Biotech Daily

Friday July 29, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: RESMED UP 7%; ADMEDUS DOWN 17%**

*** INTERNATIONAL STEM CELL IMPLANTS 1st PARKINSON'S PATIENT**

*** US NIH CEDARS-SINAI $797k FOR 4DX PRE-CLINICAL LUNG SCANNER**

*** ADMEDUS RAISES $10m, RIGHTS ISSUE FOR $8m MORE**

*** HEARTWARE H1 REVENUE DOWN 14% TO $165m, LOSS DOWN 33%**

*** RESMED REVENUE UP 10% TO $2.4b, PROFIT DOWN 0.1% TO $469m**

*** MEDICAL AUST REVENUE DOWN 5% TO $14m, HUMAN HEALTH UP 8%,**

*** OSPREY PLEADS SCHULTZ TO ASX 28% QUERY**

*** MAYNE WINS $26m FROM FOREST**

*** FDA APPROVES ANALYTICA PERICOACH SEXUAL HEALTH CLAIM**

*** PHOSPHAGENICS DETAILS TERUMO LICENCE, R&D DEAL**

*** AGENIX VOTES TO BECOME CCP FOR REFRIGERATOR CONTROL**

*** REPRODUCTIVE HEALTH HAS LESS THAN TWO QUARTERS CASH**

*** BOTANIX US PARTNER MANUFACTURES SYNTHETIC CANNABIDIOL**

*** QUEST TAKES 7.5% OF VIRALYTICS**

MARKET REPORT

The Australian stock market was up 0.1 percent on Friday July 29, 2016 with the ASX200 up 5.8 points to 5,562.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Resmed was the best, up 59 cents or 6.85 percent to $9.20 with 9.9 million shares traded. Clinuvel and Reva climbed more than five percent; Airxpanders, Medical Developments and Opthea rose more than two percent; with Actinogen, Bionomics, Biotron, Cochlear, Osprey and Sirtex up more than one percent.

Admedus led the falls, down 7.5 cents or 16.7 percent to 37.5 cents with 3.0 million shares traded. Benitec lost 7.4 percent; IDT and Pharmaxis fell five percent or more; Starpharma fell 4.35 percent; Living Cell and Oncosil lost more than three percent; Factor Therapeutics shed 2.4 percent; with Avita, Compumedics, Mesoblast, Orthocell, Universal Biosensors and Viralytics down more than one percent.

INTERNATIONAL STEM CELL CORP

International Stem Cell says it has implanted its stem cells in the brain of the first patient in its 12-patient, phase I trial for moderate to severe Parkinson's disease.

The Carlsbad, California-based International Stem Cell said that the intra-cranial transplant of its human parthenogenetic neural stem cells (ISC-hpNSC) was conducted at the Royal Melbourne Hospital.

In March, International Stem Cell said that through its Australian subsidiary Cyto Therapeutics it had ethics approval for the trial of its stem cells for moderate to severe Parkinson's disease (BD: Mar 8, 2016).

The company said the open-label, single centre, uncontrolled clinical trial would evaluate three dose regimens of 30,000,000 to 70,000,000 neural cells, with patients monitored for 12 months to evaluate the safety and biologic activity of ISC-hpNSC.

International Stem Cell said that a positron emission tomography (PET) scan would be performed at baseline, as part of the screening assessment and at six and 12 months, with evaluations using neurological assessments.

International Stem Cell said that Parkinson's disease was a central nervous system degenerative disorder, mainly affecting the motor system, with no cure and affected more than seven million people worldwide.

International Stem Cell chief executive officer Dr Andrey Semechkin said that there was "real potential for millions of people who currently suffer from Parkinson's disease to truly benefit from using ISC-hpNSC".

On the US over-the-counter market last night International Stem Cell (ISCO) was up six US cents or 3.33 percent to $US1.99 with 7,895 shares traded.

4DX LIMITED

4DX says that the US National Institutes of Health has granted Cedars-Sinai Medical Centre $US600,000 ($A796,727) to buy its first pre-clinical lung scanner.

4DX executive director Steven Peuschel told Biotech Daily that the X-ray box could scan multiple animals to assist research into lung diseases.

Mr Peuschel said that the company was developing a prototype walk-through scanner for detection of human respiratory diseases.

In a media release, 4DX said that the scanner bought by the Los Angeles, California-based Cedars-Sinai Medical Centre addressed "a dilemma of current antiquated technologies in measuring the impact of cystic fibrosis, asthma, [chronic obstructive pulmonary disease], emphysema and other disorders on the lung".

The company said its pre-clinical scanner generated high-resolution images of lung-tissue motion and airflow throughout the lungs, allowing investigators to view and measure defective functioning in specific areas of the lung, before disease progression.

4DX chief executive officer Dr Andreas Fouras said the diagnostic offered researchers images of the breathing lungs "to see how they worked, not what they look like".

Dr Fouras said that "collaboration with world leading researchers can be a key to market entry and a step forward on the pathway for the integration of 4DX technology into everyday healthcare, where 4DX can make a real difference to people's lives".

