

Biotech Daily

Monday January 30, 2012

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: BENITEC UP 5%, OPTISCAN DOWN 11.5%
- * WEHI'S DOUG HILTON: EVOLUTION AND VERY INTELLIGENT DESIGN
- * CORRECTION: GENETIC TECHNOLOGIES
- * MONASH, SERVIER WORK ON G-PROTEIN-COUPLED RECEPTORS
- * SUNSHINE HEART TRADING AS SHCDA
- * CIRCADIAN VGX-100 POTENTIAL IN CORNEAL GRAFT REJECTION
- * SWITZERLAND APPROVES SALES OF ACRUX ELLAVIE
- * NANOSONICS Q2 SALES UP 22.5% TO \$2.8m
- * BLUECHIIP RAISES \$473k, HAS TWO QUARTERS CASH
- * IM MEDICAL HAS LESS THAN ONE QUARTER CASH; SPENDING CUT

MARKET REPORT

The Australian stock market fell 0.37 percent on Monday January 30, 2012 with the S&P ASX 200 down 15.7 points to 4,272.7 points. Five of the Biotech Daily Top 40 stocks were up, 21 fell, eight traded unchanged and six were untraded.

Benitec was the best, up 0.1 cents or 5.3 percent to two cents with 4.2 million shares traded. Neuren climbed 4.35 percent; Nanosonics and Resmed rose more than two percent; Compumedics was up 1.25 percent; with Cochlear and Impedimed up less than one percent.

Optiscan led the falls for the second trading day in a row, down 1.5 cents or 11.5 percent to 11.5 cents, with 528,130 shares traded.

Circadian and Genetic Technologies lost more than seven percent; Living Cell and Tissue Therapies were down more than six percent; Prana was down 5.7 percent; Antisense and Phylogica fell more than four percent; Alchemia and Reva were down more than three percent; Acrux, Anteo, Bionomics, Clinuvel and Pharmaxis shed more than two percent; with Heartware, Mesoblast, QRX, Starpharma and Universal Biosensors down more than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

A leading medical research establishment, the Walter and Eliza Hall Institute continuously produces basic discoveries, such as last week's invisibility cloaking of the malaria parasite, as well as developing commercializable compounds and drugs.

The Sixth Director, Prof Doug Hilton, pays credit to his predecessors Prof Suzanne Cory and Prof Gus Nossal for his inheriting the major themes of the Institute, but also quotes advice from Prof Nossal following his appointment: "Make the job your own – every director has their strengths and the things they like". The end-result is a research institute created both by evolution and very intelligent design.

On a muggy tropical Melbourne morning, 47-year-old Prof Hilton in number 1 haircut, dark grey t-shirt and black check shorts keenly pays tribute to his mentors and collaborators, disarmingly showing off an advertisement for his first major discovery Esgro, the leukemia inhibition factor used globally to cultivate mouse embryonic stem cells.

Esgro was discovered with Amrad, the biotechnology company established by Victoria's John Cain Labor Government in 1986. Esgro was on the market in 1988 and still returns its inventor a small royalty.

The inventor on more than 20 patent families, Doug Hilton is an easy conversationalist, with down-to-earth concerns about collaboration, the funding of medical research, his own family and the imminent surgery required for the family Kelpie, Jessie.

The learned texts in his bookcase are adjacent to a set of Charles Darwin volumes and several books by Prof Richard Dawkins, artworks by his children as well as those by professional artists and memorabilia including an American football, awards and WEHI visitors' books.

Born near Slough about 40 kms west of London in 1964, Doug has barely any memory of the time before his parents became "£10 Poms" and immigrated to Australia in 1970. Mum was a medical secretary and Dad was a production engineer, unlikely to get much promotion in England.

The one and a half acre bush block in then rural Warrandyte and Mr Hilton's new job at CIG in Preston were a world away from England, but the immediate pleasure was not long-lived. In 1975 on what was effectively the family's first real holiday Doug's father drowned, caught in the surf and dragged out to sea.

While Doug Hilton is clearly not the product of a materially comfortable life, he pays tribute to his Year 12 Higher School Certificate teacher Libby Holland at East Doncaster High School, who encouraged him to study an option on DNA.

"What she taught me was that there was a lot still to be discovered. She would say: 'I don't know. Go and find out'.

