

# Promise beyond cancer

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## SHAREHOLDER NEWSLETTER

Quarter 4, 2014

## From the CEO's desk



Dear Shareholders,

Welcome to Biosceptre's fourth quarter 2014 shareholder newsletter. I would like to take this opportunity to wish all of our shareholders a very Merry Christmas and a Happy New Year.

### New Chief Scientific Officer

I would like to announce that Dr Shaun McNulty is Biosceptre's new Chief Scientific Officer. As referenced in the "Meet the Team" section in the last shareholder newsletter, Dr McNulty joined Biosceptre in January 2014 and has excelled during his time with us. Dr McNulty has over 20 years experience in the pharmaceutical and biotechnology sectors across drug discovery and portfolio management, to product and commercial development.

I would like to take this opportunity to thank Dr Moulder for his valued assistance to Biosceptre over the past two years and wish Dr McNulty every success in his new position.

### Sydney Shareholder Update

I'm pleased to announce that Biosceptre will be holding an informal shareholder update in Sydney for those shareholders who were unable to attend the AGM held late last month. Whilst there will be no formal voting undertaken, the update will provide shareholders the opportunity to meet with and ask questions of the management team. The meeting will be held at:

2:00pm Thursday, 29<sup>th</sup> January 2015  
Riverside Corporate Park  
11 Julius Avenue,  
North Ryde, NSW 2113

Do plan to come if you are able too.

## Grant Applications

In the Q3 2014 shareholder newsletter, we referenced grant applications that we submitted to obtain non-dilutive grant funding of £2.15 million to develop a vaccine therapy derived from our nf-P2X<sub>7</sub> technology and £1.4 million to support our topical program through to proof of efficacy in various clinical studies. Whilst we were unsuccessful in our application to obtain £2.15 million to develop a vaccine therapy, we are still progressing our application for support for our topical program and we will continue to apply for a variety of grants to minimise our overall project spend, reduce dilutive funding and to support portfolio development.

## AGM Results

Our 2014 Annual General Meeting was held on Thursday 27<sup>th</sup> November 2014 with the results as follows:

Resolution 1: That Peters Elworthy & Moore be appointed as auditors of the Company and the directors be authorised to agree the remuneration of the auditors of the Company. The motion was carried on a show of hands. Proxy votes received in respect of this resolution were as follows:

For	Against	Abstain	Undirected
8,970,395	-	590,807	660,560

Resolution 2: That Mr Peter Newton, who was appointed as a director of the Company by its board of directors, be elected as a director of the Company in accordance with the Articles of Association, details of which are set out in the explanatory notes to resolution 2 in the notice of meeting. The motion was carried on a show of hands. Proxy votes received in respect of this resolution were as follows:

For	Against	Abstain	Undirected
8,750,395	80,000	740,807	650,560

Resolution 3: That Dr Ronald Watts, who was appointed as a director of the Company by its board of directors, be elected as a director of the Company in accordance with the Articles of Association, details of which are set

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out in the explanatory notes to resolution 3 in the notice of meeting. The motion was carried on a show of hands. Proxy votes received in respect of this resolution were as follows:

For	Against	Abstain	Undirected
8,970,395	-	590,807	660,560

Resolution 4: That Mr Michael Lovett, who was appointed as a director of the Company by its board of directors, be elected as a director of the Company in accordance with the Articles of Association, details of which are set out in the explanatory notes to resolution 4 in the notice of meeting. The motion was carried on a show of hands. Proxy votes received in respect of this resolution were as follows:

For	Against	Abstain	Undirected
7,965,395	1,005,000	590,807	660,560

Resolution 5: Notwithstanding that a resolution to re-elect Mr Ivan Gunatilleke as a director of the Company was included in the Notice of Meeting, Mr Gunatilleke had provided his written resignation as a director of the Company, which was to become effective at the conclusion of the annual general meeting. Therefore, the resolution to re-elect Mr Gunatilleke as a director of the Company did not proceed to vote.

## Additional Directors appointed

Given the resignation of both Dr Kevin Moulder and Ivan Gunatilleke as directors of the Company, I am pleased to announce that Mr Andrew Walton-Green (who acted as an alternate director for Mr Gunatilleke over the past few months leading up to the annual general meeting) and Mr Jon Collins have accepted roles as non-executive directors of the Company.

Mr Andrew Walton-Green is a Chartered Accountant and a member of the Chartered Institute of Taxation. Mr Walton-Green spent the first 13 years of his career in practise predominately with Ernst & Young and then

Deloitte before becoming CEO of Gresham Computing plc (GHT.LSE) for 10 years, gaining significant exposure to the banking and financial services sector at a senior level. More recently, Mr Walton-Green was the founder and CEO of The Car Finance Company, one of the fastest growing companies in Europe over the past 4 years. Mr Walton-Green is also a part owner of a renewable energy business in the UK, a technology distribution company and a fast growing wholesale pharmaceutical business.

