



Biotech Daily

Tuesday December 13, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MESOBLAST UP 5%, LIVING CELL DOWN 10%**
- * **FEDERAL \$500m BIOMEDICAL TRANSLATION FUND**
- * **IMUGENE LICENCES BAKER IDI ARGININE MODULATORS FOR CANCER**
- * **REDHILL PHASE IIa RHB-104 'CLINICAL EFFICACY SIGNALS' FOR MS**
- * **IQ OPENS \$100m LIFE SCIENCE FUND**
- * **DORSAVI RAISES \$7m, SHARE PLAN FOR \$1m MORE**
- * **ORTHOCELL RAISES \$4m**
- * **CSL SELLS SEQIRUS WAREHOUSING, LOGISTICS TO TOLL GROUP**
- * **IMUGENE PLEADS SCHULTZ TO ASX 50% QUERY**
- * **HUNTER HALL TAKES 6.7% OF SIRTEX**
- * **POKIES BRUCE MATHIESON INCREASES, DILUTED TO 6% OF MAYNE**
- * **UK APPROVES CYNATA CYP-001 PHASE I GVHD TRIAL**
- * **COCHLEAR APPOINTS PROF BRUCE ROBINSON DIRECTOR**
- * **ALCHEMIA APPOINTS DARREN BOOK DIRECTOR**
- * **PATRYS APPOINTS DR PAMELA KLEIN, DR ALLEN EBENS ADVISORS**

MARKET REPORT

The Australian stock market fell 0.32 percent on Tuesday December 13, 2016 with the ASX200 down 17.8 points to 5,545.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and two were untraded.

Mesoblast was best, up 7.5 cents or 5.3 percent to \$1.485 with 1.1 million shares traded. Osprey climbed 4.55 percent; CSL was up 3.2 percent; Anteo and Genetic Signatures rose more than two percent; Acrux, Oncosil and Reva were up one percent or more; with Clinuvel, Compumedics, Opthea, Resmed and Sirtex up by less than one percent.

Living Cell led the falls, down one cent or 10.2 percent to 8.8 cents with 1.1 million shares traded. Orthocell fell 9.1 percent; Benitec and Ellex lost five percent or more; Admedus and Viralytics fell more than four percent; Avita, Cellmid, Neuren and Pharmaxis were down three percent or more; IDT and Impedimed shed more than two percent; Factor Therapeutics, Medical Developments and Polynovo were down more than one percent; with Airxpanders, Cochlear and Nanosonics down by less than one.

FEDERAL GOVERNMENT

The Federal Government says it has launched the \$500 million Biomedical Translation Fund to take biomedical discoveries from the laboratory to the patient.

A media release from the Minister for Industry, Innovation and Science Greg Hunt and the Minister for Health and Aged Care Sussan Ley said that Brandon Capital Partners, Oneventures Management and Bioscience Managers would manage \$250 million in government capital to be matched by more than \$250 million from the private sector.

“The Biomedical Translation Fund is ultimately about improving the lives of thousands of Australians through better healthcare, creating jobs and growing both new and established businesses,” Mr Hunt said. “The [Fund] will stimulate both the health and medical research sector and the broader economy, creating more jobs and better health outcomes.”

The investments made by [the Fund] into biomedical start-ups will help the businesses mature into internationally competitive companies solving unmet health needs and create new markets for healthcare,” Mr Hunt said.

The media release said that Brandon Capital had been licenced to manage \$230 million in Federal and matched private capital, with Oneventures licenced for \$170 million and Bioscience Managers licenced for \$100 million.

Further information on the Fund is available at www.business.gov.au/BTF.

IMUGENE

Imugene says it has an agreement with the Baker IDI Heart and Diabetes Institute to commercialize a portfolio of small molecule arginine modulators for cancer.

Imugene said it would pay no upfront costs for the exclusive, worldwide rights to the Melbourne-based Baker IDI arginine modulators for drug research, development and commercialization for oncology, but the Baker IDI would receive 1.5 percent of net revenues generated from approved cancer therapies using the technology.

The company said that it would use its expertise in tumor immunology to advance the arginine modulators to the clinic with the first proof-of-concept studies scheduled for 2017. Imugene said that arginine was a naturally-occurring amino acid critical for the activation, growth and survival of the body's own cancer-fighting cells.

The company said that depletion of arginine had been observed in renal cell carcinoma and acute myeloid leukaemia patients and researchers believed that increasing the availability of arginine “could help restore the tumor killing activity of the body’s own cancer fighting cells”.

