



# Biotech Daily

Tuesday November 12, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH EVEN: ELLEX UP 18%, ALLIED HEALTH DOWN 8%**
- \* **HEARTWARE SEPTEMBER QUARTER REVENUE UP 140% TO \$59m**
- \* **UNILIFE, MEDIMMUNE DEAL ON WEARABLE INJECTORS**
- \* **ELLEX CLAIMS SALES IMPROVEMENT**
- \* **SUDA RESTRUCTURES PROTOPHARMA ARTIMIST DEAL**
- \* **USCOM APPOINTS MEDSOURCE AS SOUTHERN US DISTRIBUTOR**
- \* **UP TO 24% OF SUDA AGM OPPOSE PLACEMENT CAPACITY**
- \* **ATCOR PLEADS SCHULTZ TO ASX 33% QUERY**

## MARKET REPORT

The Australian stock market edged up 0.11 percent on Tuesday November 12, 2013 with the S&P ASX 200 up six points to 5,393.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and five were untraded.

Ellex was best, up five cents or 17.9 percent to 33 cents with 304,993 shares traded, followed by Living Cell up 10.7 percent to 9.3 cents with 1.1 million shares traded.

Medical Developments climbed 8.4 percent; Psivida was up 5.1 percent; Avita and Neuren rose more than four percent; GI Dynamics was up 3.6 percent; Anteo rose 2.2 percent; Alchemia, Bionomics, Cochlear, Genetic Technologies, Nanosonics and Patrys were up more than one percent; with Resmed up 0.2 percent.

Allied Health led the falls, down 1.5 cents or 8.3 percent to 16.5 cents with 12.1 million shares traded.

Compumedics fell 7.8 percent; Atcor and Cellmid lost five percent or more; Clinuvel fell four percent; Pharmaxis, Phosphagenics and Reva were down more than three percent; Universal Biosensors shed 2.75 percent; Benitec and Prana were down more than one percent; with Acrux, CSL and Mesoblast down by less than one percent.

## HEARTWARE INTERNATIONAL

Heartware says that revenue for the three months to September 30, 2013 was up 140 percent to \$US54.8 million (\$A58.7 million) compared to the previous corresponding Heartware said that 549 Heartware ventricular assist systems were sold in the three months, an increase from 256 units in the three months to September 30, 2012 and more than the previous high quarterly total of 523 units in the three months to June 30, 2013. Heartware chief executive officer Doug Godshall said the results "reflect continued positive trends in the commercial launch of the Heartware system in the US, following approval from Food and Drug Administration late last year, as well as continued strong support from our international customers".

The company said that US revenue for the three months to September 30, 2013 was \$US28.2 million, a significant increase from \$US3.6 million in the third quarter of 2012. "Our strong commercial growth was complemented by advances made in clinical development, as we received full protocol approval from FDA for a supplemental patient cohort to our destination therapy trial and commenced enrollment last month," Mr Godshall said.

Mr Godshall said Heartware was "on-track" to begin the first-in-human testing of the next generation miniature ventricular assist device (MVAD) with Pal controller, next year." Heartware said that for the nine months to September 30, 2013, revenue was up 98 percent to \$US154.9 million, compared to \$US78.3 million in the first nine months of 2012. The company said that total operating expenses for the three months to September 30, 2013 were \$US45.8 million, compared to \$US35.2 million in the third quarter of 2012, with research and development expense of \$US25.9 million and at September 30, 2013, it had \$225.0 million of cash, cash equivalents and investments.

On the Nasdaq, Heartware fell 2.2 US cents or 0.02 percent to \$US89.34 (\$A95.64, equivalent to \$2.73 a share prior to departing the ASX) with 161,374 shares traded.

## UNILIFE CORP

Unilife says it has an agreement with Astrazeneca's Medimmune to customize and supply devices from its platform of wearable injectors for use with Medimmune molecules. Unilife said it would supply Medimmune with customized devices from its Readytogo platform of wearable injectors and several drug candidates from Medimmune's portfolio might be selected.

Unilife chief executive officer Alan Shortall said it was "the dawn of a new era for injectable drug delivery where a very sophisticated new class of wearable, disposable devices will allow patients to deliver the most advanced therapies with maximum comfort and convenience".

Unilife said it would generate revenue on the basis of the customization and supply of its products to Medimmune.

The company said that the wearable injection category was expected to generate device sales in excess of \$3 billion within seven years.

Unilife said the Readytogo wearable injectors addressed the unmet need of delivering high-dose volume therapies wherever the patients were and were supplied to the patient prefilled with the drug and ready-for-injection with no extra steps or parts required.

The company said that three steps were required to inject the dose, with an on-body safety interlock, a Flexwear catheter and an electronic user interface.

Unilife said the devices were designed to minimize disruption to a patient's normal daily lifestyle during the period of dose delivery.

