

# **Biotech Daily**

# Friday August 31, 2012

Daily news on ASX-listed biotechnology companies

- \* ASX FLAT, BIOTECH DOWN: BIONOMICS UP 12%, IMPEDIMED DOWN 17%
- \* SUNSHINE HEART FDA APPLICATION FOR PIVOTAL C-PULSE TRIAL
- \* FDA MEETING FOR INVION (CBIO) XTOLL FOR LUPUS
- \* PHILLIP COMANS CALL FOR BIOXYNE BOARD SPILL FIGHT LOOMS
- \* CYCLOPHARM H1 REVENUE UP 14% TO \$4m, LOSS DOWN 17% TO \$1.3m
- \* QRX (LICENCE) REVENUE UP 984% TO \$1.9m, LOSS DOWN 38% TO \$16m
- \* AVITA REVENUE UP 13% TO \$5m, LOSS UP 327% TO \$7.7m
- \* IMPEDIMED REVENUE DOWN 24% TO \$3.2m, LOSS DOWN 17% TO \$12m
- \* BIODIEM REVENUE UP 422% TO \$1.3m, LOSS DOWN 61% TO \$1m
- \* NUSEP REVENUE UP 42% TO \$2.5m, LOSS DOWN 22% TO \$5m
- \* PHARMAUST REVENUE UP 2% TO \$1.6m, LOSS DOWN 26% TO \$4m
- \* POKIES BRUCE MATHIESON BUYS 15% OF ISONEA
- \* OPTISCAN REQUESTS PLACEMENT TRADING HALT

# MARKET REPORT

The Australian stock market edged up 0.01 percent on Friday August 31, 2012 with the S&P ASX 200 up 0.4 points to 4,316.1 points. Six of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and seven were untraded.

Bionomic was the best, up 3.5 cents or 11.9 percent to 33 cents with 713,637 shares traded. Alchemia climbed 6.6 percent; Sunshine Heart was up 5.9 percent; Resmed and Tissue Therapies were up more than one percent; with CSL, Heartware and Universal Biosensors up by less than one percent.

Impedimed led the falls, down three cents or 16.7 percent to 15 cents with 337,749 shares traded, followed by Allied Health and Genera both down 11.1 percent. Circadian lost 6.7 percent; Benitec and Prana were down more than five percent; Genetic Technologies and Starpharma fell more than four percent; Acrux, Biota and Nanosonics shed two percent or more; with Psivida, QRX and Viralytics down more than one percent.

# SUNSHINE HEART

Sunshine Heart says it has filed its C-Pulse aorta pump pivotal trial investigational device exemption submission with the US Food and Drug Administration.

Sunshine Heart said the 388-patient trial should provide the data required by the FDA to permit approval to commercialize the C-Pulse system for moderate to severe cardiac failure in the US.

The company said that in March 2012, the FDA completed its review of the C-Pulse feasibility trial data and concluded that applicable requirements had been met for a pivotal trial application.

Sunshine Heart said that Ohio State University Medical Center's Dr Bill Abraham would be the national principal investigator for the trial.

The company said that the proposed primary endpoint was reduction of events such as rehospitalization due to worsening heart failure and heart failure-related mortality.

The study will evaluate results for patients that receive the C-Pulse System in comparison to a control group that is managed on optimal medical therapy.

Sunshine Heart was up 0.2 cents or 5.9 percent to 3.6 cents with 1.6 million shares traded.

#### **INVION (FORMERLY CBIO)**

CBio says it has formally changed its name to Invion and expects the ASX ticker code to change to INV in the next few days.

As Invion the company said the US Food and Drug Administration had set a date of December 14, 2012 for its pre-investigational new drug meeting for initiating clinical trials of XToll (chaperonin-10) as a treatment for systemic lupus.

Invion chairman Dr Ralph Craven said the company was "delighted with this timely and positive response from the FDA".

"This significant step forward in the development of XToll has been made possible by the efforts and expertise of our new executive directors, Dr Mitchell Glass and Dr William Garner," Dr Craven said.

"Following a successful pre-IND meeting, we anticipate initiating a phase II clinical trial in lupus in early 2013," said Dr Glass.

