitors revive interests in Cancer vaccines

Scancell is operating in a competitive arena with SCIB1, where there is a high number of Phase II and III trials currently running involving various vaccine technologies either alone or in combination with other drugs. Multiple studies conducted in man with vaccines using a number of technologies have proven to be safe and well tolerated as monotherapy or in combination with standard of care. However, they have some difficulty in showing improved efficacy when used in combination with a second therapeutic agent, as seen recently in trials from Argos Therapeutics (NASDAQ: ARGS) and Agenus (NASDAQ: AGEN). In these studies, cancer vaccines with multiple epitopes did not generate T-cells with sufficient avidity to eradicate the tumours.

In contrast, Scancell's technology is differentiated from those used by these other companies. The dual mode of action of ImmunoBody, which targets a small number of epitopes to produce a high avidity response should overcome this recurrent lack of efficacy, especially when the treatment is coupled with a checkpoint inhibitor.

SCIB2

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

SCIB2 rationale

SCIB2 uses the ImmunoBody platform to target tumours expressing the NY-ESO-1 antigen. NY-ESO-1 has restricted expression in normal cells and is over-expressed in tumour cells – non-small cell lung cancer patients 18%; prostate 39%; and bladder cancer 35%. There is also over-expression of NY-ESO-1 in oesophageal, liver, melanoma, ovarian and breast cancer. A variety of vaccination approaches targeting NY-ESO-1 have been tried using synthetic peptides, recombinant proteins and DNA encoding full length NY-ESO-1, but they have all failed to control tumour growth and induce high T-cell avidity.

SCIB2 development plan

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

A Phase I/IIa clinical trial using SCIB2 in combination with a checkpoint inhibitor, enrolling 84 non-small cell lung cancer patients, has been planned and is targeted to start recruiting during 2018. The trial will be divided in two parts:

- Dose escalation and safety assessment of SCIB2 ± checkpoint inhibitor in 18 patients
- Randomised, parallel group design of SCIB2 + checkpoint inhibitor versus checkpoint inhibitor alone in 6 patients
- Primary outcome measure: Improvement in overall response rate from 20% to 40%

Addario Foundation collaboration

In January, Scancell announced an important collaboration with the Addario Lung Cancer Medical Institute ("ALCMI") and the Bonnie J. Addario Lung Cancer Foundation ("ALCF"). Both entities are working in synergy to advance research and collaboration in genetic testing, therapeutic discoveries, targeted treatments and early detection in lung cancer. The network of investigators from 25 institutions based in the US, UK and Europe enables it to overcome barriers to collaboration, reduce development times, improve clinical trial design, reduce costs and accelerate more effective diagnostic and therapies for lung cancer patients.

With this partnership, Scancell will access the influential network of world class researchers into lung cancer as well as a dedicated research infrastructure and data system, in the expectation that it will accelerate the clinical development of SCIB2.

Financial summary

- Forecasts are broadly the same as those detailed in our initiation note. However, certain timing differences in respect of R&D suggest that the spend will be about £1.2m lower than originally forecast (from -£3.6m to -£2.4m) which drops through to the cashflow, and boosts the year-end net cash position
- Scancell is currently in discussion to raise funds with US and UK investors. The proceeds will be used to support the clinical development of both ImmunoBody and Moditope platforms in potentially five different cancer indications
- The target raise of £30m/£24m looks more likely to be concluded early in fiscal 2018 than by the end of April (fiscal 2017)

Financial summary

Year end April (£m)	2014	2015	2016	2017E	2018E	2019E
Profit & Loss						
Sales	0.00	0.00	0.00	0.00	0.00	0.00
SG&A	-0.71	-0.77	-0.75	-2.35	-2.58	-2.84
R&D	-1.45	-1.68	-2.12	-2.40	-6.00	-9.70
Licensing/Royalties	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-2.16**	**-2.45**	**-2.87**	**-4.75**	**-8.58**	**-12.54**
Share based costs	-0.02	-0.05	-0.09	-0.04	-0.05	-0.06
Statutory EBIT	-2.18	-2.50	-2.96	-4.79	-8.63	-12.60
Net financials	0.03	0.03	0.13	0.01	0.06	0.07
U/l Pre-tax profit	**-2.13**	**-2.42**	**-2.74**	**-4.74**	**-8.52**	**-12.47**
Tax payable/credit	0.25	0.25	0.41	0.48	1.20	1.94
Underlying net income	-1.88	-2.18	-2.32	-4.26	-7.32	-10.53
Underlying Basic EPS (p)	**-0.97**	**-1.00**	**-1.03**	**-1.63**	**-1.78**	**-2.56**
Statutory Basic EPS (p)	-0.98	-1.03	-1.07	-1.64	-1.79	-2.57
Balance sheet						
Share capital	0.19	0.22	0.22	0.40	0.40	0.40
Reserves	4.90	8.85	6.53	26.99	19.62	9.03
Short-term debt	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash & deposits	1.49	5.57	3.06	2.35	16.82	5.56
Invested capital	**3.60**	**3.51**	**3.70**	**25.04**	**3.20**	**3.87**
Cashflow						
Operating profit	-2.16	-2.45	-2.87	-4.75	-8.58	-12.54
Working capital	0.04	0.19	0.08	-0.01	-0.01	-0.01
Company op cashflow	**-2.07**	**-2.22**	**-2.76**	**-4.73**	**-8.57**	**-12.53**
Capital expenditure	-0.07	-0.02	0.00	0.00	0.00	0.00
Free cashflow	**-2.10**	**-2.62**	**-2.33**	**-4.18**	**-8.03**	**-11.26**
Share issues	0.00	6.16	0.00	0.00	22.50	0.00
Change in net debt	**-2.04**	**4.07**	**-2.51**	**-4.18**	**14.47**	**-11.26**
Opening net cash	1.49	5.57	3.06	6.53	2.35	16.82
Closing net cash	**5.57**	**3.06**	**6.53**	**2.35**	**16.82**	**5.56**

Source: Hardman & Co Life Sciences Research

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