objectivecapital

objective corporate research

Scancell Holdings (SCLP.PLUS) - the beat goes on as visibility increases

SCLP.PLUS
Comment by Objective Capital , May 21, 2010

Scancell continues to demonstrate the flawless execution that has characterised the Company since we began coverage.

The Company first recently announced the approval of its Phase I clinical trial on SCIB1, its melanoma cancer vaccine, by the Gene Therapy Advisory Committee (GTAC) and by the Medicines and Healthcare products Regulatory Agency (MHRA) Medicines Division. Additionally, Ichor Medical Systems, Scancell's partner in this trial and developer of the TriGrid electroporation delivery device being used in the trial, also received parallel approval from the MHRA Devices Division. This official notification of approval allows the Company to begin its site initiations in Nottingham, Manchester, and Newcastle and, ultimately, to begin recruitment of patients.

Scancell followed up this announcement in short order with the news that it had successfully licensed two necessary melanoma antigens – TRP-2 and gp100 - from the National Institutes of Health (NIH). While the licensure of these antigens was expected, the process was a laborious one and was required to commercialise SCIB1 worldwide. Although the terms of the agreement were not disclosed, Scancell agreed to pay a nominal upfront fee in addition to certain milestone payments and royalties on future commercial sales of SCIB1.

Objective's view:

While the recent news from Scancell had been expected, it is a confirmation that the Company continues to stay on track in executing its objectives.

The process of taking a biotech drug from the discovery phase to the clinic is burdened with a long list of necessary hurdles and Scancell has been successful in navigating that course. It is now poised to transition from a preclinical company to one with a drug candidate in the clinic. In our view, the manner in which this Company has moved through the process and executed its milestones has been very impressive. Although the objective is far from met at this point, we do believe that the Company's performance shown to date, both from a financial and an operational standpoint, continue to give us confidence in the outlook for Scancell.

We would characterise the recent announcements as necessary and important, but also as expected.

Scancell's management team has been working with the regulatory agencies to achieve approval for the past several months. The Company now has the green light to initiate its first clinical trial for SCIB1 and should enroll its first patient within the next several weeks. The trial will consist of nine patients and will be conducted at hospitals in Nottingham, Manchester and Newcastle. After the first three patients are administered SCIB1, however, an independent committee will assess the results and determine whether or not to continue with the trial. This milestone, likely to occur later this summer, will obviously be an important one to watch.

Scancell's other announcement of its non-exclusive licensure of two melanoma antigens from the NIH in the U.S. was also expected. The Company had preferred a non-exclusive deal from the

start and had never sought to sign an exclusive arrangement. While the terms of the agreement were not disclosed, we expect that the dollars involved are relatively small and should have little to no impact on the valuation of the Company. We would estimate that the total upfront and milestone payments associated with the deal would total in the hundreds of thousands of dollars over multiple years, with the bulk of those payments occurring years into the future and associated with the commercialisation phase of SCIB1.

As Scancell embarks on its first clinical trial for its melanoma vaccine, SCIB1, the Company has seen a huge increase in its public profile of late. On Sunday, the Company made the front page of the Sunday Express with an article discussing the promise of cancer vaccines and SCIB1, in particular, along with a half-page article in the Daily Mail, both widely read papers in the UK. As a result, the Company has seen a big rise in traffic on its webpage and interest in its upcoming clinical trial.

Within the industry, the recent buzz has focused on the regulatory approval of Provenge, a vaccine from Dendreon targeted at prostate cancer. Dendreon's stock price rocketed on the news, with the Company now sporting a market capitalisation near US$6 billion. While both SCIB1 and Provenge seek to boost the patient's own immune system to attack cancer cells, we view the SCIB1 approach to be much simpler and most likely much less expensive, with the cost of the Provenge therapy estimated at around $93,000 per patient.

Interestingly, on the same day that the FDA gave approval to Provenge, it also granted fast-track status to Denmark's Bavarian-Nordic for its similar approach to treating prostate cancer. Some have noted that the Phase II results from Bavarian-Nordic's Prostvac look better than the results from Provenge.

While we view the heightened interest in cancer vaccines as positive and a validation of the science, it is disappointing to see the lack of response from Scancell's stock price. With the shares so closely held and illiquid, however, it is not particularly surprising to see good news fail to take the stock higher. With the initiation of the Phase I clinical trial for SCIB1 just weeks away, the stakes are being raised and the coming months will provide investors with important milestones to assess. We will be watching closely and commenting accordingly.