Imugene chief executive officer Leslie Chong said there was “a growing body of evidence that drugs targeting immuno-oncology and tumor metabolism pathways have the potential to improve cancer treatment”.

“This agreement with the Baker IDI expands our clinical pipeline and potential to develop and commercialize first-in-class therapies that could significantly advance this promising field of cancer research,” Ms Chong said.

Imugene said that a patent application, entitled ‘Methods of Treating Proliferative Disorders’ protecting the compounds for oncology had been filed with IP Australia, formerly the Australian Patent Office, and if granted would provide cover until 2037.

Imugene said that arginine modulators were discovered as part of Baker IDI’s cardiovascular drug discovery research program.

Baker IDI head of hypertension and cardiac disease at Prof David Kaye said there was “increasing evidence the biology of inflammation that contributes to heart failure is also relevant to the biology that drives cancer”.

Imugene fell 0.3 cents or 15 percent to 1.7 cents with 34.1 million shares traded.

[REDHILL BIOPHARMA](#)

Israel's Redhill says its 18-patient, phase IIa, 48-week Cease-MS trial results show that RHB-104 is safe with "clinical signals" for efficacy for relapsing remitting multiple sclerosis. In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, Redhill said the proof-of-concept, single-arm, open-label study evaluated safety and potential efficacy of fixed oral-dose RHB-104 as an add-on therapy to interferon beta-1a in 18 patients with relapsing-remitting multiple sclerosis.

The company said that patients had 24 weeks of RHB-104 add-on treatment and a 24-week follow-up period with interferon beta-1a, but without RHB-104 and the 48-week results were consistent with interim 24-week results suggesting meaningful safety and clinical signals and supported further clinical development.

Redhill said 18 patients were enrolled at two Israeli sites, 17 completed dose escalation and were included in the modified intent-to-treat data set, one patient withdrew from the study and the per-protocol analysis included 10 patients who completed the 48-week study without any major protocol deviations.

The company said that the patients who completed the study showed "marked improvement over historical self-control" and the treatment effect of RHB-104 appeared to be maintained after discontinuing RHB-104.

Redhill said the annualized relapse rate was 0.0 at both 24 and 48 weeks in the per-protocol patients and 0.288 and 0.29, respectively, in the modified intent-to-treat population, comparing favorably with previously reported pivotal studies of interferon beta-1a therapies Avonex (0.67) and Rebif (0.87-0.91), with a total of five relapses of which four were in one patient.

The company said that all 10 per-protocol patients were relapse-free at both 24 and 48 weeks and 88 percent and 93 percent of the modified intent-to-treat patient population were relapse free at 24 and 48 weeks, respectively, comparing favorably with previously reported pivotal data on the use of Rebif (75%) in comparison with Avonex (63%) as standalone first-line therapies.

Redhill said that expanded disability status scale scores indicated disease was stable during the treatment period and there was a signal of improvement, with no increase in total scores observed in any of the patients during the treatment phase.

The company said that lesions noted on magnetic resonance imaging were almost entirely T2 lesions and a reduction in total T2 lesion volume was observed at 24 and 48 weeks as compared to baseline, suggesting a decreased burden of disease and comparing favorably with previously reported Avonex and Rebif data.

Redhill said that RHB-104 appeared safe and well-tolerated, with no drug-related serious adverse events or other clinically relevant or unexpected adverse events

The company said that further data analysis would drive the next steps in the development of RHB-104 for multiple sclerosis.

Redhill medical director Dr Ira Kalfus said the findings "support the therapeutic potential of RHB-104 as an add-on therapy in [relapsing remitting multiple sclerosis]".

"The final results from patients who completed the 48-week study period demonstrate marked improvement over historical self-control, suggesting the treatment effect of RHB-104 is maintained after discontinuing RHB-104," Dr Kalfus said.

"The results of this study using targeted antibiotic therapy support the hypothesis that a bacterially-induced dysregulated immune system plays a role in the pathogenesis of multiple sclerosis," Dr Kalfus said.

On the Nasdaq, Redhill was up 10 US cents or 0.88 percent to \$US11.43 (\$A15.25) with 28,545 shares traded.

[IQ GROUP GLOBAL](#)

The IQ Group says its \$100 million IQ Series 8 Life Science Fund (Global) is open for investment.

IQ said that the fund was conditionally approved as an early stage venture capital limited liability partnership (ESVCLP) registered with the Federal Government for wholesale and sophisticated investors, who would be entitled to tax concessions including potential tax free returns and a tax offset of up to 10 percent on eligible contributions.

