



Biotech Daily

Wednesday July 20, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: BENITEC UP 20%; FACTOR THERAPEUTICS DOWN 7%**
- * **CHIEF SCIENTIST: 'RESEARCH INFRASTRUCTURE CONSULTATIONS'**
- * **MASS GENERAL FOR RESAPP US PAEDIATRIC RESPIRATORY TRIAL**
- * **MAYNE RETAIL OFFER RAISES \$254m, TOTAL RAISED \$888m**
- * **US PATENT FOR ACTINOGEN'S XANAMEM FOR ALZHEIMER'S**
- * **IMMURON PARTNERS FOR COLOSTRUM IMM-124E FOR AUTISM STUDIES**
- * **IMPEDIMED HIRES REDOX FOR ELECTRONIC HEALTH RECORDS**
- * **RECCE: 'TESTING SHOWS RECCE-327 NON-CARCINOGENIC'**
- * **FIDELITY \$8m PLACEMENT TAKES IT TO 10% OF ADHERIUM**
- * **INNATE PLACES \$1.2m, TOTAL RAISED \$6.6m**
- * **COGSTATE REVENUE UP 70% TO \$14m**
- * **ADMEDUS SALES UP 40% TO \$14m**
- * **IQ3 CORP'S IQ CAPITAL WINS US INVESTMENT BANKING LICENCE**
- * **BENITEC PLEADS SCHULTZ TO ASX 40% QUERY**
- * **CELLMID APPOINTS COLOUR COLLECTIVE US DISTRIBUTOR**
- * **AUSTRALIAN ETHICAL TAKES MORE ELLEX PROFIT TO 7.7%**
- * **FIL TAKES 5% OF RESAPP, 5% OF SOMNOMED**
- * **BOTANIX HIRES MARK DAVIS, STEVE NEWHARD FOR BTX1503 FOR ACNE**

MARKET REPORT

The Australian stock market climbed 0.69 percent on Wednesday July 20, 2016 with the ASX200 up 37.4 points to 5,488.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and one was untraded. All three Big Caps rose.

Benitec was best, up two cents or 20 percent to 12 cents with 2.6 million shares traded. Cellmid climbed 19.35 percent; Admedus was up 10.5 percent; Prana rose 7.1 percent; Anteo was up five percent; Acrux and Sirtex climbed more than four percent; Biotron and Neuren were up more than three percent; with CSL and Nanosonics up 2.1 percent.

Factor led the falls, down 0.3 cents or 7.0 percent to four cents, with 275,675 shares traded. Osprey lost 6.9 percent; Compumedics and Living Cell fell more than five percent; Pharmaxis was down 3.6 percent; Psivida shed 2.1 percent; with IDT, Opthea and Polynovo down more than one percent.

FEDERAL GOVERNMENT, CHIEF SCIENTIST

Australia's chief scientist Dr Alan Finkel says consultations have opened on research infrastructure priorities.

A media release from the Office of Chief Scientist said that Federal Government's National Research Infrastructure Capability Issues Paper had been released and identified areas of research infrastructure capability needed to keep Australia "at the forefront of the research endeavour in future decades".

Dr Finkel said that identifying key capability areas would allow the Government to focus research national infrastructure investment where it would have the greatest impact.

"If we want world-class research, we need to make sure Australian researchers have access to leading-edge equipment and services," Dr Finkel said.

"The Issues Paper examines key areas where national research infrastructure investment could enable the strongest results for Australia's research and innovation," Dr Finkel said.

"But this paper is a foundation, not a finished proposal," Dr Finkel said. "We need Australia's research community, industry groups and other interested parties to provide feedback by having their say on these research infrastructure priorities."

The media release said that the Issues Paper was "a key step in the development of the 2016 National Research Infrastructure Roadmap" and submissions could be made until September 9, with consultation sessions from July 26 to September 5, 2016.

Information on the Roadmap and the Issues Paper are at www.chiefscientist.gov.au.

RESAPP HEALTH

Resapp says its first US paediatric study of its Resappdx respiratory disease diagnostic would begin at Boston's Massachusetts General Hospital.

