



Biotech Daily

Wednesday December 12, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: IMUGENE UP 9.5%; USCOM DOWN 8%**
- * **FEDERAL GOVERNMENT: NHMRC \$526m FOR 682 PROJECTS**
- * **FEDERAL \$25m GRANTS FOR MENTAL ILLNESS OPEN**
- * **REDHILL RAISES \$28m**
- * **FDA APPROVES MAYNE (HALCYGEN) SUBA-ITRACONAZOLE**
- * **US PATENT FOR STARPHARMA SPL7013 CONJUNCTIVITIS EYE DROPS**
- * **CELLMID: 'RECORD \$2.2m Q2 REVENUE'; FROM GLASS TO PLASTIC**
- * **CARDIEX EXPANDS BLUMIO WEARABLE BP MONITOR DEAL**
- * **RESONANCE PLEADS SCHULTZ, NEWS, DEALS TO ASX 29% QUERY**
- * **ASX SUSPENDS MMJ**
- * **PHOSPHAGENICS TAKES 'MYLAN TALKS' HALT TO SUSPENSION**
- * **JEREMY GREEN, REDMILE TAKE 9.4% OF AVITA**
- * **ONE FUNDS INCREASES, DILUTED TO 5% OF AVITA**
- * **ROBERT LEDERER, RTL GROUP TAKE 9% OF ANATARA**
- * **BENJAMIN KARASIK DILUTED BELOW 5% OF ESENSE**
- * **ADMEDUS: STAR BRIGHT LISHAN ZHANG, DR YANHENG WU DIRECTORS**
- * **FACTOR LOSES DIRECTOR DR ROBERT RYAN**

MARKET REPORT

The Australian stock market was up 1.39 percent on Wednesday December 12, 2018, with the ASX200 up 77.6 points to 5,653.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and six were untraded.

Imugene was the best, up 0.2 cents or 9.5 percent to 2.3 cents, with 2.0 million shares traded. Avita and Compumedics climbed more than six percent; Volpara was up 5.45 percent; Osprey and Starpharma improved more than four percent; Immutep, Nanosonics and Patrys rose more than three percent; Clinuvel, CSL, Prescient and Resmed were up more than one percent; with Telix up 0.85 percent.

Uscom led the falls, down one cent or 7.7 percent to 12 cents, with 18,000 shares traded. Optiscan, Orthocell and Paradigm lost more than five percent; Airxpanders fell 3.45 percent; Actinogen, Mesoblast and Proteomics shed more than two percent; Ellex, Medical Developments and Neuren were down more than one percent; with Cochlear and Polynovo down by less than one percent.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, FEDERAL GOVERNMENT

The Federal Government says the National Health and Medical Research Council will fund 682 grants totalling more than \$526 million.

A media release from Federal Health Minister Greg Hunt said the funding included: \$61 million for cardiovascular disease research; \$86 million for cancer research; \$41 million for mental health research; \$29 million for diabetes research; \$28 million for obesity research; and \$25 million for research on improving the health of indigenous Australians. Mr Hunt said the grants would “support our health and medical research workforce, providing greater opportunities for more life-changing medical breakthroughs”.

The media release said the 2018-'19 Budget provided “a record total of \$6 billion to Australia’s health and medical research sector, including \$1.3 billion for a health and medical industry growth plan”.

A full list of grant recipients is available at: www.nhmrc.gov.au.

FEDERAL GOVERNMENT

The Federal Government says applications have opened for \$25 million in grants for mental health research.

A media release from Federal Health Minister Greg Hunt said that the grants, under the Million Minds Mental Health Research Mission, “aimed at developing new approaches to prevent, detect, diagnose, and treat mental illness”.

The Government said the priorities for the first funding round were child and youth mental health, Aboriginal and Torres Strait Islander mental health, and eating disorders.

The media release said that a total of \$125 million would be provided over 10 years from 2017-'18 from the Medical Research Future Fund “to help a million people be part of new trials and programs aimed at improving diagnosis, treatment and recovery”.

The media release said that more than 3.8 million Australians aged between 16 and 85 years experienced a mental illness each year.

The Government said that applications would close on February 20, 2019.

To apply go to www.grants.gov.au.

REDHILL BIOPHARMA

Redhill says it has raised \$US20 million (\$A27.7 million) in an underwritten public offer for of 2,857,143 American depository shares at \$US7.00 (\$A9.69) a share.

Redhill said that the proceeds would be used with existing reserves to fund preparations for its Talicia (RHB-105) for Helicobacter pylori commercial launch and commercialization activities, clinical development programs, including initiation of a pivotal phase III study with RHB-204 for non-tuberculosis mycobacteria, preparations for a second phase III study with RHB-104 for Crohn’s disease and for acquisitions and general corporate purposes.

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, the company said that it had granted the underwriters a 30-day option to purchase up to 428,571 additional ADSs at the public offering price.