The company said that the revenue was "a significant milestone" and the collaboration would assist its on-going clinical validation in the US and Australia and the clearance process by the US Food and Drug Administration, early next year.

4DX said there were 72.6 million diagnostic procedures every year in the US, compared to one million in Australia, which was an addressable market of $US25 billion a year annum.

4DX is a public unlisted company. For more information go to: http://4dx.com.

ADMEDUS

Admedus says it has raised $10 million at 33 cents a share and hopes to raise a further $8.3 million in a one-for-nine rights issue.
In the last fortnight Admedus traded as high as 55 cents and prior to the trading halt for the capital raising announcement last traded at 45 cents a share (BD: Jul 27, 2016).
Today, Admedus said that the oversubscribed placement “places the company in a strong financial position, targeting sustainable profitability” by July 2018.
The company said that the record date for the rights issue would be August 15, the offer would open on August 18, and close on August 29, 2016.
Admedus said that Patersons Securities acted as lead manager to the offer.
The company said that the funds would be used to execute its corporate restructuring with the majority allocated for working capital, along with scale-up of manufacturing, new product and intellectual property development, market expansion across emerging markets and new product ranges and further investment and development in immunotherapy programmes in conjunction with Prof Ian Frazer.
Admedus fell 7.5 cents or 16.7 percent to 37.5 cents with 3.0 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says revenue for the six months to June 30, 2016 fell 13.8 percent to $US123.8 million ($A164.9 million), with net loss down 32.5% to $US28.3 million ($A 37.7 million).
Heartware said that fall in revenue was “primarily due to the completion of patient enrolment for our Endurance 2 clinical trial during the third quarter of 2015 and the market adjusting to the introduction of a new competitive device”.
The company said that it had $US185 million in cash, equivalents and investments at June 30, 2016, compared to $US189 million at March 31, 2016.
On the Nasdaq, Heartware was up one US cent or 0.02 percent to $US57.89 ($A77.11, equivalent to $2.20 prior to leaving the ASX) with 124, 513 shares traded.

RESMED

Resmed says that record revenue for the 12 months to June 30, 2016 was up 9.5 percent to $US1,838,713,000 ($A2,445,331,467) with net profit after tax down 0.1 percent to $US352,408,000 ($A468,654,953).
Resmed said that cash at June 30, 2016 was up 2.0 percent to $US731,434,000, with basic earnings per share even at $US2.51 and a 33 US cents a share dividend for the three months to June 30, 2016 for shareholders on the record date of August 18, 2016, would be paid on September 22, 2014.
Resmed climbed 59 cents or 6.85 percent to $9.20 with 9.9 million shares traded.

MEDICAL AUSTRALIA

Medical Australia says that revenue for the year to June 30, 2016 was down 5.0 percent to $14.11 million, with human healthcare revenue up 7.9 percent to $12.42 million.
Medical Australia said that for the three months to June 30, 2016, human healthcare revenue was up 9.1 percent to $3.12 million and the changes reflected the divestment of its animal health care business.
Medical Australia said it had $879,000 cash at June 30, 2016.
Medical Australia was up 0.1 cents or 2.3 percent to 4.5 cents.

OSPREY MEDICAL

Osprey 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 27.6 percent from 29 cents to 37 cents on July 28, 2016, and noted an increase in trading volume.
Osprey was up half a cent or 1.4 percent to 35.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has a $US19.5 million ($A26.0) million settlement agreement with Forest Laboratories relating to a Faulding patent and Forest's Namenda XR drug.
The then South Australia based FH Faulding & Co, now Mayne Pharma, patent entitled 'Analgesic immediate and controlled release pharmaceutical composition' was for a method for the therapeutic treatment of pain related to wind up in a human or animal.
The patent abstract at the US Patent and Trademark Office said "the method of the invention is practiced by administering to the subject an effective amount of an analgesic pharmaceutical composition which includes a NMDA receptor antagonist in an immediate release form combined with an NMDA receptor antagonist in a sustained release form".
Mayne said that in December 2013, it filed a patent infringement lawsuit against Forest over Forest's Namenda XR product, launched in the US in June 2013.
Mayne said it expected the settlement payment by July 2017.
In 2014 Mayne said it acquired the Esgic, Esgic Plus, Lorcet and Lorcet Plus brands and assets from the New York-based Forest Laboratories for $US12.0 million ($A13.2 million) (BD: Feb 12, 2014).
Mayne was up seven cents or 3.6 percent to $2.03 with 12.7 million shares traded.

