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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

pjn6424





December 2011

Dear Shareholder

It's been another exciting month for your Company, with the release and presentation of data from the recent phase 2a trial of BIT225 in Hepatitis C patients.

The positive headline data that was previously announced was fully confirmed. In addition, positive data was reported from the follow up of trial participants at the three month time point, two months after inclusion of BIT225 in the treatment regimen ceased.

This is an amazing result, and the culmination of years of preclinical and clinical research. It is also extremely encouraging as we progress towards commercialisation of this novel compound.

The trial design was to treat 24 subjects with either BIT225 or placebo in combination with Interferon and Ribavarin for 28 days, followed by an additional 44 weeks of these standard drugs alone.

At the conclusion of the 28 day dosing period with BIT225 the patients who had received BIT225 had significantly lower virus levels, with an average of over 90% less virus than those who had received placebo.

Following review of the data by an independent committee, and analysis of data out to three months, we now know that almost 90% of HCV patients who received BIT225 are virus free at the three month time point. This is in comparison with just over 60% of patients who did not receive BIT225 clearing the virus at that time point.

This data shows that BIT225 continued to provide additional benefit to patients after they had stopped dosing with the drug.

We are actively marketing this result to the global hepatitis community. Earlier this week, the principal investigator of the HCV trial who recruited and dosed the patients, Dr Tawesak Tanwandee, presented a report of these trial results at the prestigious bi-annual HepDART conference in the United States of America.

Several hundred delegates, including clinicians, researchers, pharmaceutical representatives and financial analysts heard that Biotron's first-in-class compound shows terrific promise in HCV patients when used in combination with current standard therapies.

The data presented now unequivocally establishes that BIT225 has potent antiviral activity, and that it leads to a 50% improvement in the number of patients who can clear the virus completely when used in combination with the current standard of care therapies, Interferon and Ribavarin.

It was also demonstrated that BIT225 was generally well tolerated. Interferon and ribavirin are associated with a high rate and broad range of side effects. The most common side effects were fevers, headaches and nausea/vomiting.

We are now conferring with clinical and industry experts to determine the most suitable next steps to develop BIT225 as an anti HCV drug.

This information all bodes well for our business strategy of building up a body of scientific and clinical efficacy data that ensures Biotron is an attractive prospect to a potential global partner. As continually reiterated, discussions with potential partners are ongoing.

HIV

You would also be aware that BIT225 is showing great promise in the HIV space. We launched a landmark phase 1b/2a proof of concept human trial in September at the same Bangkok trial site where the HCV trial was conducted.

Twenty four HIV positive patients are being dosed in this study and, based on preclinical studies, we are optimistic it too will reveal positive results.

We have already established that BIT225 presents a first-in-class opportunity to target the HIV virus in monocyte lineage cells where, until now it has been able to hide from current drug therapies.

This strategy of targeting virus reservoirs is an area of great interest to HIV researchers globally, with most programs still in very early research stages of development.

Biotron's approach is novel and relatively advanced. If successful, we anticipate that BIT225 could be used in combination with existing anti-retroviral therapies.

This trial suffered minor delays due to recent floods in Bangkok. We are pleased to report this problem has been alleviated and anticipate the trial will be concluded during Q1 2012.

**Options** 

The Company has ~107 million share options on issue with an exercise price of \$0.10. If exercised, these options will provide the Company with up to ~\$10 million in cash.

A recent independent research report put out by Edison Investment noted that Biotron "offers a highly interesting play on the HCV merger and acquisition theme, with the added bonus that its lead product has potential in HIV".

This report acknowledged the surging interest globally in new HCV technologies, as demonstrated by Gilead's recent US\$11 billion acquisition of Pharmasset. It also noted that Biotron's market capitalisation is well below the valuations of comparable USA based HCV players at a similar stage of development.

## 2012 and Beyond

As we move into 2012, we are progressing formulation studies of BIT225 into a capsule or tablet form, as well as 3 month animal toxicity studies that are required for any human trials involving dosing longer than 28 days (the current extend of the Company's animal toxicity studies).

In parallel, we are investigating potential trial designs for next stage development of BIT225. Possibilities include investigating efficacy against other HCV genotypes (until now we have only focused on genotype 1, the most common form of HCV), or progressing studies in difficult to treat populations. Of particular interest are those who are infected with both HCV and HIV, given BIT225's unique activity against both viruses.

We believe these further investigations will continue to add value to our Company and we look forward to bringing you further promising developments.

Sincerely

Michelle Miller

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**CEO & Managing Director**