In March, Resapp said it would pursue a "direct de novo premarket submission" for the diagnostic and the US Food and Drug Administration had provided targeted feedback for the regulatory pathway, clinical study protocols, planned non-clinical evaluations and data requirements for its mobile telephone software application (BD: Mar 14, 2016).

The company said at that time that the de novo process led to a class I or class II classification and had a 120-day review cycle.

Today, Resapp chief executive officer Dr Tony Keating said that working with Massachusetts General would allow the company "to enrol large numbers of patients quickly and provide the highest quality clinical results for our FDA de novo submission".

Resapp was up 1.5 cents or 4.7 percent to 33.5 cents with 10.7 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says its retail entitlement offer was 88 percent subscribed and with applications for additional shares has raised about \$254 million (BD: Jun 28, 2016).

Mayne said that the retail entitlement offer was underwritten but applications under the top-up offer were sufficient to cover the shortfall and had been scaled back, so no shortfall shares would be issued to the underwriters.

In June, Mayne said it would acquire 37 approved products and five US Food and Drug Administration filed products from Teva for \$US652 million (\$A880.7 million) and fund the acquisition through an extension of its existing debt facility and a fully underwritten \$601 million one-for-1.725 non-renounceable entitlement offer and \$287 million placement.

On June 30, Mayne said its placement at \$1.50 a share raised \$287 million and the institutional rights offer at \$1.28 a share raised \$347 million (BD: Jun 30, 2016).

Mayne was unchanged at \$1.985 with 12.0 million shares traded.

ACTINOGEN MEDICAL

Actinogen says US Patent Office has granted “the most comprehensive patent for Xanamem” providing cover to 2031.

According to the USPTO, the patent is entitled ‘3,3-disubstituted-(8-aza-bicyclo[3.2.1]oct-8-yl)-[5-(1H-pyrazol-4-yl)-thio-phen-3-yl]-methanones as inhibitors of 11 (.beta.)-HSD1’.

Actinogen said that the patent protected the use of Xanamem for use in Alzheimer’s dementia and other related diseases associated with the inhibition of the 11-beta-hydroxysteroid dehydrogenase (11-beta-HSD1) enzyme.

The company said that US grant followed previous approvals in most other major markets, including all European countries, the UK, Australia, Japan and China.

Actinogen said that Xanamem had been designed to inhibit the excess production of the stress hormone cortisol in the brain, with excess cortisol associated with cognitive decline, amyloid plaque build-up and neurotoxicity in the brain, the hallmarks of Alzheimer’s disease.

The company said that inhibition of excess cortisol was “a very promising new target for treating Alzheimer’s disease”.

Actinogen was up 0.1 cents or 1.45 percent to seven cents.

IMMURON

Immuron says it will partner with three research institutes to understand the genetic basis of autism spectrum disorder and how it relates to the gastro-intestinal tract.

Immuron said the partnership, with the University of Melbourne’s Dr Elisa Hill, La Trobe University’s Prof Ashley Franks and Murdoch Children’s Research Institute’s Prof Ravi Savarirayan, would examine how its cow colostrum-based anti-lipo-poly-saccharide IMM-124E affected changes in mouse models for autism.

The company said that the understanding would “provide information on how alterations in the gut micro-biome occur and potentially identify targets for the development of clinical therapies to restore gut balance and improve the quality of life for [autism spectrum disorder] patients”.

Prof Franks said that the scientific research team had identified that the micro-biota was altered in mutant mouse models compared to their otherwise genetically identical wild type litter-mates and the team would investigate the structure of the fecal micro-biome in wild type and mutant mice, to translate to human studies.

Immuron said that gastro-intestinal micro-biota were known to influence mood and behaviour and there was evidence that gut bacterial communities were altered in patients with autism spectrum disorder, but studies in patients had limitations due to the difficulty in controlling environmental factors.

Co-principal investigator Dr Hill said that research of mouse models for autism, where mutations in genes involved in the formation and remodelling of central nervous system synapses “will be extended to closely map the microbes in the gut and provide understanding on how the brain and bacteria interact during development”.

