



Biotech Daily

Thursday August 18, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRIMA UP 8%, PRANA DOWN 8%**
- * **MEDICAL DEVELOPMENTS REVENUE UP 33% to \$15m, PROFIT \$1.6m**
- * **SOMNOMED REVENUE UP 28% TO \$44m, PROFIT DOWN 72% TO \$165k**
- * **PROTEOMICS LICENCES PROMARKERD KIDNEY TEST TO OMICS**
- * **RESAPP TEST 'CAN SHOW ASTHMA, WHEEZE SEVERITY'**
- * **MACH7 UP TO \$5.5m MAINE HEALTH IMAGING LICENCE**
- * **DORSAVI DEVELOPS VIPERFORM-AMI TO PREVENT SPORTS INJURIES**
- * **ONCOSIL CALIBRATES BRACHYSIL FOR PANCREATIC CANCER**
- * **OPTISCAN RIGHTS ISSUE RAISES \$552k OF UNDERWRITTEN \$1.4m**
- * **US NIH GRANT FOR IMMURON IMM-124E CHILD FATTY LIVER TRIAL**
- * **MAYNE BUYS GSK ACNE, PSORIASIS PRODUCTS FOR \$65m**
- * **ADMEDUS RIGHTS ISSUE OPENS**
- * **REPRODUCTIVE HEALTH \$278k FEDERAL R&D TAX INCENTIVE**
- * **YZJ, SMK 'TRANSFERS' 5% OF MEDICAL AUSTRALIA**

MARKET REPORT

The Australian stock market fell 0.49 percent on Thursday August 18, 2016 with the ASX200 down 27.2 points to 5,507.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, eight were unchanged and two were untraded.

Prima was the best, up 0.3 cents or 8.3 percent to 3.9 cents with 1.2 million shares traded. Genetic Technologies climbed 6.25 percent; Admedus improved six percent; Oncosil was up 3.7 percent; Compumedics, IDT and Living Cell rose more than two percent; with Bionomics, Cochlear, Ellex and Polynovo up more than one percent.

Prana led the falls, down one cent or 8.3 percent to 11 cents with 227,731 shares traded. Mesoblast and Pharmaxis fell more than four percent; both Atcor and Benitec lost 3.7 percent; CSL, Medical Developments, Nanosonics and Starpharma shed more than two percent; with Airxpanders, Anteo, Biotron, Pro Medicus, Resmed, Universal Biosensors and Uscom down by more than one percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that revenue for the 12 months to June 30, 2016 was up 33.3 percent to \$15,471,000 with net profit after tax up 2.6 percent to \$1,569,000.

Medical Developments said it would pay a fully-franked final dividend of two cents for holders at the record date of September 2 on October 7, 2016, following the fully-franked two cents dividend paid in April (BD: Feb 18, 2016).

The company said that sales of both its Pentrox inhaled methoxyflurane analgesic and its respiratory devices were up 26 percent for the year to June 30, 2016.

Medical Developments said that net tangible asset backing per share rose 75.0 percent to 2.8 cents for the year to June 30, 2016, diluted earnings per share was up 1.1 percent to 2.68 cents and it had cash and cash equivalents of \$5,620,000 at June 30, 2016.

Medical Developments fell 13 cents or 2.3 percent to \$5.47.

SOMNOMED

Somnomed says that revenue for the 12 months to June 30, 2016 was up 28.0 percent to \$44,084,153 with net profit after tax down 72.4 percent to \$165,005.

Somnomed said that sales of its mouth guard anti-snoring devices were up, but it had made three acquisitions in the 12 months.

The company said that net tangible asset backing per share increased 63.4 percent to 40.56 cents for the year to June 30, 2016, diluted earnings per share fell 73.3 percent to 0.32 cents and it had cash and cash equivalents of \$17,632,252 at June 30, 2016.

