SHOVEL-STOCKS

Custom Made Equity Research

Company: Scancell Holdings Plc (LON:SCLP)
Market cap: 156M GBP (1/31/22)
Price per share: 19.14 GBX
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Macro

Skin cancer is the most common of all cancers. Melanoma is a type of skin cancer that often spreads across the body to places like lymph nodes, lungs, liver or the brain. Once the condition of the cancer spreading has arisen, it is called metastatic or advanced melanoma. Even though only 1% of all skin cancers are melanoma, it still causes the majority of skin cancer related deaths. Moreover, for 2022 the American Cancer Society estimates 99,780 new melanomas to be diagnosed and 7,650 melanoma patients to die. Current treatment options for melanoma include Surgery for Melanoma Skin Cancer, Immunotherapy for Melanoma Skin Cancer, Targeted Therapy Drugs for Melanoma Skin Cancer, Chemotherapy for Melanoma Skin Cancer and Radiation Therapy for Melanoma Skin Cancer.

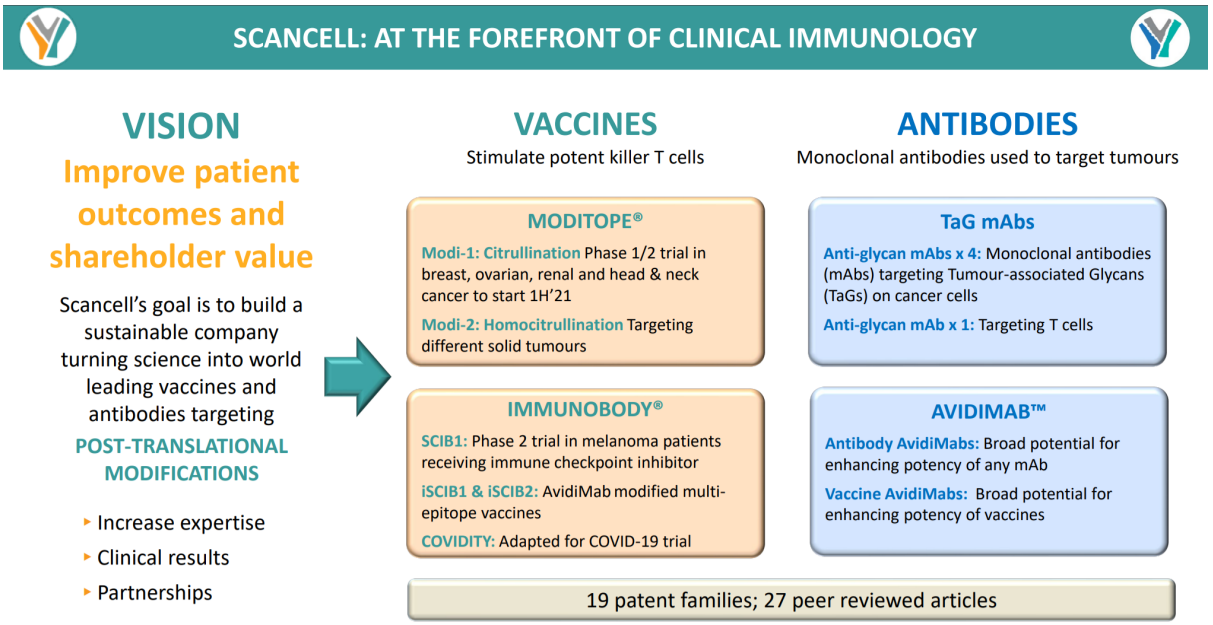
Immunotherapies have received a lot of attention in recent years by researchers and clinical stage biotech companies. Within the biopharmaceutical industry immunotherapies are the most rapidly growing and could be well worth $ 100bn by the end of 2022. These are therapies that activate the patient's own immune system in order to kill cancer cells. An example for a category of immunotherapy that is already in commercial use are checkpoint inhibitors. Checkpoint inhibitors block the binding of checkpoint proteins and thus support the T cells to kill cancer cells. Not all patients will be able to exclusively rely on their own natural defense mechanism and cannot benefit from the support provided by checkpoint inhibitors. A potential solution for these patients are therapeutic vaccines that complement checkpoint inhibitor therapies.

