



Biotech Daily

Monday July 18, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: IMPEDIMED UP 12%; SUNSHINE DOWN 22%**
- * **QRX FILES MOXDUO IR FDA APPLICATION**
- * **LANDON CLAY, EAST HILL TAKE 8% OF BIOTA**
- * **SUNSHINE HEART MEGA-PLACEMENT, OPTIONS, CONSOLIDATION EGM**
- * **IM MEDICAL TECHNOLOGY SALE, DISTRIBUTION, CONSOLIDATION EGM**
- * **JCP REDUCES TO 5% OF RESMED**
- * **ORBIS TAKES PROFIT ON 1.2m ACRUX SHARES**
- * **METAL GROUP HAS 16% OF ALLIED HEALTH**
- * **TEMPO, BLUE HAWK TAKE 8% OF ANTISENSE**
- * **PRIME BROKER UBS AG CEASES SUBSTANTIAL IN ATCOR, CATHRX**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Monday July 18, 2011 with the S&P ASX 200 down 1.5 points to 4472.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and 10 were untraded.

Impedimed was the best, up 7.5 cents or 12 percent to 70 cents with 582,143 shares traded.

Acrux and Cochlear climbed more than two percent; with Anteo, CSL, Heartware, Prima, Psivida, Sirtex and Starpharma up more than one percent.

Sunshine Heart led the falls, down as much as 30.9 percent to 3.8 cents before closing down 1.2 cents or 21.8 percent at 4.3 cents with 2.3 million shares traded.

Cellmid and Optiscan lost more than four percent; Phosphagenics fell 3.7 percent; Prana shed 2.9 percent; with Alchemia, Clinuvel and QRX down more than one percent.

QRX PHARMA

QRX says it has filed its new drug application for Moxduo immediate release (IR) for pain with the United States Food and Drug Administration.

QRX said the filing was the beginning of "the regulatory approval process for Moxduo IR for the treatment of moderate to severe acute pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the US".

QRX chief executive officer Dr John Holaday told Biotech Daily that the filing was ahead of the expected August timeline, but approval by the FDA can typically take up to 12 months from filing.

"We believe that we are the second Australian company after Chemgenex to file our own NDA," Dr Holaday said.

"So to me, that's a milestone of which we should be proud," Dr Holaday said.

"We hope to have a strategic partner for licencing and the distribution of product and are having negotiations with leading companies," Dr Holaday said.

The QRX media release said that Moxduo IR was an immediate-release dual opioid pain therapy, with a three-to-two fixed ratio combination of morphine and oxycodone.

"In just four years, we have successfully moved Moxduo IR through clinical trials and NDA submission by demonstrating its effectiveness and safety," Dr Holaday said in the media release.

"Achievement of this milestone clearly establishes the value of this dual opioid product to patients and prescribers as well as potential partners," Dr Holaday said.

"The timeframe and capital efficient manner in which these milestones were achieved are impressive accomplishments compared to conventional industry development and cost benchmarks," Dr Holaday said.

QRX said that the FDA submission was based on a full clinical and manufacturing program and was submitted under 505(b)(2) regulations where approval for a new drug may be obtained more efficiently because the approval process can rely upon historical data regarding already approved components.

The company said a 505(b)(2) approval provided commercial benefits because, in parallel to patents which cover Moxduo until 2029, it afforded additional regulatory market exclusivity, allowing companies to develop a marketing strategy with a brand consumers recognize and may prefer in a potentially wide-open market.

QRX said it would augment the filing with additional safety information derived from the recently completed comparative trial, later this year (BD: Jun 14, 2011).

The company said the US FDA package would serve as the core component of Moxduo registration submissions in Europe, Australia, Canada and elsewhere.

Clinical data have consistently demonstrated that Moxduo IR achieves equal or better pain relief with fewer incidences of moderate to severe side effects in those comparisons using current standards of care.

QRX fell three cents or 1.8 percent to \$1.62.

BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 12,874,055 shares (7.15%) to 14,867,794 shares (8.19%).

East Hill said the shares were bought at prices between \$US0.96 and \$US1.16 (90.6 Australian cents to \$A1.094) between June 15 and July 14, 2011.

Biota was up half a cent or 0.5 percent to 96.5 cents.

SUNSHINE HEART

Sunshine Heart investors will vote to place 455,113,636 shares, issue 65,682,000 options to directors and consolidate shares between one for 100 shares and one for 250 shares. Sunshine Heart has proposed 21 resolutions for the meeting including changes to bylaws and a certificate of incorporation along with the lengthening of time for 10,000,000 options held by chief executive officer David Rosa and 3,712,482 options held by medical director Dr William Peters.

The company has proposed to offer two tranches of shares of 152,816,668 shares (14.99%) and 302,296,968 shares (29.67%) as CHESS depositary interests at no less than 85 percent of the 10-day volume weighted average price to clients of Summer Street Research Partners and RBS Morgans.

Sunshine Heart has proposed a consolidation of between one-for-100 and one-for-250.