"As [learning] got more and more specific and I learned what was known from unknown, it got more exciting."

Again he pays tribute to another mentor, Monash immunology professor Richard Boyd. With a Monash Bachelor of Science, Doug transferred to the University of Melbourne for his honors year and was told by Prof Boyd that what he really needed to do was transfer to WEHI, which led to completing his Doctorate of Philosophy in molecular haematology and the invention of Esgro, which in turn led to his supervision of a group at Amrad.

Amrad became Zenyth and was acquired by CSL and Doug is extremely pleased to continue the collaboration with the biggest of Australia's biotechs.

"We need four or five CSLs to take drugs to market," he says.

And it is collaboration that is key to the evolution of WEHI. Prof Hilton says that he inherited the WEHI focus on the three major indications of cancer, infectious diseases and inflammatory disease, but it is a welcome inheritance. WEHI does not do research into cardio-vascular disease or neurobiology, with other institutes like the Baker IDI and Howard Florey more than capable of doing that work.

"It's not sensible from a strategic viewpoint to be duplicating work.

"I want the Institute to be internally and externally collaborative. I want people who enjoy working together and want to work together for long periods of time. I want people who genuinely get excited about working together," dismissing collaborations of convenience in which scientists will swap information for a specific publication on a once-off basis.

And he is proud of the age range of WEHI personnel from 18 year old students to 83 year old Prof Don Metcalf and younger luminaries like Prof Nossal, Prof Peter Colman and Prof Andreas Stasser.

"I inherited the themes from Suzanne Cory and before Suzanne, Gus, and there was no need to slash and burn research programs. Suzanne added bioinformatics and structural biology and I've pushed chemistry and biology including high-throughput screening along with new divisions of systems biology and personalized medicine."

Prof Hilton's foray into the world of politics with last year's 'Discoveries Need Dollars' campaign was not of his choosing (BD: Apr 8, 1, May 11, 2011). He was a generation after the protest movement, but as director of the Institute found that he had a national stage.

Despite subsequent Federal Government protestations, Prof Hilton says the threat of a \$400 million cut to the National Health and Medical Research Council budget was real.

"As the director you need to think more broadly than WEHI. And what is good for general research is in turn good for WEHI. [Previously] we hadn't articulated what medical research brought the community and why funding health and medical research was important."

The successful campaign forced the Federal Government to leave the NHMRC budget unscathed.

The importance of NHMRC funding is exemplified in WEHI's commitment to support indigenous health. Far from window dressing, a program has been developed with the Menzies School of Health Research in Darwin to address the 500 times disproportionate rate of rheumatic fever among indigenous populations – now funded by a grant from the NHMRC.

WEHI is contributing its skills in bioinformatics, genetics and immunology to search for a vaccine for a disease almost gone in Western populations and causing major health problems among Australia's indigenous people. The collaboration is looking at the difference in immune responses and hopes to create a vaccine for rheumatic fever.

In a WEHI biography Prof Hilton says the Institute's collaborative teams must be closeknit, trans-generational and outcomes-focused; the University of Melbourne must remain a key partner in training the next generation of researchers; the Institute must forge stronger links with clinical colleagues at the leading public teaching hospitals; and collaborations with the private sector, must continue to be actively and intensively pursued.

"We have the responsibility to make big basic discoveries that change the way scientists view the world. We are not a basic biology research institute, we are a medical research institute and we translate research into medicine with the World Health Organisation, CSL and GSK among others and we do not shy from that."

Prof Hilton says the 1999 Peter Wills Review of NHMRC funding 'The Virtuous Cycle' has taken time "to percolate through the Institute as well as the donors". The issues raised by an institute receiving funds from pharmaceutical companies, Federal Government grants and donations from wealthy and charitable families are not always easy to resolve, but Prof Hilton says that drug companies are interested in specific projects, while other work needs to have continuous funding.

He is proud of the work done with Genentech and Abbott Laboratories on the proapoptosis (cell death) drugs ABT263 in phase II trails in Australia and ABT199 in a phase I trail in Melbourne (BD: Jul 19, Aug 8, 2011). The 20 years of research includes three-way collaborations with WEHI, Genentech and Abbott on a compound discovered by Abbott in the US and developed by WEHI in Melbourne.