Scancell Plc is one of the companies developing therapeutic vaccines and has a phase 2 trial running currently targeting the melanoma indication. In addition, they are developing

a complete immunotherapy platform that uses the body's immune system to identify, attack and destroy tumors.

Company

Scancell was founded in 1997 by Professor Lindy Durrant and is a clinical-stage immuno-oncology company that is applying Prof. Durrant's research from the University of Nottingham to develop therapeutic cancer vaccines. The current pipeline is based on 19 patent families, 27 peer reviewed articles and is spread across 3 pre-clinical, plus 3 clinical trials.



Source: Scancell 2021 AGM presentation

The technology platforms developed by Scancell are focused on the treatment of multiple cancer indications. As an important part of Scancell's science is to activate T cells, the ImmunoBody platform was also used to develop a COVID-19 vaccine. The cancer vaccines developed based on the technology platforms, ImmunoBody, Moditope and AvidiMab can be used as monotherapy or in combination with checkpoint inhibitors and other agents. I will address the platforms, while discussing the current pipeline below.

Pipeline

Scancell's pipeline USP is the focus on vaccines and antibodies targeting Post-translational modifications.

"Post-translational modification (PTM) refers to the covalent and generally enzymatic modification of proteins following protein biosynthesis. Proteins are synthesized by ribosomes translating mRNA into polypeptide chains, which may then undergo PTM to form

the mature protein product. PTMs are important components in cell signaling, as for example when prohormones are converted to hormones." Wikipedia

ImmunoBody

The ImmunoBody platform activates the body's immune system to destroy tumors via T cell response. Particular cancers can be targeted in a highly specific manner, as the ImmunoBody platform is adaptable to a variety of cancer types.

SCIB 1 is Scancell's lead program currently evaluated in a phase 2 clinical study for patients with advanced melanoma who are also receiving the checkpoint inhibitor pembrolizumab (Keytruda). The study builds on an ImmunoBody stand alone phase 1/2 study that lasted 5 years and showed superior historical survival rates with 14 of 16 patients surviving for more than five years. In addition, there was no cancer recurrence for the majority of patients and no adverse effects were recorded. "The Phase 2 study is designed to assess whether the addition of SCIB1 treatment will result in an improvement in the tumor response rate, progression-free survival and overall survival in 25 patients with advanced melanoma who are also eligible for treatment with pembrolizumab". Efficacy data is expected in H1 2022.

The start of the ph 2 trial has been massively delayed by the outbreak of the Corona pandemic and was stopped for 18 months. Currently there are four clinical centers recruiting patients and the first patient has recently begun treatment.

The original plan for **SCIB 2** was a joint development as part of a partnership with BioNtech. However, BioNtech moved into another direction during the pandemic and later the financing from Cancer Research UK's Centre for Drug Development also was terminated so that Scancell had no funds to bring SCIB 2 into the clinic. Moreover, the directors are currently evaluating the idea to develop SCIB 2 into a combination therapy with SCIB 1 (iSCIB1+), to create a potentially more effective melanoma vaccine.

Covidity is a COVID-19 DNA vaccine candidate Scancell is developing together with scientists at the Centre for Research on Global Virus Infections and the new Biodiscovery Institute at the University of Nottingham, and Nottingham Trent University. The differentiation to current mRNA vaccines is that they "only induce immune responses against the spike (S) protein component of the virus. The inclusion of two protein targets, including the more highly conserved nucleocapsid (N) protein component of SARS-CoV-2, is likely to minimise the risk of mutations within the virus reducing the efficacy of the vaccine comparative to a product targeting only the S protein, which has been shown to be susceptible to mutation".