Immuron said that autism spectrum disorder patients often had gastro-intestinal problems including bloating, constipation or diarrhoea.

Immuron chief executive officer Thomas Liquard said positive data “would be an industry first, and the next step would be to conduct investigator sponsored human studies”.

“We have already identified a potential patient cohort and we look forward to potentially start human studies in 2017 following the results of this pre-clinical study in mice,” Mr Liquard said.

Immuron was up half a cent or two percent to 25 cents.

IMPEDIMED

Impedimed says that the Madison, Wisconsin-based Redox will expand its electronic health record integration for its next bio-impedance spectroscopy device.

Impedimed said the new bio-impedance spectroscopy (BIS) technology would “measure, monitor and manage fluid status and body composition in clinical and at-home settings”.

Previously, the company said the first use of the technology would be to diagnosis fluid level changes in congestive heart failure patients.

Last year, Impedimed acquired assets and intellectual property from Intersection Medical for its bio-impedance spectroscopy for chronic heart failure and has an agreement with the Harvard Clinical Research Institute to investigate bio-impedance spectroscopy in chronic heart failure patients. (BD: Oct 26, Nov 3, 2015).

Today, Impedimed said Redox had an “application programming interface” which it used to integrate electronic health records from multiple vendors.

Impedimed chief executive officer Richard Carreon said that integration “into the ecosystem of complex electronic health record systems is critical”.

“Impedimed’s BIS technology provides a precise, rapid and repeatable snapshot of a person’s lean body mass, fat mass, total body mass and intra-and-extracellular fluid,” Mr Carreon said. “Having access to historical health data can help health care providers better detect and manage chronic disease in patients, improving outcomes and reducing the costs of care”.

Impedimed was up two cents or 1.6 percent to \$1.25 with 904,651 shares traded.

RECCE

Recce says that three separate in-vitro screening tests for genetic toxicity indicate that Recce-327 is not carcinogenic.

Recce said that the screening tests were performed by an independent US contract research organization tested for chromosome damage and genetic mutations in cells exposed to wide-ranging doses of Recce-327.

Recce executive chairman Dr Graham Melrose said that he was “very pleased that Recce-327 is not demonstrating a propensity to cause cancer”.

“The results are a green light for us to continue our ... testing program with confidence,” Dr Melrose said.

Recce was up two cents or 8.3 percent to 26 cents.

ADHERIUM

Adherium says that it will place \$8,023,049 in shares at 50 cents each with Fidelity International, taking Fidelity’s holding to 10 percent of the company.

Adherium said that Fidelity was an asset manager with clients in the Asia-Pacific region, Europe, the Middle East, and South America.

The company said that the placement was managed by Bell Potter Securities.

Adherium chief executive officer Garth Sutherland said that Fidelity was “one of the world’s leading investment institutions”.

“This investment demonstrates Adherium’s growing international profile and reflects the strong confidence widely held in the international markets of our company’s global opportunities and the increasing scope of our technology,” Mr Sutherland said.

Adherium said the placement would be made under its 15 percent placement capacity and the funds raised would be used for working capital.

Adherium fell one cent or two percent to 49 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says it has raised a further \$1,200,000 in a placement of 3,542,926 shares at 26 US cents or 34 Australian cents a share, taking the total raised to \$6,626,610.

Innate said the placement completed a capital raising program over the past five weeks with a US placement raising \$2,400,000 at 18 US cents a share and a rights issue which raised \$3,026,610 at 25 cents a share (BD: Jun 10, 2016).

The company said that shareholder approval for both placements and for non-executive directors participation would be sought at its annual general meeting on August 31, 2016. Innate fell half a cent or 1.3 percent to 38 cents.

COGSTATE

Cogstate says that revenue for the 12 months to June 30, 2016 was up 69.6 percent to \$27.3 million and it had signed record sales contracts valued at \$US28.5 million.

Cogstate fell 10 cents or 12.8 percent to 68 cents.

ADMEDUS

Admedus says sales for the 12 months to June 30, 2016 were up 38.2 percent to \$14.1 million with sales for the three months to June 30 of \$4.0 million.

