

October 2012

Dear Shareholder,

While it would appear that it has been a relatively quiet quarter in terms of news flow, be assured Biotron has been diligently progressing the commercialisation path of the Company's lead compound, BIT225.

In recent months, significant advances have been achieved in all aspects of the Company's antiviral drug development program and this next quarter will lay a critical foundation for longer term development and exploitation of our technology. The current and ongoing detailed work is a prerequisite to achieving the very significant commercial valuation that could accrue if Biotron's trials are successful.

The Company is now in final preparation stages for a phase 2 trial of BIT225 in a very difficult to treat sub group of patients - those co-infected with both Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV).

This important study will be valuable on a number of levels. As well as producing the first efficacy data in this specific population with a significant unmet medical need, it is expected to generate further efficacy data for HCV genotypes 2 and 3. Until now Biotron's studies have focused on genotype 1, the most common Western world variation of the Hepatitis C virus.

Biotron is in a unique position, with BIT225 apparently capable of separately targeting both viruses. Positive results from this trial have the potential to substantially increase the Company's technology valuation. This trial will also provide important information on the impact of other anti-HIV drugs on the blood levels of BIT225.

This trial will be a 12 patient study. Trial participants must have suppressed levels of HIV and be receiving standard approved anti-retroviral drugs, but not have been treated previously with approved HCV drugs i.e. interferon and ribavirin (IFN/RBV). At the start of the trial these patients will commence treatment with IFN/RBV, and one week after starting this standard of care treatment they will have BIT225 added in for 28 days. After this time they will

continue receiving IFN/RBV for a period of up to 43 weeks, as per standard treatment guidelines.

The aim is to determine whether BIT225 improves the outcome, as measured by reduction in viral loads, in this patient population, compared to treatment with IFN/RBV alone.

The trial protocol and associated documentation is currently undergoing the approval process with the relevant hospital ethics committee. It is anticipated that this important study will be underway in early November, subject to receipt of relevant approvals and importation permits.

#### **HIV Trial**

While there have been some delays experienced in the phase 1b/2a study of BIT225 in HIV-infected patients, information from the trial site indicates that this study will be completed by the end of the year.

The trial has taken longer than anticipated, but that is the nature of clinical trial. External forces such as the very severe weather and our specific patient requirements have resulted in the trial taking longer than planned. There are specific and stringent inclusion rules preventing some potential candidates from participating. Early phase trials must be tightly controlled to ensure that underlying health issues do not compromise safety and other data from the study.

Patients enrolled in this trial need to be HIV positive, with high virus levels but still have good T-Cell counts (indicators of disease progress). Further, they must have had no previous treatment with other HIV drugs. This patient population pool is limited.

Biotron has been working closely with the trial site to improve recruitment rates and the trial is expected to conclude in the near term.

### **New formulation and drug manufacture**

As foreshadowed, Biotron has been working with a specialist formulation company in the USA to develop a new formulation of BIT225 in capsule form.

Until now, BIT225 has been delivered in powder form. Immediately prior to dosing, the powder is mixed with a taste masking liquid. The newer format is more suitable for use in extended trials with larger patient populations and is expected to result in improved and more reliable absorption of the drug.

A ten kilogram batch of clinical grade BIT225 is currently being manufactured. This is a substantial amount, the last batch of over 2 kilograms was produced six years ago. The new material should ensure sufficient stocks of drug to progress clinical trials over the foreseeable future. This material will be formulated into capsules using the methodology that is currently being finalised.

This work is progressing well, and it is expected to be completed before the end of 2012.

### **Three month toxicity studies**

Once manufacture of the new batch of BIT225 has been completed, three month non-human toxicology studies of BIT225 will commence. These studies are essential to establish a longer term toxicity profile of the drug, required for longer term human studies. This new data is expected to significantly strengthen BIT225's preclinical package.

The pharmaceutical industry is currently focused on developing several new classes of drugs, known as direct-acting antiviral (DAA) drugs for HCV. It is expected these will be used in combination with each other, and may replace the standard IFN/RBV treatment regime which is problematic due to significant side effects and efficacy issues.

Currently, clinical trials of these new DAA drug candidates have been focused on three month studies. The aim is to have BIT225 combined with other new DAA drugs, and to achieve this, three month of safety data are required.

### **HCV**

Early stage planning is in progress for a larger phase 2 trial of BIT225 in HCV-infected patients. This study is expected to have a 12 week treatment period, and will include additional HCV genotypes. Once the design of this study has been finalised further details will be released.

### **New staff members**

Biotron welcomes two new staff members to assist in furthering Biotron's development plans.

Bronwyn Williams has joined Biotron as Clinical Operations Manager. Bronwyn has extensive experience in managing all aspects of clinical trials from her years spent with major pharmaceutical companies, including Johnson & Johnson and Abbott Laboratories, as well as with biotechnology companies.

Audrey Thomson has joined Biotron as the new Business Development Associate. Audrey has tertiary qualifications in Toxicology, and has spent the last 10 years working in the USA pharmaceutical industry in contract research organisations, as well as small, early-stage, and mid-size pharmaceutical companies. She has experience working in joint ventures, partner/collaborations and post deal alliance management.

Both Bronwyn and Audrey significantly add to Biotron's in-house expertise.

### **Finally**

The Company is on track and committed to progressing and validating BIT225 in clinical trials and commercially. By the end of 2012 Biotron expects to have completed one year follow up, on participants in the 2011 HCV BIT225 IFN/RBV combination trial. The current HIV trial is expected to be completed and the co-infected HCV/HIV trial to have started.

During the first half of 2013, a further trial, with 3 month dosing, should be underway in other HCV genotypes. Timing of commencement of this trial is dependent on completion of the three month non-human toxicity studies.

Biotron is consistently engaged in promoting its technology to potential global pharmaceutical partners. Further solid data supporting the efficacy of this first-in-class drug opportunity will underpin our endeavours.

Biotron remains focused on achieving commercial outcomes for these important programs.

Sincerely,



Michelle Miller

CEO & Managing Director