ANALYTICA

Analytica says that the US Food and Drug Administration has approved its intra-vaginal Pericoach pelvic floor strength training system for "improved sexual function".
Earlier this month Analytica said the US Food and Drug Administration had granted over-the-counter clearance for the Pericoach, to assist pelvic floor exercise to reduce or eliminate stress urinary incontinence, which previously was only available by prescription (BD: Jul 12, 2016).
Today, the company said that the FDA had confirmed that the Pericoach could be marketed for sexual function under "general wellness" claims.
Analytica said that this allowed the product to say, for example, that "Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women".
The company said that the clarification provided "a level of certainty when communicating the benefits of the Pericoach with clinicians and members of the public".
Analytica said that clinicians involved in its investigational programs reported a number of therapeutic benefits from pelvic floor exercise in patients in addition to the current clinical indications to treat stress, moderate urge and mixed urinary incontinence in women.
The company said that it intended to pursue further pelvic floor indications where pelvic floor exercise was an effective conservative treatment option, such as mild pelvic organ prolapse and faecal incontinence.
Analytica said that expansion into other indications demonstrated the "focus on meeting strategic milestones and widening the market potential for a multinational partner".
Analytica was up 0.2 cents or 25 percent to one cent with 5.6 million shares traded.

PHOSPHAGENICS

Phosphagenics has named Japan's Terumo Corp as the previously unnamed company licencing its oxymorphone patch with an interest in three more products.

In April, Phosphagenics said the company had a six-month tocopheryl phosphate mixture (TPM) oxymorphone patch option licence, and a research and development alliance for the three additional pharmaceutical products (BD: Apr 29, 2016).

Today, Phosphagenics said in its 'July Newsletter' that at the time of signing "it was not possible to provide the name of the company".

The company said that the agreements were for two different types of partnerships including option agreements for both of its opioid patches and research and development alliance agreements covering multiple other TPM-based, non-patch assets.

Phosphagenics said it had received about $200,000 in upfront option payments for the six-month exclusivity and sponsorship of a US-based scientific advisory board on opioids.

The company said that Terumo would conduct additional market research to confirm the development path and commercial opportunity for the products in Japan.

Phosphagenics said that if either or both options were exercised and the companies entered into an exclusive licence agreement, it expected a licencing fee, milestone payments and royalties on commercial sales of the TPM opioid patches in Japan.

The company said the collaboration covered the development of three additional products using the TPM technology for pain, with an initial program of about 24 months.

Phosphagenics said that Terumo would lead and finance the development of injectable TPM-propofol and Phosphagenics would lead development of two additional TPM products, with Terumo paying development costs, expected to be more than $1 million and on meeting pre-defined criteria it would be entitled to success fees up to $1.5 million.

Phosphagenics said it would retain Australia and New Zealand marketing rights, Terumo would retain rights to Japan and the companies would equally share in licencing fees and revenues from commercialization of the three products in the rest of the world.

Phosphagenics rose 0.1 cents or 7.7 percent to 1.4 cents with four million shares traded.

AGENIX

Agenix shareholders have approved the backdoor listing of CCP Holdings to commercialize its critical control point refrigeration management and monitoring.

Earlier this year, Agenix said that due diligence had been completed and it proposed a one-for-five share consolidation resulting in 31,455,161 shares on issue and the issue of 109,600,000 shares to CCP shareholders along with a public offer of 60,000,000 shares at five cents each to raise $3 milion (BD: May 17, Jun 29, 2016).

Today, Agenix shareholders voted overwhelming in favour of the change with about 2.0 million votes (3.4%) opposing four resolutions with 58.3 million votes (96.6%) in favour and seven other resolutions carried by a much wider margin.

Agenix closed up 0.2 cents or 20 percent to 1.2 cents before the suspension.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says its net operating cash burn for the three months to June 30, 2016 was $499,000 with cash at the end of the quarter of $598,000.

Reproductive Health said it expected a services payment of $13,500 in July and a Federal Government Research and Development Tax Incentive of $278,000 by the October 2016 and it "continued to control operating costs".

Reproductive Health was untraded at 14 cents.

BOTANIX PHARMACEUTICALS

Botanix says its unnamed US partner will manufacture commercial scale quantities of synthetic cannabidiol for its trials of BTX1503 for acne.

Botanix said that a recent US Food and Drug Administration filing by the unnamed partner for industrial quantities of pure synthetic cannabidiol provided "a first mover advantage" to advance its first products into the clinic.

Botanix executive director Matt Callahan said that the manufacture was "an important milestone in the development of an acne treatment that can be FDA approved and supplied commercially".

"Our use of synthetic cannabidiol substantially increases the likelihood that Botanix products can satisfy the stringent FDA requirements for purity and consistency and avoids the risks associated with natural extract based products," Mr Callahan said.

Botanix fell 0.3 cents or 6.7 percent to 4.2 cents with four million shares traded.

VIRALYTICS

Quest Asset Partners says it has increased its substantial holding in Viralytics from 14,846,675 shares (6.43%) to 17,865,541 shares (7.45%).

The Sydney-based Quest substantial shareholder notice, signed by director Michael Evans, said the company bought and sold shares between December 22, 2105 and July 27, 2016, acquiring 4,590,876 shares for $3,585,101 or 78.1 cents a share and disposing of 1,566,294 shares for $1,211,425 or 77.3 cents a share.

Viralytics fell 1.5 cents or 1.65 percent to 89.5 cents.