"The grand challenge for the next 10 years is to reap the benefits of medical research that is affordable and accessible and benefits the patient."

David Langsam Editor

GENETIC TECHNOLOGIES

Friday's edition included a typographical error on one of the dates of Genetic Technologies 47.6 percent share price rise to a high of 15.5 cents. The article should have reported the company's share price rose from 10.5 cents on January 25, 2012 to 15.5 cents on January 27, 2012 and noted an increase in trading volume and not as published. We thank our diligent readers for their assistance in this matter and the sub-editor has been suitably humiliated and shamed for two minor errors in his first week back and shall have no more holidays as they interfere with his accuracy.

Genetic Technologies fell one cent or 7.1 percent to 13 cents with 1.2 million shares traded.

MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES, SERVIER LABORATORIES

Servier Laboratories and Monash University's Institute of Pharmaceutical Sciences (MIPS) will collaborate on drug discovery and research on G-protein-coupled receptors. A Monash University and Servier Laboratories media release said the collaboration would use MIPS capability to identify new G protein-coupled receptor (GPCR) targets, in understanding of GPCR functional biology and the design of chemical entities to modulate GPCR activity.

Monash University said GPCRs were the largest superfamily of receptors, about two percent of the human genome, and were the targets for nearly 30 percent of drugs. The Monash Institute of Pharmaceutical Sciences said it had developed GPCR expertise comprising technology, research facilities and scientists that enabled it to conduct fundamental research, drug discovery and preclinical drug development activities on GPCR targets with therapeutic potential.

The joint media release said that the collaboration would run for three years with the research program including known and novel GPCR targets and covering potential therapeutic fields including metabolism, cardiology, neurology and psychiatry, rheumatology, and oncology.

The media release said that Servier would pay MIPS annual support for research activities and support for up to 15 full-time equivalents to work exclusively on collaborative projects and MIPS would receive milestone payments for each collaborative project as well as royalties for any product developed as a result of the collaboration.

The media release said that Servier would have exclusive rights to any product resulting from the collaboration, as well as the first right of negotiation to any GPCR targets not immediately selected as part of this collaboration.

MIPS director and Dean of Monash University's Faculty of Pharmacy and Pharmaceutical Sciences Prof Bill Charman said his group was "delighted to partner with Servier to advance our research and to translate our GPCR-based drug discovery insights to design new therapeutic agents for major human diseases".

Servier's president of research and development Dr Emmanuel Canet said the alliance with MIPS would "significantly enhance our capacity to identify and address original targets that may lead to therapies for untreated needs".

Servier's general manager of the Institut de Recherche Dr Bernard Marchand said that GPCRs had "shown promise to be the source of targets for human diseases, however there is still a lot to learn about functional specificity".

"... substantial efforts have been made to modulate GPCRs for therapeutic use and we are now very excited to be working with leading experts in the field on a truly collaborative research program to extend our understanding of GPCR biology," Dr Marchand said. Victoria's Minister for Technology Gordon Rich-Phillips welcomed the partnership saying the collaboration reinforced the Monash Institute of Pharmaceutical Sciences position as "the largest and most successful pharmaceutical sciences research institute in Australia and consolidated Victoria's leadership in pharmaceutical sciences".

SUNSHINE HEART

Sunshine Heart is trading on the ASX under the code SHCDA following the one-for-200 consolidation of its US common stock today January 30, 2012.

The Chess depositary instruments (CDIs) will trade on a deferred settlement basis under the SHCDA code between January 30 and February 10, 2012, before the stock returns to its previous code of SHC on February 13, 2012.

Sunshine Heart was untraded at four cents.

CIRCADIAN TECHNOLOGIES

Circadian says that vascular endothelial growth factor-C (VEGF-C) expression is markedly up-regulated in corneal graft rejection and can be blocked in mice with its VGX-100. Circadian said that data published in the journal, Investigative Ophthamology and Visual Science (IOVS) showed that VEGF-C expression was markedly up-regulated in corneal graft rejection and that VEGF-C blockade, through administration of lead development candidate VGX-100, a human antibody against VEGF-C, "significantly improved corneal graft survival in an animal model".

