

# Biotech Daily

Wednesday November 6, 2013

Daily news on ASX-listed biotechnology companies

- \* ASX FLAT, BIOTECH UP: MEDICAL DEVELOPMENTS UP 12%, TISSUE THERAPIES DOWN 6%
- \* FDA ORPHAN DESIGNATION FOR PATRYS PAT-SM6 FOR CANCER
- \* RESMED SWAPS \$US400m CREDIT FACILITY FOR UP TO \$US1bn
- \* BIOTA INCENTIVE PLAN 259% RISE AGM, LAW FIRM 'INVESTIGATES'
- \* UNILIFE REQUESTS US LAWSUIT TRADING HALT
- \* AUSIMED TO SUPPORT EARLY-STAGE AUSTRALIA-ISRAEL RESEARCH
- \* IMUGENE APPOINTS DR AXEL HOOS DIRECTOR, STEVE HARRIS GOES

### MARKET REPORT

The Australian stock market edged up 0.03 percent on Wednesday November 6, 2013 with the S&P ASX 200 up 1.8 points to 5,433.8 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Medical Developments was the best, up 14.5 cents or 11.9 percent to \$1.365, with 65,698 shares traded, followed by IDT up 11.6 percent to 48 cents with 197,404 shares traded, Allied Health was up 10.3 percent to 16 cents with 17.7 million shares traded and Avita up 10 percent to 11 cents with 222,720 shares traded.

Patrys climbed 8.6 percent; Viralytics was up 6.1 percent; Ellex, Neuren and Phylogica rose five percent or more; GI Dynamics, Pharmaxis and Psivida were up four percent or more; Genetic Technologies and Phosphagenics were up more than three percent; Benitec, Cellmid, Prima and Reva rose more than two percent; Anteo, Nanosonics and Osprey were up more than one percent; with Starpharma up 0.6 percent.

Tissue Therapies led the falls, down 1.5 cents or 6.1 percent to 23 cents with 208,781 shares traded.

Circadian, Compumedics, Mesoblast and QRX lost more than three percent; Living Cell, Resmed and Universal Biosensors fell more than two percent; Cochlear, Optiscan, Prana and Optiscan were down more than one percent; with Acrux and CSL down by less than one percent.

### **PATRYS**

Patrys says the US Food and Drug Administration has confirmed orphan medicinal product designation for its lead anti-cancer antibody product PAT-SM6.

Patrys said that PAT-SM6 had orphan drug designation for multiple myeloma in Europe. The company said that orphan designation provided incentives to pursue treatments for rare diseases with high unmet medical needs and PAT-SM6 would qualify for scientific and protocol assistance, potential grant funding during development, as well as a period of seven years of marketing exclusivity in the US, pending FDA approval.

Patrys said that the US had 78,000 people living with multiple myeloma, with 22,000 new cases and about 11,000 deaths each year.

The company said that orphan designation expanded the potential market for PAT-SM6 and presented an opportunity to fast track development in both the US and Europe. Patrys said that no cure existed for multiple myeloma patients and limitations of available therapies were evident in patients that had relapsed or become resistant to treatments. Patrys said that PAT-SM6 was "showing convincing evidence of potential therapeutic benefit in its ongoing phase I/IIa clinical trial in patients with relapsed and refractory multiple myeloma and as such has a potential to improve and add to current treatments for myeloma".

Patrys chief executive officer Dr Marie Roskrow said the FDA orphan drug designation for PAT-SM6 was "yet another confirmation of the quality of our product and supports and extends our efforts for a quicker development process in the US as well as Europe". Patrys jumped as much as 0.8 cents or 22.9 percent to 4.3 cents, before closing up 0.3 cents or 8.6 percent to 3.8 cents with 78.1 million shares traded.

## RESMED

Resmed says it has entered into an up to \$US1,000 million (\$1,051 million) credit agreement with lenders, including Union Bank NA and HSBC Bank US.

Resmed said that obligations under the credit agreement were guaranteed by subsidiaries Resmed Corp and Resmed Motor Technologies and the agreement provided a \$US700 million unsecured five-year revolving credit facility, with an option to increase the facility by an additional \$US300 million and included a \$US25 million sublimit for letters of credit. Resmed said that the credit facility would terminate on October 31, 2018.

Resmed said that the outstanding principal amount due under the credit facility would bear interest at a rate equal to the London inter-bank offered rate (Libor) plus 1.0 percent to 2.0 percent, depending on the then-applicable leverage ratio.

The company said that an applicable commitment fee of 0.15 percent to 0.25 percent, depending on the then-applicable leverage ratio, applied on the unused portion of the credit facility.

Resmed said that a portion of the credit agreement was used to repay the outstanding balance under a previous revolving credit facility with Union Bank and other lenders. In 2011, Resmed entered into a similar \$US400 million facility at similar interest rates whil earning about 6.0 percent per annum on its Australian cash reserves of \$616.2 million (BD: Feb 16, 2011).