Unilife was up four cents or 8.2 percent to 53 cents with 1.4 million shares traded.

## ELLEX MEDICAL LASERS

Ellex says it has had “a solid improvement in group sales” in the four months to October 31, 2013 compared with the prior comparable period.

Ellex chief executive officer Tom Spurling told Biotech Daily that since sales began of its selective laser trabeculoplasty (SLT) glaucoma laser range in the US in July 2013, the company’s US sales had increased by 80 percent.

Mr Spurling said he was unable to disclose unit sales of specific revenue figures.

In its six month report to December 31, 2012, Ellex said it had total sales revenue of \$21,534,000, but did not provide a regional breakdown.

In a media release Ellex said there had been “a material improvement in sales in the US” following the launch of the SLT glaucoma laser range including the Tango and Solo products, with strong interest for US ophthalmologists.

“Our performance in the US has been pleasing and we expect this positive trend to continue over the coming year,” Mr Spurling said.

Mr Spurling said that planned sales and marketing initiatives, including display of the SLT laser range at the American Academy of Ophthalmology meeting in New Orleans, from November 16 to 19, 2013, were expected to boost sales.

Ellex said that “at a group level, a double digit percentage sales increase has been recorded during the four months ended October 31, 2013 compared with the prior comparable period”.

The company said the positive result in the US had been augmented by good sales in Asia but tempered by slow sales in other regions due to continued economic uncertainty in Europe, civil unrest in the Middle East and the deterioration of the Japanese yen against the Australian dollar.

Ellex was up five cents or 17.9 percent to 33 cents.

## SUDA

Suda says it has restructured its Artimist anti-malarial project agreement with the UK-based Protopharma.

Suda said the restructure was “a key element required to allow the project to be commercialized”.

Suda said it previously had a licence to Artimist in Africa, India, Asia and the Pacific region for the treatment of malaria primarily in children, subject to its funding the clinical development, along with a royalty on product sales to Protopharma.

Suda said that all of the Artimist intellectual property and rights would be owned by the Australia incorporate Malaria Research Company which would be controlled by Suda with 80 percent ownership and Protopharma retaining 20 percent, with no royalty obligations to Protopharma and all rights consolidated into the Malaria Research Company.

Suda said it would manage the company and both it and Protopharma would use their joint resources and expertise to take the project through to a commercial outcome.

The company said the both parties were working to finalize the common technical document which would form the basis of regulatory submissions for marketing approval and be central to the due diligence pack offered to prospective pharmaceutical partners.

Suda said the first regulatory submission was expected to be lodged by mid-2014.

Suda said that in consultation with its advisor Torrey Insights it would begin discussions with parties interested in collaborating to commercialize Artimist.

Suda was untraded at 3.7 cents.

### USCOM

Uscom says it has appointed Medsource-SW as the distributor for its cardiac monitor in the Southern US.

Uscom said it had signed a three-year contract with the Dallas, Texas-based Medsource which distributes medical products in Texas, Oklahoma, Louisiana, Arkansas, Missouri, and Kansas.

Uscom executive chairman Rob Phillips said the company was “very focused on building sales and distribution and the appointment of Medsource is part of the re-invigoration of the US Uscom market for us”.

The company said it was developing distribution and sales partnerships to accelerate revenue growth for the Uscom 1A cardiac output monitor and the Uscom BP+ central blood pressure monitor.

Uscom was untraded at 15 cents.

### SUDA

Suda's annual general meeting voted strong dissent against an additional placement capacity and other revenue raising measures, but easily passed the remuneration report. The placement capacity vote was opposed by 20,632,867 votes (23.7%), with 66,456,587 votes (76.3%) in favor.

The company's most recent Appendix 3B new issue announcement said that Suda had 720,708,639 shares on issue, meaning that the votes against the placement capacity amounted to 2.86 percent of the company, not sufficient to requisition extraordinary general meetings.

Approval of the issue of 20,000 convertible notes to director Joseph Ohayon, 50,000 convertible notes to Pearlcove Investments, 350,000 convertible notes to Kamala Holdings and the allotment of a prior issue of 1,480,000 convertible notes were passed with more than 70 million votes in favor and up to 16.6 million votes against, with the ratification of the prior issue of 20,545,455 shares passed with 44.85 million votes in favor and 9.3 million votes against.

Director Michael Stewart was re-elected with 81.7 million votes in favor and 5.3 million votes against, while Mr Ohayon and Ken Robson was re-elected overwhelmingly.

The remuneration report was passed by more than 84.6 million votes in favor and 985,000 votes against.

### ATCOR MEDICAL

Atcor has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 33.3 percent from 15 cents on November 8 to 20 cents on November 11, 2013 and noted an increase in trading volume.

Atcor fell one cent or 5.3 percent to 18 cents with 2.8 million shares traded.