



# Biotech Daily

Friday September 30, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: ACTINOGEN UP 10%, BIONOMICS DOWN 4%**
- \* **SUNSHINE HEART DROPS AORTA CUFF FOR FLUID OVERLOAD FILTER**
- \* **ITL \$500k MACQUARIE INVASIVE BP MONITORING CONTRACT**
- \* **JOHNSON & JOHNSON \$98k FOR BEST BIOLOGICAL TECHNOLOGY**
- \* **RHINOMED TRIAL: 'NO TURBINE BENEFIT FOR HEALTHY CYCLISTS'**
- \* **GENETIC SIGNATURES SHARE PLAN \$1m TAKES TOTAL TO \$15m**
- \* **UNIVERSAL BIOSENSORS EARNS \$9.4m FEDERAL R&D TAX INCENTIVE**
- \* **ALLAN GRAY REDUCES TO 17% OF PHARMAXIS**
- \* **AUSTRALIAN ETHICAL INCREASES, DILUTED TO 6% OF IDT**
- \* **AUSTRALIAN ETHICAL BELOW 5% OF ATCOR**
- \* **PULITANO FAMILY TAKES 9% OF BLUECHIIP**
- \* **UNILIFE REQUESTS ACCOUNTS SUSPENSION**
- \* **MEMPHASYS DR ROBERT GILMOUR GOES, STEPHANIE GEORGIU CO SEC**

## MARKET REPORT

The Australian stock market fell 0.65 percent on Friday September 30, 2016, with the ASX200 down 35.4 points to 5,435.9 points. Sixteen of the Biotech Daily Top 40 companies were up, 13 fell, nine traded unchanged and two were untraded.

Yesterday's 35.9 percent worst, Actinogen, was today's best, up 0.4 cents or 9.8 percent to 4.5 cents with 3.6 million shares traded. Dimerix climbed 7.1 percent; Cellmid and Genetic Signatures were up more than six percent; IDT and Uscom improved more than four percent; Polynovo was up 3.6 percent; Atcor rose 2.1 percent; Admedus and Living Cell were up more than one percent; with Airxpanders, Compumedics, Mesoblast, Nanosonics, Pro Medicus, Resmed and Viralytics up by less than one percent.

Bionomics led the falls, down two cents or 4.35 percent to 44 cents with 601,400 shares traded. Ellex fell 4.1 percent; Acrux, Benitec, Medical Developments and Orthocell shed more than two percent; Impedimed, Neuren, Pharmaxis and Sirtex were down more than one percent; with Clinuvel, Cochlear, CSL, Factor Therapeutics and Starpharma down by less than one percent.

## SUNSHINE HEART

Sunshine Heart says a “strategic realignment” will change its focus from its C-Pulse aorta cuff pump for moderate-to-severe heart failure to fluid overload filtration.

Sunshine Heart raised \$15 million to list on the ASX in 2004 and virtually every subsequent year raised funds totalling more than \$120 million, prior to delisting from the ASX and listing on the Nasdaq, where it raised a further \$49 million and later took a \$13 million dollar loan (BD: Jun 11, 2008; Sep 16, 2010; Aug 13, 2012; Apr 29, 2013).

Major investors included Brisbane’s CM Capital, Melbourne’s GBS Venture Partners and the San Mateo, California-based Three Arch Partners.

In its first presentation to the ASX, the company said it expected to have Australian, European and US sales by the end of 2011, but the company faced repeated trial and regulatory delays.

Sunshine Heart’s first application to the FDA for approval of its counter-pulse aorta cuff for heart failure was filed in 2007 and the company received Conformité Européenne (CE) mark approval and unconditional FDA trial approval in 2012.

In 2015, four trial deaths led to a two-month patient enrolment pause in its proposed 388-patient pivotal trial with six-year chief executive officer David Rosa resigning later that year (BD: Mar 9, May 27, Dec 1, 2015).

Today, Sunshine Heart said it would “fully focus” on the Aquadex Flexflow System acquired from Baxter International for \$US4.0 million in cash and one million Sunshine Heart shares.

The company said the Aquadex system was indicated for “up to eight hours ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended, or longer than eight hours ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization”.

No one from the company was available to say what would happen to the C-Pulse technology or the unknown number of patients in the trial.

As the company is no longer developing the Australian and New Zealand C-Pulse technology, Biotech Daily will cease coverage of Sunshine Heart.

On the Nasdaq, Sunshine Heart fell 10 US cents or 14.3 percent to 60 US cents (78.7 cents, equivalent to 0.39 cents prior to leaving the ASX, when it was trading at 2.5 cents) with 405,419 shares traded.

## ITL

ITL says it has a new five-year \$500,000 contract to supply Macquarie University Hospital the Vedette range of invasive blood pressure monitoring systems.

ITL said that Sydney’s 183-bed Macquarie University Hospital was “Australia’s first private not-for-profit teaching hospital”.

The company said that the agreement included the supply of needle-free closed arterial blood sampling system (Nabss) to prevent needle-stick injuries, hospital associated infections and minimize blood loss when taking blood samples during invasive blood pressure monitoring, as well as the cable management system (CMS) reducing the potential for errors by reducing the number of cables running from multiple transducers to hospital monitors.

ITL executive chairman Bill Mobbs said the contract “shows ITL Healthcare’s innovative products are very market relevant”.

“ITL Healthcare’s innovative approach is aligned very closely to ITL’s overall strategy and the Board is very happy to see its continued growth,” Mr Mobbs said.

ITL was up half a cent or 2.2 percent to 23 cents.

### JOHNSON & JOHNSON INNOVATION

Johnson & Johnson says it and Janssen Supply Chain will award \$US75,000 (\$A98,284) for “the best biological technology or solution”.