Redhill said that Ladenburg Thalmann & Co and Nomura Securities International were the joint book-running managers, with HC Wainwright & Co lead manager and Lifesci Capital, Ascendant Capital Markets, SMBC Nikko Securities America and WBB Securities as co-managers, while Roth Capital Partners was the financial advisor for the offer.

On the Nasdaq, Redhill was up two US cents to \$US7.00 with 150,035 shares traded.

MAYNE PHARMA (FORMERLY HALCYGEN)

Mayne says the US Food and Drug Administration has approved Suba-itraconazole, to be marketed as Tolsura, 65mg capsules for certain systemic fungal infections in adults.

Mayne said that Tolsura was indicated for blastomycosis, histoplasmosis and aspergillosis in patients who were intolerant of or who are refractory to amphotericin B therapy.

The company said the infections most commonly occurred in vulnerable or immune-compromised patients, such as people with a history of cancer, transplants, HIV/AIDS, or chronic rheumatic disorders, and were often associated with high mortality rates.

Mayne chief executive officer Scott Richards said itraconazole incorporated its Suba, or super bioavailability, technology to improve the bioavailability of poorly soluble drugs.

“After many years of research and development and working closely with key global opinion leaders in infectious disease management, Tolsura represents a major milestone in the Suba ... drug delivery platform,” Mr Richards said.

The company said Tolsura had four granted US patents with expiry dates ranging from 2023 to 2033 and it planned to launch the product in January 2019.

In 2008, the then Halcygen said it had filed an investigational new drug application for Suba-intraconazole with the FDA (BD: Nov 29, 2007; May 14, 2008).

The company said in May that it had regulatory approval for its Suba-itraconazole capsules in Australia, Argentina, Belgium, Germany, Mexico, Italy and Spain, and would seek approval in other countries.

Mayne was up 5.5 cents or 6.15 percent to 95 cents with 10.3 million shares traded.

STARPHARMA

Starpharma says the US Patent and Trademark Office has granted a patent for its SPL7013 ophthalmic drops for viral conjunctivitis.

Starpharma said that the patent, had broad claims for treating and preventing microbial infections of the eye, including adenoviral conjunctivitis, bacterial conjunctivitis and other eye infections and provided intellectual property rights until 2033.

According to the USPTO the patent title was ‘Method of treatment or prophylaxis of infections of the eye’.

The USPTO cited Starpharma chief executive officer Dr Jackie Fairley as a co-inventor along with Dr Colin Barrett and Dr Jeremy Paull.

The company said that viral conjunctivitis was the most common cause of infectious conjunctivitis, affecting about six million people in the US and four million in Europe each year, with a market estimated at about \$US700 million a year.

Starpharma said there were no approved therapies for viral conjunctivitis and it was an area of significant unmet medical need globally.

The company said that SPL7013 ophthalmic drops demonstrated “compelling efficacy in animal models of viral conjunctivitis ... [showing] potent anti-viral activity, decreased infectivity and importantly, they are non-irritating”.

Dr Fairley said that independent market research found positive responses from 87 percent of clinicians surveyed.

The company said there was partnering interest for the product and it was evaluating the optimal development strategy for the novel therapy.

Starpharma said that SPL7013 was a proprietary dendrimer which was the active ingredient in its Vivagel products and given the extensive pre-clinical and clinical data already available, there would be significant development advantages both in terms of cost and time.

Starpharma was up six cents or 4.2 percent to \$1.49.

CELLMID

Cellmid says its hair growth products revenue for the three months to December 31, 2018 is expected to be a record \$2.2 million, and it will move to plastic packaging.

Cellmid said a "scheduled sales event" on a Japanese television shopping channel delivered sales revenue of about \$1.1 million.

The company said that with retail sales of more than \$2.2 million its Jo-Ju branded Japanese hair growth products were "one of the most successful cosmetics ever on the Japanese television shopping channel".

Cellmid said that it had changed its Jo-Ju packaging from glass to plastic bottles, increasing net profit margins by about 10 percent, with manufacturing time reduced from seven months to three months.

Cellmid was up five cents or 19.2 percent to 31 cents.

CARDIEX

Cardiex says it has expanded its Blumio deal to develop sensor technology integrated into wearable devices, such as fitness trackers, smartwatches, and medical devices.

Cardiex said it would provide algorithms and its US-approved Sphygmocor technology for central blood pressure and Blumio would supply blood pressure sensor technology.

The company said the co-developed wearable device would measure both upper arm and central blood pressure and assess arterial stiffness and general cardiovascular health.

In March, Cardiex said it had a collaboration and development agreement with the San Francisco-based Blumio to co-develop wearable blood pressure technology based on Blumio's sensor and Cardiex's blood pressure analytics algorithms (BD: Mar 14, 2018).

