Biotech Daily

Thursday June 25, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN : PATRYS UP 29%; LIVING CELL DOWN 4%**

*** US CLASS ACTION FILED AGAINST QRX, EX-CEO DR JOHN HOLADAY**

*** BENITEC DOSES 1st 'POTENTIALLY THERAPEUTIC' TT-034 HEP C PATIENT**

*** PROF CHRISTIAN BEHRENBRUCH AND 'THE LONG TAIL'**

*** PATRYS PAT-SC1 GASTRIC CANCER CHINA LICENCE**

*** 3D SIGNS 25 TITANIUM JAW JOINTS DEAL**

*** MAYNE BORROWS $171m TO PAY $US45m DEBT, EXPANSION**

*** ANALYTICA UK, US PERICOACH FOR INCONTINENCE LAUNCHES**

*** BVF PARTNERS, MARK LAMPERT TAKE 18% OF CIRCADIAN**

*** AUSTRALIAN ETHICAL TAKES 6% OF ATCOR**

*** MEDICAL DEVELOPMENTS REQUESTS 'EURO LICENCE' TRADING HALT**

*** SUDA APPOINTS DR PULLMAN, DR RALPH, PROF CHUNG ADVISERS**

MARKET REPORT

The Australian stock market fell 0.95 percent on Thursday June 25, 2015 with the S&P ASX 200 down 54.1 points to 5,632.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and two were untraded. All three Big Caps fell.

Patrys was the best, up 0.2 cents or 28.6 percent to 0.9 cents with 58.8 million shares traded. Analytica climbed 9.1 percent; Antisense was up 8.7 percent; Benitec, Cellmid, Genetic Technologies, GI Dynamics and Viralytics were up three percent or more; Clinuvel, IDT and Tissue Therapies rose two percent or more; Acrux and Oncosil were up more than one percent; with Medical Developments up 0.4 percent.

Living Cell led the falls, down 0.2 cents or four percent to 4.8 cents with 400,058 shares traded. Neuren, Starpharma and Universal Biosensors lost more than three percent; Actinogen, Admedus, Anteo, Bionomics and Sirtex shed more than two percent; Avita, Cochlear, Compumedics, CSL, Mesoblast, Prima and Resmed were down one percent or more; with Psivida down 0.8 percent.

QRX PHARMA

QRX says a class action has been filed against it and former chief executive officer Dr John Holaday in the US District Court for the Southern District of New York.

QRX administrators TPH Insovency said it had been made aware of a media release issued on the US Over-The-Counter Disclosure and News Service advising that a class action complaint was filed against the company and Dr Holaday.

TPH Insovency said that QRX had not been served with any documents and TPH was "considering the position of the company and obtaining advice in relation to the appropriate response to this proceeding".

The OTC notice said that the Connecticut-based law firm Scott+Scott alleged violations of the Securities Exchange Act of 1934 and was filed on behalf of all purchasers of QRX American depository receipts (ADRs) between January 24, 2011 and April 23, 2014.

Signed by Scott+Scott attorney Michael Burnett, the notice said that the complaint alleged that QRX "issued false and misleading public statements and omitted material facts concerning the commercial prospects for its experiment drug Moxduo".

"Specifically, the complaint alleges that QRX failed to disclose to investors that it received a "no agreement letter" from the Food and Drug Administration regarding its Moxduo trials and further misrepresented and concealed other material facts concerning its attempts to get Moxduo approved," Mr Burnett said. "Upon the disclosure of an FDA memorandum which denied QRX's application to get Moxduo approved, the price of QRX ADRs plummeted over 83 percent on April 23, 2014."

The complaint is at: www.scott-scott.com/cnt/cp/qrx_pharma_complaint.pdf

QRX last traded at 2.8 cents.

BENITEC BIOPHARMA

Benitec says its sixth patient and the first in the third cohort has been dosed in its phase I/IIa dose escalation clinical trial of TT-034 for hepatitis C virus.