Somnomed fell eight cents or 2.4 percent to \$3.30 with 385,572 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has licenced its Promarkerd assay for diabetic kidney disease to the Puerto Rico-based Omics Global Solution for the Dominican Republic.

Proteomics said the deal with Omics was worth more than \$US1.5 million over nine years and "paves the way for other markets including the United States, China and Japan".

The company said the Promarkerd test used "the unique make-up of proteins in a person's blood to provide an early detection of the onset of diabetic kidney disease" and manufacturing would be conducted in Puerto Rico.

Proteomics said the licence terms were confidential but included upfront and milestone payments and royalties on sales revenue.

The company said that Omics would manufacture the kits and its sister company Macrotech Farmacéutica would distribute them.

Proteomics said that 860,000 people or 8.1 percent of adults in the Dominican Republic had diabetes, a lower rate than the US at 12.8 percent and China with 10.6 percent.

The company said that 35 percent of adults with diabetes had chronic kidney disease and 20 percent would result in kidney failure, with no commercially available test for predicting the onset of the disease.

Proteomics managing director Dr Richard Lipscombe said the diagnostic kit would be manufactured in a US territory subject to US Food and Drug Administration guidelines with the potential to act as a stepping stone for commercialization in the US.

"We're also in discussions with diagnostic and pharmaceutical companies in other global markets, including China and Japan," Dr Lipscombe said.

Proteomics said the agreement would extend for the lifetime of the Promarkerd patents to 2031 and Omics would have the opportunity to add other territories in Latin America.

Proteomics climbed 3.5 cents or 15.9 percent to 25.5 cents.

RESAPP HEALTH

Resapp says that a study of its respiratory algorithm in 224 paediatric patients shows it can determine the severity of asthma or viral wheeze with implications for treatment.

Resapp said that a preliminary analysis of the 224 children by the University of Queensland's Prof Udantha Abeyratne "demonstrated the potential for Resapp's algorithms to measure severity in paediatric asthma patients".

The company said that using only coughs, the algorithms were able to separate patients either without asthma or with controlled asthma, including those with wheeze severity scores of one, which might include the presence of mild wheeze, from patients with wheeze severity scores of two or greater, that is, patients where additional treatment was recommended with 86 percent accuracy, comprising 87 percent sensitivity and 86 percent specificity.

Resapp said that when additional clinical observations were used, accuracy increased to 94 percent, with 91 percent sensitivity and 97 percent specificity.

The company said that the trial was being conducted at Perth's Joondalup Health Campus and the study's clinical lead Dr Paul Porter said the preliminary results "suggest that we may be able to improve current asthma treatment by giving parents and caregivers more confidence in using their asthma action plans".

"Recognising the presence and severity of acute asthma or viral induced wheeze enables appropriate ... treatment and the subsequent monitoring of response," Dr Porter said.

Resapp chief executive officer Dr Tony Keating said the results gave the company confidence that it could expand from diagnosis to management of respiratory disease.

The company said it was working with lung function test laboratories at Joondalup and Brisbane's Wesley Hospital to record adult asthma and chronic obstructive pulmonary disease patients' breathing and cough sounds with comprehensive lung function tests.

Resapp said that lung function tests, including spirometry and bronchodilator response, were used for diagnosing and assessing the severity of lung disease and were used to monitor the course of the disease and the response to treatment and medication.

The company said that adult patient recruitment at both lung function test laboratories had begun, with 130 patients enrolled to date.

Dr Keating told Biotech Daily that the company expected to begin its US paediatric trial by October 2016 (BD: Mar 14, Jun 30, 2016).

Resapp was up 1.5 cents or 4.7 percent to 33.5 cents with 4.6 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has an up to \$5.5 million seven year software licence to provide its imaging software products to the Portland, Maine-based Maine Health.

Mach7 said that Maine Health "indicated ... [it] was selected ahead of the competitors due to their ability to deliver on key success factors of functionality, reliability, performance, reduced solution lifecycle costs and the strength of their partnership and collaborative approach".