Circadian said the article entitled 'Vascular Endothelial Growth Factor-C Promotes Alloimmunity by Amplifying Antigen Presenting Cell Maturation and Lymphangiogenesis' indicated that VGX-100 could improve corneal graft survival. An abstract of the article is available at: <u>http://www.iovs.org/content/early/2012/01/25/iovs.11-8668.abstract</u>.

Circadian quoted the Eye Bank Association of America reporting that more than 40,000 corneal transplants were performed each year in the US with between 10 and 30 percent of grafts rejected within 12 months, particularly in at-risk patients who have a highly vascularized eye bed or in whom a graft has previously failed, and that improving graft survival in these patients was a major unmet clinical need.

Circadian said the study was led by Harvard Medical School Department of Ophthalmology's Prof Reza Dana and Dr Amir Hajrasouliha and showed that VEGF-C was markedly up-regulated in rejected corneas and that administration of VGX-100 was able to significantly improve corneal graft survival.

Prof Dana said that corneal grafting could have "enormously positive results for patients who may otherwise become blind".

"While grafting success has improved significantly over the past 20 years there are still a large number of grafts which continue to fail," Prof Dana said.

Circadian chief executive officer Robert Klupacs said the data "provides a significant new therapeutic development opportunity for our VGX-100 program in addition to our ongoing clinical oncology programs".

Mr Klupacs said his company was undertaking preclinical studies with VGX-100 for corneal grafts with the aim to begin clinical trials by July 2013.

Circadian fell four cents or 7.4 percent to 50 cents.

<u>ACRUX</u>

Acrux says that Swiss regulator Swissmedic has granted a marketing authorization for its Ellavie estradiol spray for menopause.

Acrux said the estradiol spray was approved for marketing in the US and Sweden, with applications under review by regulatory authorities in South Korea and South Africa.

The company said the approval in Sweden enabled it to seek marketing approvals in other European countries under a mutual recognition procedure.

Acrux said it was in commercial discussions with potential marketing and manufacturing partners for the estradiol spray in the European Union and in Eastern Europe.

Acrux chief executive officer Dr Richard Treagus said his company was "delighted that our marketing partner in Switzerland has achieved approval for Ellavie".

"We expect to advance the commercialisation of our estradiol spray product in the broader European market through further partnerships," Dr Treagus said.

Acrux said the estrogen therapy market outside the US was valued at \$US360 million a year and in Europe, transdermal therapies such as skin patches and gels accounted for about half of the estrogen therapy market.

Acrux fell seven cents or 2.1 percent to \$3.29.

NANOSONICS

Nanosonics says that sales revenue for the three months to December 31, 2011 was up 22.5 percent to \$2,797,000 compared with the quarter to September 30, 2011. Nanosonics has developed the Trophon EPR ultrasound transducer cleaning system. Nanosonics was up 1.5 cents or 2.6 percent to 59.5 cents.

BLUECHIIP

Bluechiip says it has raised \$473,000 through a placement at 20 cents a share. Bluechiip said the placement was on January 27, 2012 after the cut-off for its December 31, 2011 appendix 4C Quarterly Report which showed a cash burn of \$430,171 for the three months with cash at December 31, 2011 of \$501,000.

The company said that net cash inflow from investing activities was \$94,795 representing outlay in capital expenditure of \$49,201 and off-set by short-term loan repayment by chairman lain Kirkwood of \$144,000.

Bluechiip said that the net cash outflow from financing activities was \$36,232 due to payment of balance of costs related to the initial public offer prior to June 30, 2011. Bluechiip said it was "pursuing grants from state and federal government programs, as well as some international programs ... [and] expects to receive a material tax refund through the R&D tax incentive program for 2011-2012 and to start generating positive margins from sales in 2012".

Bluechiip was unchanged at 24 cents.

IM MEDICAL

IM Medical says its net operating cash burn for the three months to December 31, 2011 was \$1,390,000 with cash at the end of the quarter of \$1,212,000.

IM Medical said it was working to complete the sale agreement with Capitol Health. IM company secretary Richard Wadley told Biotech Daily said the company expected to have significantly reduced expenditures in the coming quarters. IM was unchanged at 0.6 cents.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: <u>editor@biotechdaily.com.au</u>; <u>www.biotechdaily.com.au</u>; twitter: @biotech_daily