



AVEXA



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## Chairman and CEO's Letter

Dear Shareholders,

Prior to the end of calendar 2007, Avexa achieved a major milestone with the initiation of the first of the two pivotal Phase III clinical trials necessary to achieve FDA registration and marketing approval for apricitabine (ATC), your Company's lead product candidate. Over the two years since the acquisition of the marketing rights to this promising HIV treatment, the Avexa executive team has created significant value through the design and successful implementation of Phase IIb clinical trials and of the various other ancillary trials necessary to demonstrate the compound's safety and efficacy.

We recently released impressive 48 week data from this Phase IIb trial, showing that ATC maintains both safety and efficacy over this period. Particularly encouraging is the improvement in the function of the patients' immune system, as indicated by the rise in CD4 cell counts seen at week 24 and the further rise seen by week 48.

Your Company's management team has thought it prudent to work closely with US (FDA) and European (EMEA) regulators and to incorporate their feedback into the Phase III clinical trial design. As a result, the FDA has granted ATC accelerated review and fast track status which means that the ATC data should be filed with the FDA on the basis of 24 week Phase III data, in the second half of 2010.

However, this regulatory review has expanded the Phase III program beyond the scope envisaged when the Company raised \$79.9 million last year and, at the recent AGM, we advised that we would be seeking a partner to provide additional funding to enable the enlarged Phase III clinical trial program to be successfully completed, among other benefits a partner may bring. While the regulatory review with the FDA and EMEA has increased the costs of the clinical trial program, it has also significantly increased the likelihood of a successful regulatory outcome. The search for a suitable partner to share the costs and rewards of successful commercialisation is well under way.

Avexa has also recently entered into a collaboration agreement with Monogram Biosciences, based in San Francisco, a world leader in testing resistance to drug therapies, and this will make a valuable contribution to Avexa's discovery and development programs, including the Phase III clinical trials now under way.

The Avexa management team remains actively involved in a variety of HIV/AIDS forums. Key personnel regularly participate in major conferences around the world, and have presented at several. In addition to ensuring that the latest insights into pharmaceutical development are brought to bear on the Company's programs, this is also important in building awareness of the Company's objectives – for ATC in particular – and to maintain the international network of contacts which is invaluable in successful pharmaceutical development.

Finally, it is difficult for all of us, as shareholders, not to be distracted and concerned about the turmoil in global sharemarkets in recent months and to worry about the impact on Avexa (and, for that matter, on other companies in which we may have an interest). But while markets usually eventually recover people who are infected with HIV/AIDS still have it and have it for life. They still inevitably develop resistance to their existing drug therapies and they still badly need drugs like ATC.

It remains our mission to press forward, using all the technical and financial resources we can access, to bring ATC successfully to market for the benefit of both our shareholders and those suffering from the scourge of HIV/AIDS. We intend to succeed.

Kindest regards,

Dr Hugh Niall  
Chairman

Dr Julian Chick  
Chief Executive Officer



## Avexa Initiates Phase III Trial

In the latter part of calendar 2007, the Company finalised the design and preparations for the pivotal clinical trials for the ATC Phase III development program. Feedback received from both the FDA and the EMEA was encouraging and was incorporated into the protocols. The response from patients concluding the Phase IIIb trial and enrolling in the extension study provided further confirmation of the value that ATC adds to their treatment regimens.

A significant milestone was reached with the initiation of the first site of the Phase III program prior to 31 December 2007. This first

site is located in the USA and further sites have since been initiated. At the beginning of February 2008, Avexa held the Phase III 'kick-off' meeting for clinicians based in North America, providing the training and instruction necessary to achieve the next major milestone: the screening and enrolment of the first patient.

The Phase III program will consist of two trials, each with about 900 patients. The endpoints are very similar to those of the Phase IIIb trial, namely the percentage of patients with undetectable levels of HIV in the blood after 24 weeks' treatment.

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## 48 Week Data Update – Phase IIIb Clinical Trial

Avexa recently announced excellent 48 week data from its ATC Phase IIIb clinical trial. At week 48, the proportion of patients with HIV levels below the level of detectability was greater than 90 per cent. Patients who were initially treated with 3TC but who were switched to ATC at week 24 also improved their response.

Avexa also reported that the CD4 cell count of ATC treated patients continued to increase out to 48 weeks. Patients initially treated with 3TC and then switched to ATC doubled their CD4 cell counts at week 48 (after 24 weeks of ATC) compared to their cell count after 24 weeks of 3TC.

"These exciting results indicate that the clinical and immunological benefit of ATC continues to increase with long term treatment out to 48 weeks. This is compelling evidence of the improvements that can be obtained when patients switch to ATC from 3TC" said Dr Julian Chick, CEO of Avexa.

This is compelling evidence of the improvements that can be obtained when patients switch to ATC from 3TC.