Last month, Cardiex said that Blumio would conduct a 200-subject study of its non-invasive wearable blood pressure sensor (BD: Nov 1, 2018).

Cardiex said the parties would share equal ownership and rights in the final developed product and on completion it would be granted an additional 2.5 percent converting equitable interest in Blumio, taking its holding to 10 percent.

Cardiex was up 0.3 cents or 10 percent to 3.3 cents.

RESONANCE HEALTH

Resonance 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 climbed 28.95 percent from 7.6 cents on December 10 to 9.8 cents on December 11, 2018, and noted a "significant increase" in trading volumes.

Resonance told the ASX that on December 3 it announced US Food and Drug Administration clearance for its Ferrismart diagnostic for liver iron quantification.

On that day, Resonance shares climbed as much as 138.5 percent to 6.2 cents before closing 100 percent to 5.2 cents with 190.4 million shares traded (BD: Dec 3, 2018).

Today, the company said it was seeking "additional collaboration opportunities with various pharmaceutical and therapeutic companies for the use of its services as well as assessing opportunities to expand core business through acquisitions, to distribute [its] products through channel partners and to provide distribution services for third-party products and services that fit with the existing ... core business and distribution network". Resonance said it had "no immediate knowledge of the date of finalization of any potentially material information".

Resonance fell one cent or 10.3 percent to 8.7 cents with 96.7 million shares traded.

MMJ GROUP

The ASX says MMJ securities “will be suspended from quotation immediately under Listing Rule 17.3, pending response to ASX queries”.

MMJ last traded down half a cent or 1.9 percent to 25.5 cents.

PHOSPHAGENICS

Phosphagenics has requested a voluntary suspension to follow the trading halt requested on Monday, pending an “pending an announcement ... in relation to advanced negotiations with Mylan” (BD: Dec 10, 2018).

Phosphagenics last traded at 0.25 cents.

AVITA MEDICAL

Jeremy Green and the Redmile Group LLC say they have become substantial shareholders in Avita with 155,023,507 shares or 9.38 percent of the company.

The San Francisco-based Redmile and Mr Green said they bought the shares for eight cents each in last week’s placement which raised \$40 million (BD: Dec 4, 2018).

Avita was up half a cent or 6.5 percent to 8.2 cents with 1.1 million shares traded.

AVITA MEDICAL

Sydney’s One Funds Management says it has increased but been diluted in Avita from 81,747,669 shares (6.40%) to 83,347,669 shares (5.04%).

One Funds Asia-Pacific Healthcare Fund II said that in a previous placement it bought 1,600,000 shares for \$80,000 or 5.0 cents a share (BD: Jun 6, 2018).

The company said it did not participate in the recent placement and was diluted.

ANATARA LIFESCIENCES

The Sydney-based Robert Anthony Lederer says he has increased his substantial shareholding in Anantara from 3,977,000 shares (8.05%) to 4,477,000 (9.06).

Mr Lederer said the shares were held by RTL Group Investments Pty Ltd and his superannuation fund, with 500,000 shares acquired on-market between August 21, and December 11, 2018.

Mr Lederer yet again failed to state the price paid for the shares, as required under the Corporations Act 2001 (BD: Nov 14, 2017; May 16, 2018).

Anantara was up one cent or 2.2 percent to 46 cents.

ESENSE-LAB

The Ra’anana, Israel-based Benjamin Karasik says he has been diluted below the five percent substantial shareholder level in Esense through recent placements.

In 2017, Mr Karasik said he held 6,298,226 shares (10.18%) and in February this year, Esense said that Mr Karasik had been appointed a director, was a founding investor and one of the largest shareholders in the company (BD: Apr 19, 2017; Feb 9, 2018).

In October, Esense said it had raised \$3.15 million through the placement of 105,000,000 shares (BD: Oct 15, 2018)

Esense fell 0.3 cents or 9.4 percent to 2.9 cents with 1.2 million shares traded.

ADMEDUS

Admedus says it has appointed Lishan Zhang and Dr Yanheng Wu as non-executive directors, representing major investor Star Bright Holding.

Admedus said that Ms Zhang was a “businesswoman and entrepreneur with a significant network in China” and was the chair of Hong Kong’s Constellation International Group Holdings as well as vice-chair of Guangzhou Hearty-Care Biotechnology Ltd.

The company said that Dr Wu was Constellation’s managing director, established Guangzhou Hearty-Care Biotechnology in 2016 and held a Doctor of Philosophy from the University of Queensland.

Admedus fell 0.3 cents or 4.2 percent to 6.8 cents with 1.3 million shares traded.

FACTOR THERAPEUTICS

Factor says that non-executive director Dr Robert Ryan appointed in September 2016 would retire from the board.

Factor chair Dr Cherrell Hirst said “the board and the entire team will always be grateful to Robert for his expertise, skill and deep commitment to Factor Therapeutics and its shareholders”.

Factor was unchanged at 0.2 cents.