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10 April 2013

The Manager Companies ASX Limited 20 Bridge Street Sydney NSW 2000

(3 pages by email)

Dear Madam

# SHAREHOLDER UPDATE

In accordance with Listing Rule 3.17, I attach a copy of a document as sent to the Company's shareholders.

Yours sincerely

Peter J. Nightingale Company Secretary

pjn7161





April 2013

Dear Shareholder

Welcome to the latest edition of BIT News.

Recently, Biotron was very pleased to report positive headline results from its important HIV clinical trial, which examined the potential of the company's first-in-class drug BIT225 to treat HIV infection 'hidden' in reservoir cells.

No existing treatment has been able to work on the HIV virus in this way and this mechanism has been a 'holy grail' for HIV researchers internationally.

The potential benefit of BIT225 in treating HIV can be explained with the analogy that BIT225 works by hosing down the remaining burning coals that remain after the fire in HIV infected patients is put out with current approved treatments.

The phase 1b/2a trial successfully demonstrated that BIT225 targets HIV replication in monocyte cells in treated patients. These cells become infected with HIV and are the seeds of hidden HIV pools in patients, setting up long-lived macrophage reservoir cell populations in various sites in the body. The trial showed that BIT225 can significantly reduce virus levels in these cells.

The monocytes that were analysed in the trial are present in the blood, and so can be more easily sampled. Directly analysing HIV within the macrophage reservoir cell populations targeted by BIT225 is difficult as access would require invasive sampling.

This Phase 1b/2a placebo-controlled, double-blinded study was undertaken on patients with high levels of virus and good CD4 T cell counts. None had previously received treatment with anti-retroviral drugs approved for treating HIV infection. Patients received either BIT225 (400 mg twice daily) or placebo for a period of 10 days.

The outcomes of this trial are extremely encouraging and it is anticipated that data will be presented at an upcoming international scientific conference.

As you would be aware, these results follow on from the 2011/12 phase 2 trial data in Hepatitis C (HCV) patients, which demonstrated that 100% of HCV patients receiving the highest dose of drug in combination with current approved treatments were virus free at the 48 week, end of treatment time point.

This latest information further validates the potential of BIT225 for treatment of both patient populations. It should be noted that while Biotron has cutting edge technologies, the design and implementation of trials is not a fast process, and outcomes cannot be guaranteed.

While these results provide hope to the millions of HIV sufferers around the globe, at a commercial level the data has placed Biotron in an enviable position internationally.

From here, it is Biotron's intention to continue ongoing discussions with potential pharmaceutical partners. The Company's aim is to seek a strong international collaborator to help progress this promising technology through the final hurdles of late stage pivotal trials.

## **HIV/HCV Co-infected Trial**

In other key milestone for this year, Biotron continues to progress with the Phase 2 trial of BIT225 in patients co-infected with both HIV and HCV.

This unique population typically responds poorly to standard treatments.

In this study, twelve HIV/HCV-infected patients will receive 28 days treatment with BIT225 (300 mg, twice daily) in combination with interferon and ribavirin (IFN/RBV), which is the standard approved treatment for HCV. All trial participants will be receiving standard antiretroviral (anti-HIV) drugs throughout the study.

At the conclusion of the treatment with BIT225 they will continue to receive IFN/RBV as per standard treatment guidelines (up to 48 weeks in total).

While BIT225 appears to target both HIV and HCV, this particular study is focused on the HCV aspect of the disease in these dual-infected patients.

The pharmaceutical industry and international regulatory authorities are keen to develop new treatments in this difficult-to-treat population.

It is anticipated that recruitment and dosing with BIT225 will be completed in the first half of this year, with preliminary end-of-treatment results expected in the 3Q13. Further data will be available at three, six and twelve month time points.

### **New Capsule Formulation of BIT225**

In trials undertaken to date, BIT225 has been dispensed in powder form, and then mixed with a liquid taste-masking agent immediately before dosing. While this has been successful, it was important to progress to a formulation that would be patient-friendly and suitable for longer-term dosing.

During 2012, significant effort was made to develop an optimised formulation of BIT225 in capsule form. In parallel, over 10 kg of clinical grade (GMP) BIT225 was manufactured. Biotron's first batch of clinical grade BIT225 was made in 2006. This 2 kg batch remained stable for intervening 7 years, but stocks had run down, necessitating manufacture of another batch. Formulation studies were performed on the new material, and in late 2012 capsules of BIT225 were successfully produced.

These new capsules are now being tested in a small trial in healthy volunteers here in Australia. Participants will be randomised to receive a single dose of either the new capsule or the old powder formulation of BIT225, followed by extensive blood sampling over a 96 hour period. Two weeks later the participants will receive the alternative formulation, and further blood samples will be taken. The aim of this study is to compare blood levels of the drug with the old and new formulations, and to assess safety parameters.

Information from this trial will guide dosing in future trials of the new BIT225 capsules.

The trial is a short term study and is expected to be completed this month.

### Diversification

While the primary focus to date has been the HCV and HIV programs, Biotron has been progressing with the characterisation of a potential next generation drug from Biotron's compound library. In addition, the company has compounds which may be capable of targeting other medical conditions with significant unmet needs, including Dengue Fever. As resources become available, we are confident Biotron has the expertise and technology to accelerate these further opportunities.

#### Next 12 months

During 2013 we expect to bring you further results from the phase 1b/2a HIV trial as data is released to scientific and industry-relevant conferences. Conferences of these types have embargoes over data being presented, so specific data cannot be released ahead of time. It is also anticipated that data from the HIV/HCV co-infected population study will be released in the second half of the year.

As mentioned in the December 2012 Half-Year Report, Biotron is in the early planning stages 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. The 3 month preclinical toxicology studies that commenced in 2012, and the current human trial with the new capsules, are key steps towards this longer study. In March, Biotron held scientific and clinical advisory meetings with key international experts in the USA, to review results and recommend the next stage of commercial development. The design of this study is currently being considered in light of these meetings, and further details will be released during the second half of 2013.

These are all important milestones and we are optimistic they will assist us in delivering solid investment returns to our shareholders.

I look forward to the coming months and again thank you for your interest and continued support.

Sincerely,

Michelle Miller

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**CEO & Managing Director**