The phase 1 clinical study started on October 5th 2021 with targeted end date of June 2022. So far only one subject has been dosed in the clinical trial in South Africa, with 16 patients of 40 having been recruited to date.
As we all know from living through 24 months of the pandemic so far, the virus is mutating fast and the current trial design is only focused on the delta and beta variant, not the omicron variant. Obvious questions would be, if the trial n of 40 can be fully

recruited, if the results will even be relevant to other variants and if Scancell can progress from ph 1 to 3 fast enough to still make an impact on the pandemic?

Moditope platform:

The Moditope platform offers a new class of potent and selective immunotherapy agents based on stress-induced post-translational modifications (siPTM). It is believed that Moditope has the potential to eradicate hard to treat solid tumors.
"Examples of such modifications are citrullination, an enzyme-based conversion of arginine to citrulline, and homocitrullination, in which lysine residues are converted to homocitrulline. Expression of peptides containing these modifications have been demonstrated to induce potent CD4 cytotoxic T cells to eliminate cancer" Scancell Interim results letter.

Modi-1 will start a phase ½ clinical trial in patients with solid tumors including triple negative breast cancer, ovarian cancer, renal cancer and head and neck cancer in H1 2022 with efficacy data being received in 2023. Modi-2 is even further out with clinical development planned for sometime in 2023.

ANTIBODIES platform

Monoclonal antibodies are used to target tumors and AvidiMabs has the broad potential for enhancing potency of any mAb or vaccine.
"AvidiMab has broad potential to increase the avidity or potency of any therapeutic monoclonal antibody (mAb) including those being developed for autoimmune diseases, as well as cancer. Scancell's development pipeline includes mAbs against specific tumor-associated glycans with superior affinity and selectivity profiles, that have now been further engineered using the Company's AvidiMab technology; this confers the Scancell mAbs with the ability to directly kill tumor cells. The tumor-specific mAbs can also be used to deliver cytotoxic payload to cancer or to redirect T cells." Scancell Interim results letter.

Even though AvidiMab is still pre-clinical, in my opinion this platform holds the most potential to generate cash flows or capital injections over the other assets, as it could be a licensing opportunity to combine their antibodies with antibodies of existing therapies offered by big pharma. Scancell "intends to achieve these developments through strategic partnerships with third parties" and based on Scancell's low market cap, I could even see big pharma making a takeover bid.

Comments

Scancell's pipeline holds a lot of promise, but it is obvious that there has not been much progress during the last 20 months. During a recent interview CEO Durrant mentioned that it is hard for a small company to compete with big pharma. As an example she mentioned that they are at the bottom of the queue as a small company in terms of manufacturing vials etc.

I have written about a company (Immunitybio) following a similar approach to immunotherapies as ScanCell here and am of the impression that ImmunityBio is further

along with developing their pipeline, plus they have built up internal manufacturing capacity and have the scale to bring their vision to life.

The AvidiMab platform holds the most promise and could be an attractive asset for big pharma to acquire.

Management

The instability in Scancell's C-suite is worrisome. After Dr Richard Goodfellow (until 31 December 2017) and Dr Cliff Holloway CEO (from Jan. 2018–Aug. 2021), Professor Lindy Durrant, founder, Board Director and Chief Scientific Officer (CSO) took over the role of CEO. She is a Professor of Cancer Immunotherapy at The University of Nottingham and her connections are most likely the reason Scancell has the collaboration with University of Nottingham. Lindy Durrant has been Prof at the university for 38 years and has no commercial experience that I could find. In complex indications like cancer it is important to have a track record of getting drugs through the regulatory approval process, especially when the company in question is a microcap.
Chairman Dr. John Chiplin could fulfill the role of negotiating the deals, as he has many years' international CEO experience in listed life science companies and is Managing Director of Newstar Ventures Ltd. However, it is questionable how involved he is in Scancell, as he doesn't even list his role at Scancell on his linkedIn profile.

