Biosceptre International Limited

Biosceptre International Limited Company Number 8729489
Phone: +44 1223 496 090
Address: Jonas Webb Building, Babraham Research Campus, Babraham, Cambridge, CB22 3AT, United Kingdom
www.biosceptre.com

SHAREHOLDER NEWSLETTER Quarter 3, 2014

From the CEO's desk

Dear Shareholders,

Welcome to Biosceptre's third quarter 2014 shareholder newsletter. As mentioned in our last shareholder newsletter, I have requested Dr Kevin Moulder, our Chief Scientific Officer, to provide an update on the scientific progress that has been made over the past 6 months (see his report later in this newsletter).

Funding Update

Many of you will recall in our last shareholder newsletter we noted our intention to undertake a large external capital raising of £20 million by the end of the first quarter next year. While these efforts continue, I'm happy to report that we were recently able to secure our first £1.6 million towards this goal.

These funds will be directed towards the cost of undertaking the planned systemic and topical clinical trials (see Dr Kevin Moulder's report), however further significant funding must be raised to progress through the clinical trials and to develop and commercialise our other assets including imaging, diagnostic and veterinary.

Should any current shareholder wish to participate in this funding round, subject to meeting any applicable 'qualified', 'accredited' or 'sophisticated' investor requirements and all applicable laws in the United Kingdom and in the jurisdiction in which you are resident (in the case of an individual) or the jurisdiction in which you are incorporated (in the case of an incorporated entity) including, without limitation, that the issuance of securities does not and will not require the publication of a prospectus, product disclosure statement or other like or similar offer document, we invite you to make contact at ceo@biosceptre.com to discuss the opportunity and to register your interest.

Grant Applications

Grant applications and their subsequent funding can cover anywhere from sixty percent to one hundred percent of a project's total cost, depending on the awarding body and the type of grant. These awards are peer reviewed, highly competitive and prestigious, providing external validation of our development activities. With our first grant award running successfully (as mentioned in our last update, Biosceptre secured a Technology Strategy Board Feasibility Study Award of £150,000), Biosceptre continues to remain focused on obtaining additional non-dilutive funding to further support our research and development activities.

During the past quarter, Biosceptre was successful in the first and second rounds of an application to develop a vaccine therapy derived from our nf-P2X$_7$ technology. Our application for £2.15 million was very well received and Biosceptre has been invited to a final panel assessment taking place in late October in the United Kingdom. The referees described our approach as being "highly innovative" and demonstrating "excellent underpinning science".

Further, Biosceptre has also submitted a grant application for £1.4 million to support our topical programme through to proof of efficacy in various clinical studies. Moving forward, Biosceptre will continue to apply for a variety of grants to minimise the overall project spend, reduce dilutive funding and to support portfolio development.

As always, if you have any questions or suggestions, please do not hesitate to contact me, or the management team, at ceo@biosceptre.com.

Gavin Currie
Chief Executive Officer

From the CSO's desk

Dear Shareholders,

The scientific program during the past six months has concentrated on improving our intellectual property position with a number of patents proceeding to grant in what Biosceptre believes to be critical jurisdictions for the future success of the company. Additionally, the program has facilitated further external collaborations to quantify the underpinning science. This will assist to develop acceptable material and documentation to progress to a Phase 1 systemic safety and efficacy study in human cancer patients with multiple tumour types. This has included the scale up of upstream and downstream processes as well as the development of acceptable release assays. In addition, we are also progressing our polyclonal topical program into a Phase 1B FDA approved clinical trial.

Systemic Program

It has been 'all hands on deck' in both our Sydney and Cambridge labs as we progress our 2-2-1:Fc antibody through the regulatory pathway towards a clinical trial (we estimate that the humans ethics committee submission should be lodged by the end of calendar 2014).

Further *in-vivo* studies have shown inhibition of tumour growth in a human derived colon cancer mouse model. Importantly, we have reviewed responding and non-responding tumours and believe we may be able to correlate responsiveness to our 2-2-1:Fc antibody with certain cell phenotypes. Subject to further conformational studies, this will permit differentiated patient selection / stratification in our clinical trials.

We believe that we have considerable safety data to support a successful clinical trial application including the absence of our 2-2-1:Fc antibody binding to cell surface tissues of the full FDA panel of normal tissues and limited clinical safety data from Category A patients treated with our 2-2-1:Fc antibody. Tumours from the rat species have been shown to bind to our 2-2-1:Fc antibody, representing a good toxicology species for safety studies.

A contract research organisation (CRO) has been selected and the necessary prerequisite studies have been initiated. Further, we are in the process of writing the investigator brochure that will form part of the necessary suite of clinical trial documentation and it will be the key application document that will be submitted to the human ethics committee for their review and approval.

Work has also been ongoing to elucidate the mode of action of our antibodies against target tumour cells. This data will be important for the future development of delivery systems for our antibodies and will help determine the type of dosing schedules that will lead to efficacy and acceptable safety in our clinical trial.

An alternate construct, to aid delivery of the antibody, has been investigated and shows some potential for both an imaging and therapeutic agent. If the continuing work is successful, it would dramatically reduce the antibody doses required for treatment with a potential significant concomitant reduction in treatment costs.