In April, Benitec chief executive officer Dr Peter French told Biotech Daily the third cohort would be dosed at 4.0×10^{11} vg/kg TT-034, which was "the first potentially therapeutic dose cohort" (BD: Apr 29, 2015).

Today, the company said that a review of the second cohort by the data safety monitoring board, indicated there were no serious drug related adverse events.

Benitec said the patient would be monitored for six weeks and the data reviewed by the board before dosing the next patient or patients in the cohort, and with three clinical trial sites screening additional patients it expected to report data by the end of 2015.

Benitec was up two cents or three percent to 69 cents.

THE LONG TAIL

Biotech Daily has become aware that a web-log has recently appeared analyzing ASX-listed life sciences companies.

The author of the blog, Prof Christian Behrenbruch, could best be described as "pulling no punches" and providing frank and fearless commentary and opinion.

Prof Behrenbruch holds a Bachelor of Engineering degree from Monash University and a Doctorate of Philosophy in biotechnology from the University of Oxford.

The blog is at: http://asxlongtail.com/.

Prof Behrenbruch's website said that he was currently an adjunct professor at Melbourne's RMIT University and a vice-chancellor's professorial fellow at Monash University and a member of the Monash Engineering Foundation Board.

PATRYS

Patrys says it has an agreement with China's Hefei Co-source Biomedical for the development and commercialization of anti-cancer drug candidate PAT-SC1.
Patrys said the financial and other key terms of the deal were confidential, but were "on par for similar transactions of this type in this territory, including potential back-loaded payments, sharing of revenue and double digit royalties on end sales and it would receive an upfront payment when the agreement was executed, expected by October 2015, and it retained the right to commercialize PAT-SC1 outside China.
In 2009 Patrys acquired the rights to commercialise PAT-SC1 from Debiopharm's Debiovision and it was the first of its immunoglobulin M antibodies to be trialled clinically.
The company said that between 1997 and 2001, 51 patients with CD55-positive gastric cancer were treated with a single intravenous low dose of PAT-SC1 for 48 hours prior to gastrectomy and of the 51 patients, 35 had no evidence of metastatic disease at operation and were classified as having R0 stage disease.
Patrys said patients did not receive any additional radiotherapy or chemotherapy and the survival of the patients was followed and compared to a control group of patients with R0 stage gastric cancer who did not receive PAT-SC1 before surgery.
The company said that 10-year data was published last year on 30 of the PAT-SC1 treated patients, with 55 percent still alive while only 30 percent of the control group survived, indicating that PAT-SC1 conferred a significant benefit (BD: Jan 22, 2014).
Patrys chief executive officer Dr James Campbell said that China had "one of the highest incidences of gastric cancer globally, accounting for over 40 percent of all new gastric cancer cases in the world".
"This is the first collaboration and out-licencing agreement for Patrys," Dr Campbell said.
Patrys said that Hefei planned to provide up to RMB30 million ($A6.3 million) to support future PAT-SC1 development in China.
Patrys climbed 0.2 cents or 28.6 percent to 0.9 cents with 58.8 million shares traded.

3D MEDICAL

3D Medical says it will develop and produce 25 individual temporo-mandibular prostheses over the next 12 months with initial delivery for six prostheses.
3D said that the manufacturing agreement was with an unnamed "industry specialist in prosthetic treatment of jaw disorders, congenital, degeneration and injuries" and the initial cases were primarily treating osteoarthritis of the temporo-mandibular jaw joint.
Earlier this week, 3D Medical said that with oral and maxillofacial surgeon Dr George Dimitroulis, it had developed a 3D-printable and customized titanium joint for corrective jaw surgery and a 32-year-old male patient underwent a five hour operation at the Epworth-Freemasons Hospital to correct a rare jaw deformity (BD: Jun 22, 2015).
Today the company said that temporo-mandibular joint surgery was complex and required precision in the prosthesis used and was "a large market opportunity".
3D said that the initial cases comprised six prostheses for five patients, with one of the patients having an Australia-first bilateral procedure with both sides of the jaw replaced with a three-dimensional printed titanium prosthesis.
The company said that in Australia in 2014 private health insurers paid more than $1.8 billion for more than 2.3 million prosthetic items, and while not all prostheses required the customization and precision of three-dimensional printing, the ageing population, increasing diagnosis of degenerative conditions such as osteoarthritis and improved outcomes could lead to a wider adoption of personalized prostheses.
3D Medical was unchanged at 12 cents with 3.3 million shares traded.