In its September quarter statement, Resmed said it had cash and cash equivalents of \$US976,574,000 at September 30, 2013.

Today, Resmed said that agreement with lenders including Union Bank, HSBC Bank, Commonwealth Bank of Australia and Wells Fargo Bank had been terminated and the commitments terminated.

Resmed fell 11 cents or 2.0 percent to \$5.28 with 7.5 million shares traded.

## **BIOTA PHARMACEUTICALS**

Biota's annual meeting proposal to increase the employee and director incentive plan by 259 percent is the subject of an 'investigation' by a New York securities and law firm. The Biota meeting, to be held in Alpharetta, Georgia next week, proposes to amend the 2007 Omnibus Equity and Incentive Plan to increase the number of shares reserved under the plan by 3,000,000 shares, from 1,157,978 shares to 4,157,978 shares, revise certain limitations on the awards intended to qualify as performance-based awards and reapprove the performance goals for performance based awards.

Biota's notice of meeting said that all employees, directors and consultants were eligible to participate in the plan.

In an announcement on its website and reported on the Biota Nasdaq site, New York securities and law firm Faruqi & Faruqi said that partner Juan Monteverde was investigating the board of directors of Biota "for potential breaches of fiduciary duties in connection with their conduct in seeking shareholders' approval for an amendment of the Company's 2007 Omnibus Equity and Incentive Plan".

Faruqi & Faruqi said that in the proxy statement filed by the company with the US Securities and Exchange Commission the board of directors recommended that shareholders vote to approve the amendment and "the issuance of the additional shares could have a substantial dilutive effect on the shares of Biota common stock". Biota said that other resolutions to the meeting include a decrease in the number of the authorized shares of the company's common stock from 200,000,000 shares to 70,000,000 shares.

Biota said that the 200,000,000 authorization was part of the Biota-Nabi merger conditions and with 28.4 million shares on offer and options over a further 1.7 million shares, the reduction in the allowable number would leave it at more than double the number of shares on issue.

Biota chief executive officer Russell Plumb told Biotech Daily the measure was a reduction in the allowable number of shares and not a consolidation.

The notice of meeting also proposed the election of directors Mr Plumb, chairman Dr James Fox, Geoffrey Cox, Michael Dougherty, Richard Hill, John Richard, Anne VanLent; a non-binding advisory vote on the compensation to named executive officers; and the ratification of the selection of Pricewaterhousecoopers as the independent registered public accounting firm for the year ending June 30, 2014.

Biota said that Mr Plumb's base salary would remain at \$US525,000 (\$A552,656) for 2014 while corporate development executive vice-president Dr Joseph Patti's base salary would increase from \$US400,000 to \$US408,000.

The meeting will be held at 2500 Northwinds Parkway, Suite 100, Alpharetta, Georgia on November 12, 2013 at 9am (US EST).

Last night on the Nasdaq, Biota fell 10 US cents or 2.53 percent to \$US3.86 (\$A4.06, equivalent to 50.75 cents pre-merger) with 891 shares traded.

#### **UNILIFE**

Unilife has requested a trading halt "pending an announcement regarding a lawsuit in the United States".

Trading will resume on November 8, 2013 or on an earlier announcement.

Unilife last traded down seven cents or 14 percent to 43 cents with two million shares traded.

## **AUSIMED**

Ausimed says it will support early-stage, pre-clinical translational research connecting Australian and Israeli research scientists.

Ausimed chief executive officer Roz Kaldor-Aloni said that the organization had charitable status for tax deductible donations and intended to fund several projects that were ineligible for National Health and Medical Research Council funding and were too early for commercial investments.

Ms Kaldor-Aloni said that Ausimed's first networking event would be held at the Melbourne offices of the South Africa-based Investec on November 25, 2013.

Ausimed said that the event would focus on 'Succeeding as a start-up' with an address from Mesoblast chief executive officer Prof Silviu Itescu.

For further information contact Ms Kaldor-Aloni by email: <a href="mailto:roz@ausimed.org">roz@ausimed.org</a> or by telephone on +613 9272 5699.

## **IMUGENE**

Imugene says it has appointed Dr Axel Hoos as a non-executive director, subject to shareholder approval of the Biolife Science Qld acquisition (BD: October 23, 2013). Immugene said that non-executive chairman Steve Harris would retire from the board at the conclusion of the acquisition.

The company said that Dr Axel Hoos was Glaxosmithkline's oncology research and development vice-president directing clinical and translational research on molecular mechanisms of cancer and tumor-host interactions for rational combination of therapies to optimize patient outcomes.

Imugene said that previously Dr Hoos was the medical lead in immunology and oncology at Bristol- Myers Squibb where he developed the Yervoy monoclonal antibody in melanoma and other indications, the first therapy to extend survival in metastatic melanoma.

Imugene said that Dr Hoos was formerly a co-director of the Cancer Immnunotherapy Consortium.

Imagene fell 0.2 cents or 9.5 percent to 1.9 cents with 10.6 million shares traded.