Topical Program

Since our last update, we have sought further advice from key opinion leaders in the areas of dermatological clinical trials and product formulation, regulatory specialists and industry professionals. The aim of this dialogue was to build a wider view of the existing product, its performance in the Phase 1 FDA clinical trial and to consider alternative product development pathways.

The consensus view, given the Phase 1 indications of efficacy, was that we have a very exciting potential product and that we should continue along the clinical development pathway. However, the current product formulation created some application difficulties for the patients in the Phase 1 clinical trial and consequently we have begun to re-formulate the product. This re-formulation should improve clinical utility (easier to dispense and apply in a clinical setting) which will aid in its application and maximise the release of the active pharmaceutical ingredient. This re-formulation process will involve discussions with the FDA to minimise the impact on the start date of the Phase 1b clinical trial.

An extensive RFP process has been completed for the selection of a contract research organisation (CRO) which will conduct the clinical trial and a contract manufacturing organisation (CMO) which will re-formulate and produce enough material for the trial. Both the CRO and the CMO have been selected and in order to maintain project momentum, contract negotiations have been initiated.

Further, we have developed a three year business case which includes production re-formulation, a Phase 1b and a Phase 2 clinical trial. The business case is currently awaiting final approval from the Biosceptre board and we expect (subject to having adequate funding) for this approval to be granted shortly, which will see the commencement of the Phase 1b trial in Q1 / Q2 2015.

Dendritic Program

In the third quarter 2013 shareholder newsletter, we advised shareholders that we believed that the approval for our dendritic clinical trial in Singapore to be imminent and that we would hope to commence the trial in October 2013. Since that time, we have provided responses to two further requests for information. In January 2014, the regulatory authority requested that we undertake a further study to show that the proposed methodology and use of our target peptide could induce a T-cell activation and proliferation *in-vitro*. We are currently undertaking this study in Singapore and should have the final report within the next month.

If there is clear evidence of *in-vitro* activation, a recommendation will be made to continue the proposed clinical trial.

Kevin Moulder
Chief Scientific Officer

Meet the Team

Biosceptre would like to take the opportunity to introduce David and Shaun, both of whom joined Biosceptre late last year / early this year, and wish them success in their respective roles.

Dr. David Chin

Director of Bio-Production and Research Collaborations

David has worked in biopharmaceuticals for nearly 20 years with significant experience in recombinant protein expression, in both microbial and mammalian cell systems, and monoclonal antibody discovery and engineering. On completion of his PhD at the University of New South Wales, he was awarded a research fellowship by the Australian Research Council (ARC) through which he researched various biopharmaceuticals in the fields of oncology and inflammation.

With further training in business administration, David has taken up several senior management positions. Prior to joining Biosceptre, David was operations manager at the National Biologics Facility at the Australian Institute for Bioengineering and Nanotechnology, University of Queensland, in the area of recombinant protein production, cell line generation and protein characterisation. In this role, David managed over 20 scientific staff, controlled a budget of over A$30 million, established over 30 collaborations between the biotech industry and academia, accomplished over 300 commercial and research projects and was also appointed as Chief Operating Officer at Stem Cell Limited, a spin-off from the University of Queensland and Monash University.

Dr. Shaun McNulty

Alliance & Commercial Manager

Shaun joined Biosceptre as a commercial manager in January 2014. With over 20 years of experience working in the pharmaceutical and biotechnology sectors across a range of functions from drug discovery and portfolio management to product and commercial development, Shaun brings broad industry understanding to the commercial side of the business.

Having obtained his doctorate from the University of York, Shaun undertook five years of post-doctoral study at the University of Cambridge. He then held positions at GSK and Pfizer, managing a number of scientific teams and international drug discovery projects prior to joining Syntaxin to lead its internal drug discovery portfolio. Shaun subsequently joined ImmunoBiology in 2008 and established the strategy that led to the company obtaining multiple grants providing non-diluting funding to develop its vaccine products.

Shaun will work to ensure that Biosceptre may obtain external non-diluting funding and integrates these awards to ensure they are aligned to meet our strategic commercial objectives.

Disclaimer

This newsletter has been prepared by Biosceptre International Limited (company number 8729489) and its affiliates (Biosceptre). The information contained in this newsletter is for informational purposes only. The information contained in this newsletter is not investment or financial product advice and is not intended to be used as the basis for making an investment decision. This newsletter has been prepared without taking into account the investment objectives, financial situation or particular needs of any particular person. Past performance is no guarantee of future performance.

No representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this newsletter. A number of statements in this presentation have been based on internal estimates by Biosceptre and have not been independently verified. To the maximum extent permitted by law, none of Biosceptre and their respective directors, officers, employees, contractors or agents, nor any other person accepts any liability, including, without limitation, any liability arising out of fault or negligence, for any loss arising from the use of the information contained in this newsletter. In particular, no representation or warranty, express or implied, is given as to the accuracy, completeness or correctness, likelihood of achievement or reasonableness of any forecasts, prospects or returns contained in this newsletter. Such forecasts, prospects or returns are by their nature subject to significant uncertainties and contingencies. Actual future events may vary from these forecasts and you are cautioned not to place undue reliance on any forward looking statement.

The statements in this newsletter are made only as at the date of this newsletter unless otherwise stated and remain subject to change without notice. None of Biosceptre and their respective directors, officers, employees, contractors or agents, nor any other person accepts any obligation to correct or update any information in this newsletter.