Invion or CBio was up half a cent or 1.1 percent to five cents.

#### **BIOXYNE**

Phillip Comans through Wigram Trading has called for the removal of Bioxyne directors Dr Doug Wilson, Dr Jeremy Curnock Cook and Glenn Crisp to be replaced by Anthony Ho. In the requisition letter, Mr Comas said he was a founder of the original Hunter Immunology that developed HI-164OV, which failed to meet its phase II trail endpoints for exacerbations of chronic obstructive pulmonary disease (BD: Jun 28, 2012). Mr Comas said he believed he was the second largest non-institutional investor in

Bioxvne.

Earlier this week, Bioxyne's largest shareholder Octa Phillip Asset Management (formerly Intersuisse) requisition a meeting to replace chief executive officer David Radford and chairman Ian Mutton with director Dr Stewart Washer (BD: Aug 27, 2012).

Mr Comans said Mr Ho was a Bioxyne shareholder, an accountant and an experienced company director.

Bioxyne was unchanged at 2.1 cents.

## **CYCLOPHARM**

Cyclopharm says revenue for the six months to June 30, 2012 was up 14 percent to \$4,122,090, with a net loss after tax down 17 percent to \$1,275,129.

Cyclopharm said its molecular imaging division was subdued but losses were reduced as revenue from the cyclotron picked up and no further losses were recorded for its share of Macquarie Molecular Imaging's losses as the investment had been fully written down. The company said the molecular imaging loss "was primarily attributed to the impact of [the Australian Nuclear Science and Technology Organization's] competitive actions in the [New South Wales] market and a slower than expected ramp-up of Macquarie University Hospital", but the the Technegas business continued to perform strongly.

The company said its net tangible assets per share fell 16.7 percent to five cents and diluted loss per share fell 28.9 percent from 0.9 cents to 0.64 cents.

Cyclopharm said it had cash and cash equivalents of \$1,939,216 at June 30, 2012 compared to \$2,043,814 at June 30, 2011.

Cyclopharm fell one cent or 4.9 percent to 19.5 cents.

#### QRX PHARMA

QRX says that revenue the year to June 30, 2012, primarily a licence fee, was up 984 percent to \$1,919,000 reducing its net loss after tax 38 percent to \$15,949,000. QRX said the increase in revenue was due to the recognition of \$1.8 million of a non-refundable, non-creditable up front signing fee of \$5.9 million, (\$US6 million) received from Actavis on the signing of a binding letter of intent on December 20, 2011 to commercialize immediate release Moxduo for the US market.

QRX said that at June 30, 2012, it had recognized \$1.8 million as revenue and \$4.1 million as deferred revenue.

QRX said that diluted loss per share fell 48.4 percent from 21.7 cents in the previous year to 11.2 cents for the year to June 30, 2012, with net tangible assets per share up 142.3 percent from 5.2 cents at June 30, 2011 to 12.6 cents at June 30, 2012.

The company said it had cash and cash equivalents of \$22,950,000 at June 30, 2012, compared to \$7,291,000 at June 30, 2011.

QRX fell one cent or 1.45 percent to 68 cents.

#### AVITA MEDICAL

Avita says that revenue for the 12 months to June 30, 2012 was up 13 percent to \$5,180,448 with net loss after tax up 327 percent to \$7,671,682.

Avita said that total revenue was up 13 percent to \$5.18 million, with Recell spray-on skin sales revenue up 90 percent over the previous year.

The company said that losses due to continuing operations were \$5.69 million, an increase of 39 percent compared to the previous years and it had made significant investment and directed increased efforts towards sales and marketing, research and development and clinical marketing studies.

Avita said its net tangible asset backing per share fell 36.8 percent from 5.7 cents at June 30, 2011 to 3.6 cents at June 30, 2012.

The company said that diluted loss per share was up 106.4 percent to 3.22 cents, compared to 1.56 cents in the year to June 30, 2011.

Avita said it had \$8,230,593 in cash and cash equivalents at June 30, 2012, compared to \$12,669,020 at June 30, 2011.

Avita was unchanged at 14 cents.

# IMPEDIMED

Impedimed says its net loss after tax for the 12 months to June 30, 2012 was reduced 17 percent to \$12,342,000 on revenue down 24 percent to \$3,184,000.

