



ASX Release

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Avexa passes the 100 Phase III site mark

Avexa Limited (ASX: AVX) announced today its financial result for the year ended 30 June 2008.

Since announcing the initiation of the first Phase 3 sites in February's half-yearly financial report, Avexa has now opened up more than 100 Phase III sites in North America, Europe, Israel, Australia and South America.

During the 2008 year, the formal stage of the Phase 2b study of apricitabine (ATC) was concluded with outstanding results achieved in terms of antiviral activity, safety, increases in CD4 cells and lack of drug-resistance. ATC is now in a FDA approved Phase III trial and is progressing well. It is encouraging that the majority of patients that enrolled into the Phase 2b trial have opted to enter the extension study and are still receiving ATC, some for over three years now.

Subsequent to year end and as announced this week, Avexa has renegotiated its license arrangements with Shire plc for ATC. As part of the renegotiation Shire's holding in Avexa will increase to 11.1% through the issue of 18.6 million shares, these new shares remaining in escrow for 12 months subject to the occurrence of certain events. While the other terms and conditions of the renegotiation remain confidential, Avexa has approved the renegotiation to secure a substantially greater proportion of the future commercial value of ATC that could accrue for the benefit of Avexa shareholders through a reduction of sales royalties and removal of future milestone payments.

In addition to the continued development of ATC, considerable progress has been made in all three of Avexa's preclinical programs. The antimicrobial program continues to clearly demonstrate the required safety and antimicrobial properties necessary to move the lead compound forward into the clinic. Since the marketing approval of Merck's HIV integrase inhibitor, Isentress, Avexa's scientists have been able to modify the Avexa series of HIV integrase inhibitors to enable them to compete with this newly approved product's properties. The discovery of compounds which are not cross-resistant with Isentress but which have similar potency epitomises the progress in this program. Avexa's HCV program was initiated relatively recently, and the speedy progress in setting up the new assays and screens has been rewarded with the discovery of a number of novel compounds with activity against Avexa's undisclosed but essential target.

Commenting on the result CEO Dr Julian Chick said "During the year we have obtained positive feedback on our proposed development path for ATC from the FDA and initiated over 100 sites in 13 countries for the first of our pivotal Phase III trials.



We are actively recruiting patients into this study. We continue to closely monitor the status of the Phase II extension studies which have to date demonstrated both extremely high levels of continued participation and absence of adverse events. The fact that some patients have been receiving ATC treatment for over three years is a very positive indicator of the product's long term market potential."

"We have also made sure that we develop a portfolio of attractive products behind ATC based on stringent scientific hurdles and commercial criteria, and during the year commenced activity on an innovative approach to treating HCV" concluded Dr Chick.

Financial highlights

The audited operating result for the year ended 30 June 2008 was a loss of \$36.1 million, which included interest revenues on funds invested of \$4.3 million and Commercial Ready grant income of \$0.9 million. Contract research and development costs reported of \$30.0 million include product manufacturing and comparator purchase costs, site initiation and commencement of enrolment for the Phase III clinical trials as well as the close out of the formal Phase IIb study and costs associated with the continued participation by the vast majority of patients in the Phase IIb extension studies.

Operating cash flows of \$29.3 million for the year are within internal forecasts and include the bulk of the set up costs and product requirements, both ATC and comparator, associated with the Phase III trials.

Equity movements for the period comprised only the conversion of options to increase equity by \$44,000. The Company reports a net asset position of \$55.8 million and issued share capital of \$137.2 million comprising 406,033,175 ordinary shares on issue at balance date.

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Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development of drugs for the treatment of infectious diseases. Avexa has dedicated resources and funding for key projects including its HIV integrase program and an antibiotic program for antibiotic-resistant bacterial infections which have both entered the IND-enabling study stage. The Company's lead program is apricitabine (ATC), an anti-HIV drug which has successfully completed the 48 week dosing of its Phase 2b trial and has recently initiated Phase 3 trials.