Johnson & Johnson said it would award a prize or a series of prizes to the person, team or teams that submitted “the best solution to key manufacturing and supply chain challenges that address the issues of higher costs and reliability in supply chains”.

The company said that it was looking for innovative methods to stabilize protein formulations in liquid stage without refrigeration; optimize process environment methodologies to significantly increase cell production titer in the range of 50 to 100 percent improvement from common monoclonal antibodies baseline; and protect proteins from gastric digestion so as to enable oral absorption.

Johnson & Johnson said that products would be evaluated on their ability to meet criteria including: quality of foundation of technology feasibility; ease of ability to implement in a good manufacturing practice environment; low cost and high reliability; commercial scalability and flexibility; and short lead time to implementation.

The company said that applications close on November 2, 2016, with winners to be announced by the end of 2016.

To apply go to: <http://jllabs.jnjinnovation.com/quickfire-challenges/current-challenges>.

### RHINOMED

Rhinomed says a 20km cycling time trial of 15 healthy male volunteers showed “no differences ... between Turbine, Breatheright and the control”.

Rhinomed said that participants in the Perth, Western Australia-based Murdoch University study were cycling at least 150km a week, had previous racing and time trial experience and undertook a 15 minute standardized warm-up followed by a 20km cycling time trial.

The company said that no differences were observed in total time ( $p = 0.65$ ) or mean power output ( $p = 0.78$ ) between its Turbine, the Breatheright strip and the control.

Rhinomed said that perceived dyspnea, or breathing difficulty, measured during the 30 percent stage was lower during the Turbine ( $p = 0.01$ ) and Breatheright ( $p = 0.03$ ) compared with controls, but “no other differences were observed”.

Rhinomed said that “neither internal or external nasal dilation provide performance enhancement during a 20km cycling time trial with trained athletes when compared with a control” and the study authors “noted no individual response to both internal and external nasal dilators and no presence of a placebo or nocebo effect”.

Rhinomed said that future investigations into the impact of nasal dilation in sport would focus on subjects suffering from nasal congestion and obstruction, rather than healthy volunteers.

Rhinomed was unchanged at two cents.

### GENETIC SIGNATURES

Genetic Signatures says its oversubscribed share purchase plan at 47 cents a share has raised \$1,018,504 taking the total raised to \$15,018,504.

Earlier this month, Genetic Signatures said it had raised \$14,000,000 through a two-tranche placement at the same price (BD: Sep 2, 2016).

The company said at that time that the funds would be used for “commercial expansion in Australia, the European Union and US, obtaining further regulatory approvals for Genetic Signatures’ products, continued product development and working capital purposes”.

Genetic Signatures was up three cents or 6.4 percent to 50 cents.

### UNIVERSAL BIOSENSORS

Universal Biosensors says it has received \$9,362,172 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Universal Biosensors said the rebate related to the year to December 31, 2015. Universal Biosensors was unchanged at 29 cents.

### PHARMAXIS

Allan Gray says it has reduced its shareholding in Pharmaxis from 56,302,797 shares (18.06%) to 53,999,216 shares (17.02%).

Allan Gray said it bought and sold shares between March 18, 2015 and September 27, 2016, with the single largest sale on July 8, 2016 of 2,990,791 shares for \$762,652 or 25.5 cents a share.

Pharmaxis fell half a cent or 1.85 percent to 26.5 cents.

### IDT AUSTRALIA, AUSTRALIAN ETHICAL INVESTMENT

Australian Ethical Investment says it has increased its substantial holding in IDT from 14,272,698 shares to 15,704,981 shares but has been diluted to 6.33 percent.

Australian Ethical said that it bought shares from February 8 to May 10, 2016 and sold shares from September 15 to 28, 2016 with the single largest purchase 800,000 shares for \$220,451 or 27.6 cents a share and the single largest sale 254,827 shares for \$53,396 or 21.0 cents a share.

IDT was up one cent or 4.8 percent to 22 cents.

### ATCOR MEDICAL, AUSTRALIAN ETHICAL INVESTMENT

Australian Ethical Investment has reduced its substantial holding in Atcor from 11,302,239 shares (5.56%) to 10,106,286 shares (4.97%).

Australian Ethical said it sold 1,195,953 shares between September 26 and 29, 2016, for \$112,165 or 9.4 cents a share.

Atcor was up 0.2 cents or 2.1 percent to 9.8 cents.

### BLUECHIIP

The Pulitano Family has increased its substantial shareholding in Bluechiip from 11,484,292 shares (5.93%) to 23,052,671 shares (8.57%).

The substantial shareholder notice signed by the Melbourne-based Giuseppe Pulitano said that the shares were held by Giuseppe and Verona Pulitano and the Pulitano Family Superannuation Fund.

The notice said 10,207,614 shares were acquired for \$226,790 or 2.2 cents a share on May 18 and September 16, 2016 in the company's placement and rights offer, but did not explain the remaining 1,360,765 shares acquired (BD: May 19, Aug 15, 2016).

Bluechiip fell 0.2 cents or 7.1 percent to 2.6 cents.

### UNILIFE

Unilife has requested a voluntary suspension from trading on the ASX saying it could not file audited accounts for the year to June 30 by September 30, 2016.

Unilife last traded at 5.5 cents.

## MEMPHASYS

Memphasys says that non-executive director Dr Robert Gilmour has resigned with immediate effect and Stephanie Georgiou would replace company secretary Mark Studd. Memphasys said that as part of Dr Gilmour's resignation he had agreed to a settlement terminating his consulting services and the options to be granted to him would be reduced from 20,000,000 to 4,000,000.

Memphasys was unchanged at half a cent with 6.9 million shares traded.