The company said it was guaranteed a minimum of \$3.8 million with potential to earn up to \$5.5 million for licences to its enterprise imaging platform and Clinical Studio.

Mach7 said it expected to recognize \$1.6 million of the contract this calendar year, with an annual support fee of between \$US260,000 and \$US390,000 a year for at least seven years, adding to its growing annuity of support fee revenue.

The company said that the Maine Health network included Maine's only academic medical centre and largest hospital with more than 600 beds.

Mach7 was up 0.7 cents or 18.4 percent to 4.5 cents with 4.5 million shares traded.

DORSAVI

Dorsavi says it has partnered with Dr Trent Nessler to develop an athletic movement index to run on its wearable sensor Viperform platform.

Dorsavi said that the Brentwood, Tennessee-based Dr Nessler was Select Medical's national director of sports medicine innovation and a sports injury expert who developed the athletic movement index (AMI) to identify risk of sports injuries, such as anterior cruciate ligament rupture, to prevent injuries.

The company said that Viperform-AMI was a screening program to optimize performance in college and school athletes with seven physical tests, assessing strength, flexibility, balance, coordination, in the core, hip, knee, ankle and surrounding muscle groups, with the Viperform sensors capturing angles, speed, direction and consistency of movements. The company said that the algorithms underpinning the Viperform-AMI had been developed and tested over 10 years in athletes throughout the US, Europe and Australia, with a pilot study conducted in 13 US states and more than 700 athletes.

Dorsavi said that Viperform-AMI would be available to clinical customers in Europe and the Asia Pacific.

Dorsavi climbed 10 cents or 23.8 percent to 52 cents.

ONCOSIL MEDICAL

Oncosil says it has completed a supply chain validation process including the first radioactive calibration delivery of its Brachysil treatment for pancreatic cancer.

Oncosil said it restarted manufacturing the micro-particles in January in preparation for its planned pancreatic cancer study (Oncopac-1) and commercialization pending Conformité Européenne (CE) mark approval (BD: Dec 14, 2015; Mar 1, Jun 30, 2016).

The company said that manufacturing, supply chain validation and delivery to clinical and commercial centres was "a key step to commercial sales and the treatment of patients in the Oncopac-1 study".

Oncosil said that the calibration run was conducted yesterday in Sydney's Royal North Shore Hospital Department of Nuclear Medicine and included initial training and calibration of equipment to ensure dose accuracy.

The company said that the calibration run included the manufacturing of radioactive micro-particles, packaging, shipping and delivery to the hospital.

Oncosil head of manufacturing David James said the company was "delighted with the safe and successful validation shipment of the dose to a typical clinical site as it demonstrates that we are prepared for the commencement of Oncopac-1 and commercialization".

Oncosil was up half a cent or 3.7 percent to 14 cents.

OPTISCAN IMAGING

Optiscan says its underwritten non-renounceable two-for-nine rights issue at 2.5 cents to raise \$1,415,777 has received acceptances for 22,078,044 shares or \$551,951.

Optiscan said that the shortfall of 34,546,874 shares would be placed to the underwriter Life Sciences Pty Ltd and/or sub-underwriters.

Life Sciences Pty Ltd is a Western Australian company first registered on June 11, 2015 with Perth Bell Potter broker Jeremy Baldock named as a director (BD: Jul 10, 2015).

Optiscan chief executive officer Archie Fraser told Biotech Daily that expected the underwritten component of the rights issue to be completed next week.

Optiscan was untraded at two cents.

IMMURON

Immuron says that Emory University has won a US National Institutes of Health grant for a phase II study of IMM-124E for paediatric non-alcoholic steato-hepatitis.

Immuron did not quantify the size of the Atlanta, Georgia-based Emory University grant.

The company said it was its second NIH grant targeting fatty liver diseases, with the first for the on-going phase II trial in alcoholic steato-hepatitis in cooperation with the University of Virginia.

