14 May 2009

Arana Half Year Results

Arana Therapeutics Limited (ASX: AAH) ("Arana") today announced its financial results for the half year ended 31 March 2009.

Highlights for the half year were:

- Commencement of Phase II rheumatoid arthritis trials for ART621
- Results of Phase II psoriasis trial for ART621
- Payment of fully franked special dividend of $0.05 on 15 April 2009
- Share buy back completed with 7.4 million shares acquired at a cost of $5.8 million
- Revenues up 23% to $24.2 million
- Total R & D spend up 90% to $20.5 million
- Half year loss of $4.4 million compared with a profit for the previous corresponding period of $1.6 million
- Cash reserves of $179.3 million

Acting CEO, Dr Steffen Nock said "We are proud of our performance over the last six months. Our revenues are up 23% and our lead asset ART621 continues to be developed according to plan. We are also pleased to see that our research and development projects are progressing having led to a 90% increase in our total R & D spending."

Clinical Developments

We have continued to progress the clinical development of ART621 as a potential treatment for inflammatory disease such as rheumatoid arthritis (RA). Recent developments include the acceptance of our Investigational New Drug Application by the US Food and Drug Administration (November 2008), commencement of two international trials for RA (November and December 2008) and the completion of our initial psoriasis study (March 2009). Further updates are provided below:

Pilot RA study - ART621/223

This randomised double-blind trial is designed to quickly obtain initial safety data and preliminary indications of efficacy in RA by comparing four different dose regimens of ART621. Patient recruitment has commenced in Sri Lanka and we expect to report on this trial in late Q3 2009.

Formal dose ranging study in RA - ART621/221

This multicentre, randomised, double-blind, placebo-controlled study is designed to establish the efficacy of ART621 by evaluating three doses of ART621 in patients also taking methotrexate. The study is being conducted in Australia, the U.S., New Zealand, Czech Republic, Poland, India, Malaysia and Argentina. Our team has worked diligently to secure the essential regulatory approvals in these countries, the final two of which (Poland and Argentina) are expected on target by June 2009. Recruitment of the 200 patients has commenced and is expected to be completed by December 2009. Formal results of the study are expected to be available in mid-2010.

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Repeat dose psoriasis study – ART621/201

We announced the successful completion of study ART621/201 within stated timelines in March 2009. The primary endpoint was met with repeat doses of ART621 being well tolerated and exhibiting a safety profile consistent with anti-TNF activity, the method of administration and the underlying study population. In addition, signs of efficacy were seen with four subjects in the ART621 group achieving a 50% reduction in Psoriasis Area and Severity Index (PASI) score at week 12 compared to zero in the placebo group. Data from this study has been used to successfully secure regulatory and ethical approvals for our ongoing RA program.

Research Pipeline

We have continued to progress development of projects for the treatment of inflammatory disease and cancer, as well as the development and application of Arana's technology platform. Highlights for the last half year are provided below:

The development of a new anti-inflammatory antibody candidate (ART123) targeting inflammatory diseases continues. Patent applications have been filed around the novel mechanism of action of ART123 and preclinical safety studies are expected to commence in 2010.

Arana has commenced GMP manufacture and the development of ART010 preclinical work to enable entry into a Phase 1clinical trial in the first quarter of 2010. Arana has filed for patent protection for the product until 2025. Arana's confidence in taking this drug candidate forward for the treatment of cancer-related bone loss has been strengthened by the success in Phase III clinical trials of the antibody denosumab (in development by US company Amgen). The success of denosumab clinically validates RANKL as a target. ART010 and denosumab both target RANKL – a protein involved in the formation and activation of cells that erode bone.

Progress continues in the collaborative development of ART104 for the treatment of colorectal cancer with the Japanese company Kyowa Hakko Kirin (KHK). This project combines Arana's technology with KHK's technology, aimed at achieving enhanced anti-tumour potency of the antibody and thus maximising its chances of successful development as an anti-cancer product.

Completion of a project for Vegenics and a second project for partner GlaxoSmithKline (GSK) represents a total of five partner antibodies engineered to date using Arana's proprietary platform technologies. Longer term commercial returns to Arana will be realised in the event these antibodies are taken forward as therapeutic products.

Refinement of the protein biologics focus of Arana with the decision to discontinue the clinical development of the small cyclic peptide compound PMX53 for ocular indications and focusing efforts on high priority projects aligned to Arana's core technology strengths. All ongoing pre-clinical studies for PMX53 are being taken to completion, including an osteoarthritis study which is expected to be completed in the third quarter of 2009. A data package is being assembled for out-licensing and the recent issuance of patents for PMX53 in Australia with terms running to 2022 and 2023 strengthens the package.

Financial Results

Income statement

Revenues for the period increased by 23% to $24.2 million. The increase was the result of higher underlying royalties and license income, a weaker Australian dollar generating greater revenues from US dollar denominated revenues. Grant income increased to $2.4 million from $1.4 million. Expenses for the period increased from $20.7 million to $30.5 million due to increased expenditure on R & D (increase of $9.7 million) as the company continues to develop its programs, in particular ART621. During the period, there was also a net impairment charge of $1.4 million arising from the decision to cease development of PMX53 for ocular indications.

Balance sheet

At 31 March 2009, Arana had cash of $179.3 million plus a security deposit of $1.9 million. Intangible assets have reduced from $121.6 million at September 2008 to $109.5 million at

March 2009 due to the impairment in relation to PMX53 and the amortisation charge for the period.

Trade and other payables increased from $5.6 million at September 2008 to $16.3 million at March 2009 due to the accrual of the special fully franked dividend of $11.4 million. Non-current payables decreased from $16.3 million at September 2008 to $9.1 million at March 2009 reflecting the reversal of the contingent payment to former equity owners of Promics Limited. This is now reported as a contingent liability.

Contributed equity reduced in the period from $215.5 million at September 2008 to $209.7 million at March 2009 due to the share buy back. Over the period October 2008 to February 2009, 7.4 million shares were bought back at a cost of $5.8 million. The share buy-back ceased on 2 March 2009.

Cash flow

The net cash outflow for the period was $2.1 million with positive operational cash flows of $5.2 million offset by funds spent on equipment ($1.4 million) and the share buy-back program ($5.8 million). Closing cash at the end of the period was $179.3 million.

Takeover Offer

On 27 February 2009, Arana received an unsolicited takeover offer from Cephalon International Holdings, Inc. The offer is currently still open.

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About Arana Therapeutics:

Arana Therapeutics (ASX: AAH) is a biopharmaceutical company focused on developing next generation antibody based drugs that will improve the lives of patients with inflammatory diseases and cancer.

Arana Therapeutics' innovative engineering technologies provide the basis for developing its next generation antibody candidates. Arana Therapeutics has the financial strength and management expertise to develop its product pipeline.

Arana has a significant track record of commercialising its technologies and has collaborations with GlaxoSmithKline (GSK), CSL, Kyowa Hakko Kirin (KHK), and licensing arrangements with Centocor (J&J) and Abbott Laboratories.

For further information: www.arana.com.