Mr Jon Collins joined a growing industrial group in 1967 which had interests in capital equipment sales and equipment rental. Initially in junior management, he accepted postings in the USA and Ireland where the group were pushing Greenfield expansion for a specialised range of machines. On returning to the UK, Jon became a regional manager before being appointed as a director. Jon then moved to Australia in 1987 to rebuild an existing group business. He led a successful management buy-out and purchased the business from the UK owners in 1993, before becoming the sole owner in 1997. The Australian business developed into a major manufacturer of specialised pumping equipment with offices in the USA, Indonesia, UK, Middle East and South Africa, where both rental and sales contributed to significant growth. The company was sold to an ASX-listed company in November 2010, and he now owns and is Chairman of the Coco Group. With a keen interest in rugby, Jon has also served as a director of the New South Wales Waratahs (Super 15) and the Australian Rugby Union.

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

### Gavin Currie

Chief Executive Officer

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## From the CSO's desk



Dear Shareholders,

I am pleased to have been appointed CSO at this key stage in Biosceptre's continued progress. Biosceptre has made significant advances in 2014 and is entering an exciting phase with pivotal clinical trials

for our systemic, topical and vaccine programmes, all scheduled for 2015. To effectively deliver these trials, we have restructured operations, particularly at our Cambridge site. This has enabled our activities to be focused on optimising development activities and plans to ensure we maximise the probability of success in our upcoming clinical trials and beyond. In addition to delivering the programmes detailed below, we have continued to develop ground breaking new technological approaches with the likelihood to broaden our commercial potential, including new imaging approaches for diagnosis and advanced antibody delivery systems.

### Systemic Program

We have been working hard in both Sydney and Cambridge sites to progress our 2-2-1:Fc antibody through regulatory clearance towards a phase I clinical trial. We have now completed drafting of the investigator brochure, a necessary prerequisite to obtain clearance from the human ethics committee before a trial can take place.

Having reviewed cell phenotypes of both responding and non-responding tumours, we have demonstrated the ability to correlate responsiveness to 2-2-1:Fc with antibody binding. This establishes the possibility for us to undertake differentiated patient selection and stratification in our clinical trials. We have extensive pre-existing 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. We also have strong supportive clinical safety data from Category A patients treated with our 2-2-1:Fc antibody. A formal toxicology study, a key component of the investigator brochure will be completed by February 2015 and data from this study will be incorporated into the final brochure to be submitted to the ethics committee for review and approval in Q1 2015. We are on track to initiate our phase I trial in Q3 2015. Work is continuing to validate alternative antibody delivery approaches that have the

potential to reduce the dose of antibody required to achieve efficacy and to improve diagnostic imaging approaches. Together these approaches have the potential to deliver improved products at reduced production costs.

### Topical Program

Key clinical opinion leader input has been obtained in the UK and their feedback has strengthened the consensus view that our exciting phase I clinical data strongly justifies further advanced clinical studies. The potential clinical utility of our topical product in certain melanoma and advanced basal cell carcinoma patient groups has also been identified, indicating the potential for broader commercial opportunities than targeting basal cell carcinoma alone. It is striking that clinical opinion leaders believe strongly that we have an exciting new therapeutic approach that would be ground breaking both in its mechanism of action and therapeutic potential. Senior clinicians at Addenbrooke's Cambridge UK and the Freeman Hospital Newcastle UK, both leading UK cancer centres, have expressed strong interest in supporting our clinical plans/activities and advising Biosceptre moving forward.

It is appropriate to improve the formulation from that used for the original phase I trial to develop a therapeutic that is suitable for the market and this work is ongoing with a UK contractor with expertise in dermatological products. We continue to establish plans for a phase Ib clinical study that will test this formulation alongside dosing levels. The new formulation will improve clinical utility by optimising its application and will maximise the release and delivery of the active pharmaceutical ingredient. This, in conjunction with increasing the treatment period in the phase Ib trial will provide strong data to support advanced phase II clinical trials and later Biosceptre commercial activities. We have developed a three year business case which includes GMP production, a Phase Ib and a Phase II clinical trial. The business case has approval from the Biosceptre board subject to raising funds required. We expect to commence the Phase 1b trial in Q2-Q3 2015.

We have discussed with clinical experts and regulatory consultants the potential to undertake a phase II study in advanced basal cell carcinoma patients. This would offer the potential to apply for orphan drug status that, if successful, would reduce time/cost to market and provide beneficial marketing exclusivity and financial incentives. Biosceptre will evaluate the potential to obtain orphan status in both the USA and European Union.

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## Vaccine Program

Dr Oliphant, who will manage this programme moving forward, has established a plan that has received executive approval to develop a peptide-protein conjugate vaccine product. The aim is to undertake in parallel; key preclinical vaccine activities to establish assays, vaccine delivery options and formulations for candidate development activities, and a small phase I clinical trial in Australia. This work will build on strong preclinical and very interesting category A patient data

that provides initial proof of concept for a peptide-protein conjugate vaccine approach to target nfP2X7. Key opinion leaders, regulatory, scientific and clinical have been contacted to drive project development activities. Contract organisations, necessary to deliver vaccine material for pivotal studies have been identified. Preclinical activities will initiate Q1 2015 with clinical activities targeted for Q3 2015.

**Dr Shaun McNulty**  
Chief Scientific Officer

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