The company said that applications for the IQ Series 8 fund, “for early-stage life science companies actively involved in the late-discovery to preclinical development stage of new medicines and medical technologies” would close by June 30, 2017.

IQ said that the \$100 million fund sought to achieve significant returns through the realization of capital gains by a thematic investment in opportunities within the life sciences and biotechnology sector.

IQ chief executive officer George Syrmalis said the group was “excited to launch this fund to support the Australian life science sector”.

“Our success relies on in-depth research and avoiding preconceptions,” Mr Syrmalis said. “We need to clearly see the benefits of the innovation these life sciences enterprises are pursuing, accruing to the companies, and by extension to the shareholders, not just the potential customers,” Mr Syrmalis said.

“In my opinion, the advent of genomic and molecular medicine is the biggest investment theme of this lifetime and we see a huge opportunity in storing and processing the vast amounts of data being generated in the biotech-life science industry,” Mr Syrmalis said.

IQ Group is a private company with subsidiaries including IQX and the ASX-listed IQ3.

[DORSAVI](#)

Dorsavi says it has commitments to raise \$7,000,001 in a placement at 46 cents a share and hopes to raise a further \$1 million in a share plan.

Dorsavi said that the placement to sophisticated and institutional investors would be completed in two tranches with the first raising \$5.0 million under the 15 percent placement capacity and the second tranche raising \$2.0 million from major shareholder Starfish Technology Fund II, subject to shareholder approval.

The company said that shareholders at the record date of December 12, could apply for shares in parcels up to \$14,996, to raise a maximum of \$1 million, the offer would open on December 14 and close on January 19, 2017.

The company said the funds would be used for the recruitment of additional occupational health and safety agents in the US “to rapidly scale revenue”, working capital and to fund the sixth generation sensor system product launch of the new V6 mini-sensor system.

Dorsavi said that Bell Potter Securities was the lead manager and book-runner for the placement.

Dorsavi was unchanged at 51 cents.

[ORTHOCELL](#)

Orthocell says it has raised \$4,000,000 in a placement at 40 cents a share.

Orthocell said that the funds would be used to progress its portfolio of products and for working capital purposes.

The company said that Argonaut Securities Pty Ltd was the sole lead manager of the placement.

Orthocell fell four cents or 9.1 percent to 40 cents.

CSL

CSL subsidiary Seqirus has partnered with the Toll Group to manage Seqirus' warehousing and logistics business.

CSL said that Seqirus had a speciality cold-chain logistics business in Australia since 1986, distributing its vaccines and pharmaceuticals as well as plasma products manufactured by CSL Behring and provided third-party logistics services to a range of pharmaceutical companies and government departments.

The company said that Toll would acquire Seqirus warehousing and logistics business and would provide third party logistics services for products distributed by CSL Behring and Seqirus in Australia.

Seqirus head of operations Chris Larkins said the core business was the manufacture and marketing of vaccines and pharmaceuticals and "we have determined that our customers would be better served by a company that has specialist capabilities in the cold-chain transport of important medical products".

CSL was up \$2.93 or 3.2 percent to \$95.03 with 1.3 million shares traded.

IMUGENE

Imugene has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 50.0 percent from 1.4 cents on December 8 to 2.1 cents on December 12, 2016 and noted a significant increase in the trading volume. Imugene said that it had released an announcement regarding an agreement with the Baker IDI Heart and Diabetes Institute but did "not believe this agreement had any impact on the recent trading in company securities".

"To the company's knowledge, the information announced remained confidential and was subject to one or more exemptions from disclosure, as set out in Listing Rule 3.1A, prior to its release this morning," Imugene said.

SIRTEX MEDICAL

Hunter Hall Investment Management has increased its substantial holding in Sirtex from 2,842,614 shares (4.97%) to 3,857,489 shares (6.69%).

Hunter Hall said it bought and sold shares between October 30, 2015 and December 9, 2016, acquiring 1,469,666 shares on December 9, following the Sirtex profit warning with for \$22,985,301 or \$15.64 a share (BD: Dec 9, 2016).

Last week, Sirtex fell as much as 52.5 percent to \$12.20 closing at \$16.00.

Last year, Hunter Hall fell below the five percent substantial holder mark selling shares at \$37.44 a share (BD: Nov 2, 2015).