Admedus said it had \$8.8 million in cash at June 30 with \$3.5 million expected from a Federal R&D Tax Incentive by June 30, 2017.

Admedus was up four cents or 10.5 percent to 42 cents with 2.2 million shares traded.

BENITEC BIOPHARMA

Benitec 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 four cents or 40 percent from 10 cents to 14 cents, today, and noted "a significant increase in the volume of ... securities traded".

Last night on the Nasdaq, Benitec climbed 38.04 US cents or 29.04 percent to \$US1.6904 with 209,678 shares traded.

Benitec closed up two cents or 20 percent at 12 cents with 2.6 million shares traded.

IQ3 CORP

IQ3 says its wholly-owned subsidiary IQ Capital has a licence to operate its New York-based life sciences investment banking business.

IQ3 said IQ Capital was registered by the US Securities and Exchange Commission and had been admitted to membership of the Financial Industry Regulatory Authority.

The company said that IQ Capital could offer clients a range of investment advisory services as well as debt and equity offerings through public or private placements.

IQ3 chief executive officer Dr George Syrmalis said the company had been "building our deal book focused on the US markets and with IQ Capital now fully operational we can move these deals to the next level".

"IQ Capital ... with IQ3 Corp and our [Asia Pacific] business unit in Shanghai all align in such a way that enables us to efficiently execute cross border arbitrage transactions, ultimately resulting in capital and deal flow, across [the US], Australia and China connecting informed strategic investors to life science companies," Dr Syrmalis said.

IQ3 was up six cents or 24 percent to 31 cents.

CELLMID

Cellmid says the Dallas, Texas-based Colour Collective, a specialist in the launch of high-end hair brands, will distribute its Evolis hair loss products.

Cellmid was up 0.6 cents or 19.35 percent to 3.7 cents with 61.5 million shares traded.

ELLEX MEDICAL LASERS

Australian Ethical Smaller Companies Trust says it has again reduced its holding in Ellex from 10,036,340 shares (8.79%) to 8,757,718 (7.67%).

Australian Ethical became substantial in Ellex in 2013, acquiring 8,794,563 shares or 9.01 percent with 5,000,000 shares acquired in a capital raising at 26 cents (BD: Oct 3, 2013).

In 2013 and 2014 Australian Ethical bought more shares at about 30 cents a share and first reduced its holding this year, selling shares at 75 cents and 78 cents.

Today, Australian Ethical said it sold 1,278,622 shares between April 15 and July 18, 2016, with the single largest sale 500,000 shares for \$546,296 or \$1.09 a share.

Ellex was unchanged at \$1.17.

RESAPP

The Hong Kong, London and Sydney-based FIL Limited says it has become a substantial shareholder in Resapp with 32,842,028 shares (5.06%) and bought the shares between May 4 and July 15, 2016, at prices ranging from 22 cents and 44 cents.

SOMNOMED

The Hong Kong and Singapore-based FIL Limited says it has become a substantial shareholder in Somnomed with 2,863,471 shares (5.05%).

FIL said it bought the shares between April 6 and July 15, 2016, at prices ranging from \$2.50 and \$3.45.

Somnomed fell one cent or 0.3 percent to \$3.32.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Mark Davis and Steve Newhard to lead its development program for its cannabidiol BTX1503 for acne.

Botanix said that Mr Davis would lead the clinical and regulatory functions and Mr Newhard would lead the manufacturing and quality programs.

The company said that Mr Davis previously led the Changler, Arizona-based Insys Therapeutics Inc synthetic cannabidiol epilepsy treatment program.

Botanix said that Mr Davis held clinical and regulatory roles at Medicis and Connectics and led development programs for the treatment of acne and other skin diseases.

The company said that Mr Newhard had 35 years' experience in the quality operations, development, scale up and manufacturing of pharmaceutical products.

Botanix said Mr Newhard would lead formulation testing and manufacturing activities in conjunction with the company's contract laboratory in Pennsylvania.

Botanix was up 1.1 cents or 28.95 percent to 4.9 cents with 18.9 million shares traded.