In 2012, Immuron's then chief executive officer Joe Bains told Biotech Daily that the grant to Prof Arun Sanyal was for a program for alcoholic steato-hepatitis but included about \$750,000 for the phase IIa trial (BD: Jan 22, Aug 6, 2012).

Today, Immuron chief executive officer Thomas Liquard said the second NIH grant "illustrates the importance the agency attributes to Immuron's IMM-124E as a potential treatment for fatty-liver diseases".

Mr Liquard said that paediatric non-alcoholic steato-hepatitis was a growing health crisis with no approved treatments available and a more than billion dollar opportunity.

The study's principal investigator Emory University's Dr Miriam Vos said that paediatric non-alcoholic fatty liver disease was "the most important liver disease today and IMM-124E shows great potential for treating children due to its unique safety profile and its mechanism of action which targets the underlying mechanisms of the disease, on multiple levels".

Immuron said the phase II trial aimed to enrol 40 patients to determine whether a three-month treatment with IMM-124E, in combination with standard of care lifestyle advice was safe and results in greater improvement in hepatic inflammation, insulin sensitivity and blood lipids when compared to placebo with standard of care advice and define the mechanism of action-related endpoints.

The company said that paediatric non-alcoholic steato-hepatitis affected up to 10 percent of the US paediatric population, with no approved drug therapies.

Immuron was unchanged at 30 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has acquired a portfolio of dermatology foam products and assets from Glaxosmithkline for \$US50.1 million (\$A65.0 million).

Mayne said the assets included Fabior and Sorilux which were complementary dermatology assets to its Doryx and would be marketed through its specialty brands division, along with Canadian rights to Luxiq and Olux-E and Mexican rights to betamethasone foam.

The company said that the products were expected "to contribute modest incremental" revenue in the year to June 30, 2017, with potential for growth in future years.

Mayne said it would acquire the approved regulatory filings, trademarks, marketing materials, select product inventory, related medical and technical data and would acquire or obtain licenses for related patents.

The company said that Fabior was a topical product for acne and Sorilux was a topical product for mild to moderate plaque psoriasis.

Mayne chief executive officer Scott Richards said the acquisition would strengthen the company's position in the US dermatology market, diversify earnings and create opportunities for growth.

Mayne was up three cents or 1.5 percent to \$2.05 with 5.8 million shares traded.

ADMEDUS

Admedus says its fully underwritten one-for-nine rights issue at 33 cents a share to raise \$8.3 million has opened with the market price at 32.5 cents

Prior to the Admedus announcement of its \$10 million placement and rights issue at 33 cents a share, the company had traded as high as 55 cents and prior to the trading halt for the capital raising announcement traded at 45 cents a share, falling 7.5 cents or 16.7 percent to 37.5 cents on the announcement (BD: Jul 27, 29, 2016).

Today, the company said that the closing price on August 9, 2016 was 32.5 cents which was below the 33 cents rights issue price and while that triggered "a termination right ... the rights issue continues to be fully underwritten by Patersons Securities".

The offer closes on August 29, 2016.

Admedus was up two cents or six percent to 35.5 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it has received \$278,104 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Reproductive Health was up 1.3 cents or 14.1 percent to 10.5 cents.

MEDICAL AUSTRALIA

The Sydney based YZJ Trading for the SMK Trust says it has transferred 6,420,159 in Medical Australia shares reducing its holding to 12,840,318 shares (9.39%).

In 2015, YZJ said that it held 19,260,477 shares or 14.1 percent (BD: Mar 20, 2015).

The substantial shareholder notice, signed by YZJ director Shaneel Khan of Blacktown, Sydney, said that the change of holding was due to a "transfer to beneficiary".

In 2015, YZJ Trading also said that its reduction in shares was through the transfer of 6,420,159 shares to a "beneficiary".

Medical Australia fell 0.1 cents or 2.1 percent to 4.7 cents.