Remarkably, in ATC treated patients, the level of CD4 cells in the patients' blood rose by more than 250 cells per microlitre on average. This marked increase demonstrates that ATC is not only able to halt the decline in CD4 cell counts typical of HIV infection but is even able to reverse that decline. This indicates that ATC is having a clinically significant, beneficial effect on the patients' immune system.

Key highlights from the 48 week data:

- increase in the percentage of patients with viral loads below detectable at week 48 compared with week 24;
- patients switching from 3TC to ATC improved their response, with the percentage of patients with viral loads below detectable and the levels of CD4 cells both increasing after switch to ATC at week 24;
- patients switching from 3TC to ATC obtained, on average, approximately a further 0.5 log decrease in their viral load;
- the safety profile for ATC remains excellent and is very similar to that seen with 3TC; and
- after 48 weeks, no clinical resistance to ATC has been detected.

# New Collaboration with Monogram Biosciences to Support HIV Drug Discovery and Development Efforts

Avexa has signed an agreement with Monogram Biosciences (of San Francisco, USA) to be the exclusive provider of HIV resistance and tropism testing technology in support of Avexa's drug discovery and development programs.

Monogram is the world leader in testing resistance to drug therapies. Its products are designed to help doctors optimise

treatment regimens for their patients leading to better outcomes and reduced costs. Monogram's technology is also used by numerous biopharmaceutical companies to assist in developing new and improved antiviral therapeutics and vaccines as well as targeted anti-cancer therapeutics.

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## CROI Conference

In February, 2008, Dr Susan Cox, Avexa's Head of Development, presented at the 15th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. This annual conference is a scientifically focused meeting of the world's leading researchers working to understand, prevent and treat HIV/AIDS and its complications.

Numerous subjects are highlighted including immunology, vaccines (preclinical and clinical trials), virology (including other retroviruses), pathogenesis, neuropathogenesis and neurologic complications, antiretroviral therapy (preclinical, clinical, randomised trials, clinical observational studies, and complications), therapeutic vaccines and immune-based therapies, primary/acute infection, clinical pharmacology, HIV resistance (including molecular mechanisms) clinical implications and epidemiology of HIV drug resistance, opportunistic infections (including tuberculosis) and so on.

This annual conference is a scientifically focused meeting of the world's leading researchers working to understand, prevent and treat HIV/AIDS.

This annual conference provides a unique opportunity to keep in contact with world leaders in the HIV research community, to keep abreast of current developments and to present the Company's work on ATC to its peer group of pharmaceutical product development experts.

Dr Cox's poster presentation is available on the Company's website at [www.avexa.com.au](http://www.avexa.com.au)

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## 10th Annual BIO CEO & Investor Conference

During February 2008, Dr Julian Chick presented to analysts at the BIO CEO & Investor Conference in New York. Now in its 10th year, this is the largest independent investor conference on publicly traded biotechnology companies.

The Conference features issues-oriented plenary sessions, educational sessions focused on hot therapeutic areas and key business issues, company presentations, one-on-one meetings and networking opportunities.

Dr Chick's presentation may be viewed on the Company's website at [www.avexa.com.au](http://www.avexa.com.au)

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## 2008 Interim Result

For the six months ended 31 December 2007, Avexa reported net operating cash outflow of approximately \$9.9 million, which was within internal forecasts, resulting in a closing cash balance of \$66.6 million at the end of the period.

The operating result for the period was a loss of \$17.3 million, after interest revenues on funds invested of \$2.4 million and Commercial Ready grant income of \$0.4 million. Contract research and development costs of \$14.3 million include product manufacturing and comparator purchase costs in preparation for the Phase III clinical trials.

During the half year, the Company identified candidates for both the antibiotic resistance and anti-HIV integrase programs. Formal clinical development programs are in preparation aimed at IND filings for both programs by the end of calendar 2008.

# Financials

Avexa Limited cash flow report for the six months ended 31 December 2007

	Six months ended 31 December 2007 \$A'000
Operating cash flows	
Payments for:	
Staff costs	(2,636)
Advertising and marketing	(108)
Research and development	(7,560)
Leased assets	(127)
Laboratory consumables	(222)
Occupancy	(587)
Consulting	(246)
Legal and professional	(91)
Corporate administration	(180)
Travel and entertainment	(424)
Insurance	(241)
Intellectual property	(485)
Other working capital	(212)
Interest and other items of a similar nature received	2,301
Other - GST refunds	349
- Property sub-rental proceeds	137
- Commercial ready grant	408
Net operating cash flows	(9,924)
Cash flows related to investing and financing activities:	
Payment for physical non-current assets	(380)
Proceeds from issues of shares, options, etc. net of raising costs	41
Net investing and financing cash outflows	(339)
Net decrease in cash held	(10,263)
Cash at beginning of year	76,873
Cash at 31 December 2007	66,610

## Timetable for the next 12 months

Quarterly *Avexa News*  
Annual Report

June 2008  
September 2008

Quarterly *Avexa News*  
Quarterly *Avexa News*

December 2008  
March 2009



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### Editor's Note

We value shareholder feedback.  
Your comments can be emailed to:  
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