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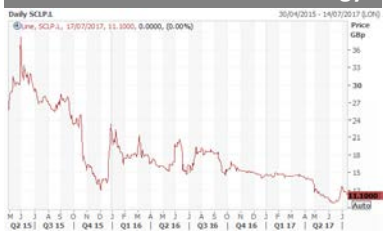
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	SCLP
Price (p)	11.1
12m High (p)	19.7
12m Low (p)	9.7
Shares (m)	312.1
Mkt Cap (£m)	34.6
EV (£m)	25.8
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	Lindy Durrant
US Office	+1 858 900 2646
UK HQ	+44 1865 338 069
	www.scancell.co.uk

Key shareholders

Directors	5.9%
Calculus Capital	15.8%
Share Nominees	9.2%
Hargreaves Lansdown	7.9%
Barclayshare Nominees	6.1%
Legal & General	5.1%

Diary

Sep-17	FY
3Q 17	SCIB1 US-IND submission
2018	US SCIB1 Phase II
2018	Modi-1 Phase I trial

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Scancell Holdings

SCIB1 – Strong survival data

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. Scancell has released new survival data for its Phase I/II in melanoma, with 69% recurrence-free survival after 3 years. Eight patients have now reached the 5 year survival, with four with no disease relapse.

- **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
- **SCIB1 survival data:** Unprecedented survival data with SCIB1 as a monotherapy in melanoma patients, with 69% recurrence-free survival at 3 years compared to 46.5% with the checkpoint inhibitor Yervoy, the current standard of care. It is still early days but these data provide reassurance for the ImmunoBody platform
- **US trial on schedule:** With the new batch of SCIB1 being manufactured, Scancell remains on schedule for the US Investigational New Drug application for the Phase II trial with melanoma patients. The SCIB1 combination study with a PD-1 checkpoint inhibitor is expected to start in 2018 with first data available in 2019
- **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's proprietary technologies are in the 'hot' area of immuno-oncology and are targeting markets of unmet medical need. Scancell is progressing two distinct technologies, spreading the risk, and 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	-2.12	-2.01	-2.4	-6.0	-9.7
Underlying EBIT	-2.45	-2.87	-3.01	-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	-1.12	-1.6	-1.8	-2.6
Statutory EPS (p)	-1.03	-1.07	-1.14	-1.6	-1.8	-2.6
Net (debt)/cash	5.57	3.06	6.53	2.3	14.0	2.7
Capital increase	6.16	0.00	5.79	0.0	19.7	0.0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	-	-	-

Source: Hardman & Co Life Sciences Research

SCIB1 – Five year survival data

SCIB1 continues to deliver 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.

The SCIB-001 study is a proof of concept Phase I/II trial that enrolled 35 patients with advanced melanoma (Stage III/IV). The main study period for this trial was completed in October 2015, with the clinical report being finalised in December 2016. In a corporate update, 8 patients have now reached the 5 years post-treatment survival time point.

Study update

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 late stage melanoma patients. The excellent safety and tolerability of SCIB1 has allowed the trial to be extended with some patients receiving treatment for over three years. Eight patients have now survived for more than 5 years since starting study treatment, and four of them have not had any recurrence of the disease:

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

- In the 20 patients with resected melanoma, 90% remain alive which is well beyond established norms. The two patients that have died were in the 4mg dose cohort. This represents one additional death since the statement in March
- Of the 16 resected patients who received 2mg or 4mg doses, six have had a recurrence of their melanoma, of whom two have died
- Eight patients have reached the 5 years post-treatment survival time point; seven in the 2/4mg arm, and one with unresected disease and subsequent disease progression
- The data provided show that SCIB1 was safe and well tolerated at all doses tested (0.4mg to 8mg) with no serious adverse events recorded that were related to SCIB1

… and with excellent safety and tolerability

Of the eight patients who were previously receiving long term continuation treatment until this was suspended in June 2016 pending the manufacture of a new batch of SCIB1:

- Three have experienced a recurrence of their melanoma
- Five remain disease-free

Five patients still disease free following long term SCIB1 injections

Remarkably, five of the eight patients who received long term continuation treatment with SCIB1 before this treatment was interrupted in June 2016, remain disease-free. Scancell does not intend to restart treatment as the effects of treatment would be difficult to interpret and to justify to the regulatory authorities.

The following table represents a comparison with the previous statement disclosed by Scancell in March 2017:

Comparing March and July statements		
	March update	**July update**
20 stage III/IV melanoma patients with resected melanoma	19 patients remain alive	18 patients remain alive
16 resected patients who received 2-4mg doses of SCIB1	5 patients have recurrence of the disease	6 patients have recurrence of the disease of whom two have died in the 4.75 year median observation time
5 year post treatment survival	2 patients	8 patients, including 1 patient with unresected disease
In the 8mg SCIB1 cohort of 4 resected patients	2 patients experienced disease recurrence	No further patients have experienced disease recurrence

Source: Scancell Holdings

Comparison with current therapy

Yervoy (ipilimumab, BMS) is currently used as a treatment in advanced melanoma patients. It is a monoclonal antibody checkpoint inhibitor targeting the protein receptor CTLA-4 that down-regulates the immune system. Marketed since 2011, sales peaked in 2014 at $1.3bn and are now already in the decline, due to the poor tolerability with many patients discontinuing treatment following serious adverse event. Hence the need of a new efficacious and tolerated treatment.

SCIB1 early results show a higher recurrence-free survival data at 3 years of 69% compared to Yervoy

With these results, an element of caution is required due to the small number of patients in the Scancell trial, but they do provide an early indication of the efficacy of SCIB1 compared to the standard of care, with the 3 year median recurrence free observation time at 69%, compared to a 46.5% median recurrence free survival for Yervoy. The median recurrence free survival, when 50% of patients have experienced a recurrence of the disease, has not been reach for SCIB1.

Yervoy – SCIB1 3 year survival comparison			
	Number of patients under treatment	**Median recurrence-free survival at 3 year**	**Stage melanoma**
Yervoy	475	46.5%	Stage III
SCIB1	16	69%	Stage III/IV

Source: Hardman & Co Life Sciences Research

The Yervoy trial enrolled 951 patients, with 475 patients to the ipilimumab arm and 476 patients to the placebo arm; the latter having 34.8% median recurrence-free survival rate. 52% of patients discontinued the treatment due to adverse events and death.

US Investigating New Drug on schedule

The US IND for a Phase II trial with SCIB1 in combination with a PD-1 Checkpoint inhibitor is on schedule

The IND application for the planned Phase II study using SCIB1 in combination with a PD-1 checkpoint inhibitor (Keytruda) in the US is on schedule to be submitted in 3Q 2017 and is expected to start in early 2018. It is scheduled to take about 18 months, suggesting first data available in 2019. The 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 new batch of SCIB1 has been manufactured successfully and will be released for use later in the year in readiness for the start of the US clinical trial.

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(Disclaimer Version 3 – Effective from May 2017)

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