In March 2015, following the failure of the Sirtex trial to meet its primary endpoint, the Sirtex share price fell as much as 55 percent and Hunter Hall bought 1,251,375 shares at \$17.44 a share, the first time Hunter Hall had bought Sirtex shares since May 2013 when it reached an internal maximum and as the Sirtex price increased, Hunter Hall was required to sell down to remain under the limit (BD: Mar 17, 19, 2015).

Sirtex was up one cent or 0.06 percent to \$16.61 with 1.2 million shares traded.

MAYNE PHARMA

Mayne director Bruce Mathieson has increased his shareholding but has been diluted from 42,394,122 shares (7.77%) to 90,469,499 shares (6.1%).

In his substantial shareholder notice, gambling machine operator Mr Mathieson said he acquired 33,126,419 shares for \$42,401,816 or \$1.28 a share in a July 2016 rights issue as well as 12,688,332 shares for \$7,739,883 or 61 cents a share in a February 2015 rights issue and most recently bought 200,000 shares on market for \$290,333 or \$1.45 a share. In July, Mayne raised \$888 million in a placement at \$1.50 a share and an institutional rights offer at \$1.28 a share, and in 2015 raised \$115 million in a rights issue at 61 cents a share and a placement at 75 cents a share (BD: Feb 12, 2015; Jul 20, 2016) Mayne fell 2.5 cents or 1.7 percent to \$1.44 with 5.8 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has UK National Health Service Health Research Authority approval for its phase I trial of its Cymerus stem cells for steroid-resistant graft-versus-host disease. Cynata said the trial would use its Cymerus mesenchymal stem cell product CYP-001 in the trial approved by the UK Medicines and Healthcare Products Regulatory Agency, so all approvals required for patient recruitment were in place would begin “as soon as possible” with Australian sites to be opened in the near future. Cynata was up two cents or 3.3 percent to 62 cents.

COCHLEAR

Cochlear says it has appointed Prof Bruce Robinson as an independent, non-executive director, effective from today, December 13, 2016.

Cochlear said that Prof Robinson had more than 20 years experience as an academic physician and scientist across research, healthcare, medicine and tertiary education.

The company said that Prof Robinson was previously the University of Sydney’s Medical School dean and head of medicine at Sydney’s Royal North Shore Hospital as well as the head of the cancer genetics laboratory at the Kolling Institute for Medical Research.

Cochlear said that since 2015, Prof Robinson had been the National Health and Medical Research Council chair and chair of the Medical Benefits Schedule Review Taskforce and was currently a director of Mayne Pharma, medical device start-up Firefly and Qbiotics.

The company said that Prof Robinson’s appointment meant it had nine directors. Cochlear fell 15 cents or 0.1 percent to \$114.48 with 154,410 shares traded.

ALCHEMIA

Alchemia says it has appointed Darren Book as a non-executive director effective from December 12, 2016.

Alchemia said that Mr Book had more than 15 years’ experience in business and corporate finance and had knowledge and experience in a variety of finance transactions and industry sectors.

The company said that Mr Book had worked with “high net worth family groups” as well as advising other companies on restructuring, mergers and acquisitions and other strategic initiatives including roles at Ferrier Hodgson and Deloitte.

Alchemia said that Mr Book currently worked with a Melbourne family office and held a Bachelor of Economics degree from Melbourne’s Monash University.

Alchemia was untraded at one cent.

PATRYS

Patrys says it has appointed Dr Pamela Klein and Dr Allen Ebens to a newly-convened scientific advisory board.

Patrys said that Dr Klein completed her medical training at Chicago's Loyola University before working at the US National Cancer Institute, and was appointed as Genentech's development vice-president, where she led the development of a portfolio of drugs including all the HER compounds, Herceptin, Tarceva and Perjeta, as well as drugs for apoptosis and haematology compounds.

The company said that more recently Dr Klein was the La Jolla, California-based Intellikine's chief medical officer.

Patrys said that Dr Klein was currently an advisor to biotechnology and investment companies, with roles on scientific advisory boards and corporate boards.

The company said that Dr Ebens completed a Doctorate of Philosophy at the University of California Los Angeles (UCLA) and completed a post-doctoral qualification at the University of California San Francisco before joining Exelixis as a scientist in the discovery biology group.

Patrys said that Dr Ebens later worked for Genentech for more than 11 years in the research oncology group and was recruited by Juno Therapeutics to establish the oncology research laboratory and was currently the San Francisco-based NGM Biopharmaceuticals senior director of immune oncology.

Patrys was up 0.1 cents or 20 percent to 0.6 cents.