Impedimed has been marketing its L-Dex test for post-breast cancer treatment lymphoedema.

Impedimed said that net tangible asset per share fell 25 percent from 12 cents at June 30, 2011 to 9.0 cents at June 30, 2012.

The company said diluted loss per share was 8.0 cents compared with 10 cents in the previous corresponding period.

Impedimed said it had cash and equivalents of \$14,514,000 at June 30, 2012 compared to \$17,899,000 at June 30, 2011.

Impedimed fell three cents or 16.7 percent to 15 cents.

#### BIODIEM

Biodiem says that revenue the year to June 30, 2012, primarily licence fees, was up 421.7 percent to \$1,331,000 reducing its net loss after tax 61.46 percent to \$1,009,000. Biodiem chief executive officer Julie Phillips said the results reflected "strong revenue growth from vaccine licencing activities in India and China".

Biodiem said that diluted loss per share fell 61.5 percent from 2.57 cents in the previous year to 0.99 cents for the year to June 30, 2012.

The company said it had cash and cash equivalents of \$1,369,347 at June 30, 2012, compared to \$2,580,399 at June 30, 2011, with net tangible assets per share down 40 percent from 2.45 cents at June 30, 2011 to 1.47 cents at June 30, 2012. Biodiem fell one cent or 15.4 percent to 5.5 cents.

#### NUSEP

Nusep says that revenue for the year to June 30, 2012 was up 42 percent to \$2,549,000 reducing its net loss after tax 22 percent to \$4,924,000.

Nusep said that diluted loss per share fell 50 percent from 10 cents in the previous year to five cents for the year to June 30, 2012.

The company said it had cash and cash equivalents of \$173,447 at June 30, 2012, compared to \$29,009 at June 30, 2011.

Nusep said that net tangible assets per share was constant at one cent. Nusep was untraded at 6.5 cents.

#### PHARMAUST

Pharmaust says that revenue the year to June 30, 2012 mainly from its Epichem division was up two percent to \$1,626,000 reducing its net loss after tax 26 percent to \$4,260,000. Pharmaust said the principal continuing activities were the development of its drug discovery intellectual property as well as providing specialized medicinal and synthetic chemistry services on a contract basis.

Pharmaust said that diluted loss per share fell 54.6 percent from 2.05 cents in the previous year to 0.93 cents for the year to June 30, 2012.

The company said it had cash and cash equivalents of \$122,905 at June 30, 2012, compared to \$86,160 at June 30, 2011, with net tangible assets per share down 37.5 percent from 0.4 cents at June 30, 2011 to 0.25 cents at June 30, 2012.

Pharmaust was up 0.1 cents or 8.3 percent to 1.3 cents.

# **ISONEA**

Isonea says it has raised \$1,050,000 through a placement to Investment Holdings, an entity owned and controlled by gambling machine operator Bruce Mathieson. Isonea said the issue of 17,500,000 shares at six cents a share meant Mr Mathieson had

become the largest shareholder, with about 15 percent of the company.

The company said the placement would be followed by an entitlement issue to all shareholders.

Isonea chief executive officer Michael Thomas said the investment recognized "the pioneering nature of Isonea's asthma and acoustic respiratory monitoring technologies" and the funds would support the development of the Airsonea smart phone-based asthma monitoring system.

Isonea said Mr Mathieson had "a passionate interest in the [information technology] revolution and the impact of mobile technology on the future of healthcare".

"Isonea is strongly positioned in the new area of digital health," Mr Mathieson said. "The asthma monitoring device they are developing to operate with smart phones has enormous potential to help asthmatics worldwide and generate impressive recurring revenue," Mr Mathieson said.

Isonea said Mr Mathieson was a current director and held a 25 percent stake in gambling machine operator Australian Leisure and Hospitality Group and was currently a non-executive director of Mayne Pharma Group.

Isonea was up 0.8 cents or 14.0 percent to 6.5 cents.

#### <u>OPTISCAN</u>

Optiscan has requested a trading halt pending the "announcement of a placement". Trading will resume on September 4, 2012 or on an earlier announcement. Optiscan last traded at nine cents.