MAYNE PHARMA

Mayne Pharma says it has raised $US125 million ($A161 million) to refinance a $US45 million existing debt and fund further expansion.

Mayne said that the unsecured facilities were provided by two unnamed Australian lending institutions and comprised “a fully revolving $US125 million debt facility which matures in June 2020 and a $A10m working capital facility”.

In February Mayne said it would raise $115 million to acquire the Doryx brand acquire rights to two other drugs and fund the start-up costs of a US specialty brands division (BD: Feb 10, 12, 2015).

Mayne fell 2.5 cents or 2.4 percent to $1.03 with 1.8 million shares traded.

ANALYTICA

Analytica says it has launched its intra-vaginal Pericoach pelvic floor exercise system in the UK and US this week.

Analytica said that marketing campaigns were timed to coincide with the International Continence Society’s World Continence Week.

The company said that the launch had gained attention with several media releases reported in major media outlets.

Analytica was up 0.1 cents or 9.1 percent to 1.2 cents with 5.3 million shares traded.

CIRCADIAN

BVF Partners and Mark Lampert say they have increased their substantial holding in Circadian from 19,428,572 shares (13.12%) to 26,005,102 shares (17.56%).

The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said that on June 23, 2015 they acquired the 6,556,530 shares for $1,313,991 or an average price of 20 cents a share.

BVF and Mr Lampert became substantial through participation in the company’s $17.4 million placement and rights issue at 17.5 cents (BD: Oct 6, Nov 6, 2014).

Circadian was unchanged at 19.5 cents.

ATCOR MEDICAL

Australian Ethical Smaller Companies Trust has returned to a substantial holding in Atcor with 10,277,778 shares (5.68%).

In 2013, Australian Ethical reduced its holding in Atcor from 10,673,860 shares (7.22%) to below the 5.0 percent substantial level, having acquired 4,166,667 shares for $250,000 or six cents a share in 2012 and selling the shares at 11.2 cents and 12.2 cents a share (BD: Jun 28, 2012; Mar 4, 2013).

Today, Australian Ethical said it bought shares between March 20 and May 4 2015, with the single largest purchase 591,250 shares for $130,666 or 22.1 cents a share.

Atcor was unchanged at 18.5 cents.

MEDICAL DEVELOPMENTS

Medical Developments has requested a trading halt “pending the finalization of a significant European licencing deal”.

Trading will resume on June 29, 2015 or on an earlier announcement.

Medical Developments was up one cent or 0.4 percent to $2.41.

SUDA

Suda says it has appointed Dr William Pullman, Dr David Ralph and Prof Eric Chung to its SUD-003 oral spray of sildenafil citrate for erectile dysfunction advisory board.

Suda said the three specialists would provide advice and guidance on the pivotal development plan to be submitted to the US Food and Drug Administration.

The company said that Dr Pullman was a physician with more than 25 years' experience and had worked in large and small pharmaceutical companies, handling small molecules and biotechnology products across all phases of drug development, including at Pfizer, Eli Lilly and Sanofi-Aventis.

Suda said that Prof Chung was a consultant urological surgeon in Brisbane and was the current chair of the Urological Society of Australia and New Zealand andrology group, supervising current clinical trials .

The company said that Dr Ralph was a urological microsurgeon and an honorary senior lecturer at the University College London Institute of Urology and Nephrology.

Suda chief executive officer Stephen Carter said the company was "thrilled to have attracted three of the world's leading experts with unparalleled clinical and medical experience in erectile dysfunction to advise Suda on the development of SUD-003".

Suda was up 0.1 cents or 3.85 percent to 2.7 cents with 13.1 million shares traded.