The company said that post placement it would have 1,359,754,801 shares on issue.

Sunshine Heart has proposed the approval of 10,000,000 shares for an 'employee stock purchase plan' along with and 'equity incentive plan' for directors and executives.

The company has requested approval for 5,842,000 options exercisable at 6.4 cents each.

Sunshine Heart requested approval for options exercisable at 3.5 cents each with 30,890,000 for Mr Rosa, 16,149,000 for Dr Peters, 3,841,000 for chairman Nicholas Callinan, with 2,240,000 options each to directors Dr Geoff Brooke, Crispin Marsh, Donal O'Dwyer and Paul Buckman.

The company further requested a doubling of the directors' remuneration pool from \$250,000 to \$500,000.

The meeting will be held at Henry Davis York, Level 10, 44 Martin Place, Sydney, on August 18, 2011 at 9am (AEST).

Sunshine Heart fell as much as 30.9 percent to 3.8 cents before closing down 1.2 cents or 21.8 percent at 4.3 cents with 2.3 million shares traded.

IM MEDICAL

IM Medical shareholders will vote to sell the recently acquired Mark Scott radiology business to Capitol Health, distribute Capitol shares and consolidate IM shares.

Mark Scott Group radiology acquired IM Medical but the company saw a raft of board changes and dissent at meetings, which followed IM's inability to commercialize its Intelliheart cardiac testing system (BD: Jun 20, 2008; Jun 10, 30, Nov 22, 2010; Feb 7, Mar 10, 2011).

The extraordinary general meeting resolutions include the sale of the radiology business to Capitol Health; approve a 50-to-one share consolidation; issue 150,000,000 shares at half a cent each and 150,000,000 options exercisable at half a cent each by March 31, 2012 and if exercised entitle the holder to one additional option exercisable at 1.5 cents by June 30, 2015; and approve a three-for-two rights issue, with attaching options.

IM Medical shareholders will also vote to re-elect directors Nigel Blaze, Paul Quarrell and Richard Wadley.

IM Medical said Capitol would pay 45,559,021 of its shares along with three \$200,000 performance bonuses.

IM company secretary Richard Wadley told Biotech daily that the resolutions would leave IM Medical as the major shareholder in Capitol Health and the company retaining the Intelliheart technology.

The meeting will be held at The Quest Beaumont, 7 Studley Park Road, Kew, Victoria, on August 16, 2011 at 2pm (AEST).

IM Medical was untraded at 0.1 cents.

RESMED

JCP Investment Partners has decreased its substantial shareholding in Resmed from 93,181,797 shares (6.07%) to 77,922,075 shares (5.04%).

JCP of Level 23, 600 Bourke Street, Melbourne said it acquired the shares in a series of transactions, including purchases and sales, between April 12 and July 14, 2011, on behalf of JP Morgan Nominees, JP Morgan Nominees Australia, Cogent Nominees and HSBC Custody Nominees.

Resmed was unchanged at \$3.08 with 4.8 million shares traded.

ACRUX

Orbis Investment Management has reduced its substantial holding in Acrux from 25,395,773 shares (15.56%) to 24,154,588 shares (14.51%).

The substantial shareholder notice said Orbis sold 1,241,185 shares between November 26, 2010 and July 14, 2011 for \$4,366,774 or an average price of \$3.52 a share.

Acrux climbed nine cents or 2.4 percent to \$3.87.

ALLIED HEALTHCARE GROUP

The Perth-based Metal Group says it is a substantial shareholder in Allied Healthcare with 90,647,712 shares or 15.94 percent of the company.

The initial substantial shareholder notice said the Metal Group, a private company of Fortescue Metals chairman Andrew Forrest, acquired the holding in relation to the takeover of Biomed by Allied Medical (BD: May 19, Jun 14, 2011).

Allied Health was up half a cent or 9.1 percent to six cents with 2.3 million shares traded.

ANTISENSE THERAPEUTICS

Tempo Capital has increased its substantial shareholding in Antisense from 62,500,000 shares (6.57%) to 75,000,000 shares (7.89%).

The Caulfield North-based Tempo said it acquired the 12,500,000 shares on market for \$112,478 or an average price of 0.9 cents a share and named Blue Hawk Capital of East St Kilda, Victoria, as an equal beneficiary to the shares.

Antisense was unchanged at 0.9 cents with 11.2 million shares traded.

ATCOR MEDICAL, CATHRX

UBS AG says it has ceased its substantial holdings in Atcor and Cathrx following an Australian Securities and Investments Commission 'prime broker' ruling.

UBS AG said that ASIC had provided class order relief "so that a prime broker with a borrowing right must defer the time at which it takes into account its relevant interest ... to the time at which it exercises that borrowing right".

The Hong Kong-based UBS AG said the ruling affected 9,837,605 Atcor shares and 18,000,000 Cathrx shares.

Atcor was untraded at 12.5 cents.

Cathrx was untraded at 15 cents.