Currently I see no key personnel that can drive forward the company stand alone or get a compelling M&A deal over the line. In addition, as per the share structure below, the majority owner Redmile has too much voting power, while insiders have minimal ownership. A setup I am critical of, especially in microcap stocks.

Financials & Share structure

Group cash on hand: £35.6 M (Oct 31st 2021)
Liabilities: Convertible Loan Notes and Derivative Liabilities. The total amount of the CLNs which remain outstanding is £19.65 million which were originally due to be redeemed in August 2022 (£1.75 million) and November 2022 (£17.9 million).
with all outstanding CLNs held by funds managed by Redmile Group, LLC.
The maturity date has been extended to H2 2025, as stated in the deed of agreement dated Oct 28th 2021.
Cash burn: £ 4.6 M (6 months 10/31/2021)

Stock price chart

Source: TradingView

In the monthly chart above there was a noticeable increase of 78% during Feb 12th and 19th 2021 which might have been caused by hype for Scancell's covid vaccine candidate. An article published on Feb 14th 2021 mentioned Scancell and the University of Nottingham.
Before this run up in share price, the trading range was between 8.72 - 13.75 GBX and reflected a more realistic valuation based on trial progress.

Share structure
Issued share capital: 815,218,831 ordinary shares of 0.1p each, all of which are called up and fully paid.
Fully diluted shares outstanding: 1,019,693,626 (after conversion of convertible loan notes and exercise of share options).

The management team holds some options which will expire in 2023. Please find below the option price per ordinary shares, number of ordinary shares under option and expiry date:

Lindy Durrant	4.5p	3,850,000	7/30/2023
Richard Goodfellow	33.2p	3,500,000	12/31/2023
Richard Goodfellow	4.5p	2,880,000	7/30/2023

The insider ownership is too low for a risky speculation on the clinical trial success of extremely complex indications like cancer. Biotech is anyway hard and the chances of

success are not high. As of December 8th 2021 the identity and percentage holdings of significant shareholders were:

Vulpes Life Science Fund: 14.41%
Calculus Capital: 5.57%
Scancell Holdings plc directors: 1.81%

Risks

Scancell is a pre-revenue biotech microcap stock and thus comes with a high risk profile.

- Currently only one of the clinical trials is in phase 2. The rest is mainly pre-clinical and will take years to progress.
- Cancer research is very challenging and clinical trials with this indication often fail because they do not show a treatment extends survival in a meaningful way.
- Competition is further along in the clinical trial phases.
- No internal manufacturing capacity
- Low insider ownership could lead to mismanagement or hinder insiders to prevent an hostile takeover/unlucrative takeover bid.
- Further trial delays.
- Regulatory bodies requesting further studies because of low trial n.

Conclusion

While Scancell offers a pipeline filled with promising assets and their science makes sense, current conditions in the broader equity market and the bear market life sciences stocks face since Feb 2021 are major headwinds for speculative, small biotech companies. To make matters worse, the majority of pipeline is pre-clinical and the single phase 2 trial is months away from data readouts.

Based on my experience with small biotech stocks tackling complex indications, it is essential for the management team to have a track record in bringing a drug through the regulatory approval process. A research background is important as well, but too many biotech companies just focus on the research and neglect the commercial obligations of really building a business. Moreover, the last 36 months were filled with too much CEO turnover, lost partnerships and no real pipeline progression.

When it comes to immunotherapies & vaccines, companies like ImmunityBio are further along and are close to entering the commercialisation phase this year. As Scancell's management team mentioned the intention to investigate strategic partnerships with big pharma, I think the most beneficial outcome for them would be being bought out and thus being able to progress their pipeline, have access to manufacturing capacity and use connections to regulatory bodies for the approval process.

In conclusion, Scancell could be interesting for those investors speculating on a buyout. Further research could be done in finding out which big pharma has strategic initiatives

targeting melanoma and will look to complement their approach. However, judging from current market conditions and the unclear timeline, the opportunity costs could be too high to justify investing in the Scancell stock.

Rating: bearish

Sources

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