



# Biotech Daily

Thursday August 31, 2017

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: STARPHARMA UP 14%, DIMERIX DOWN 10%**
- \* **CSIRO, MONASH M2 FOR PROTOTYPES, IMAGING**
- \* **ADMEDUS REVENUE UP 57% TO \$22m, LOSS DOWN 49% TO \$13m**
- \* **CLINUVEL REVENUE UP 165% to \$17m, \$7m MAIDEN PROFIT**
- \* **SUDA REVENUE UP 23% TO \$7m, LOSS DOWN 46% TO \$1.2m**
- \* **CELLMID REVENUE UP 21% to \$5.6m, LOSS UP 28% TO \$4.5m**
- \* **MEDLAB REVENUE UP 70% TO \$4.4m, LOSS UP 3% TO \$4m**
- \* **ATCOR REVENUE DOWN 14% TO \$4.3m, LOSS DOWN 9% TO \$4.4m**
- \* **IMMURON REVENUE UP 40% to \$1.4m, LOSS UP 21% TO \$6.8m**
- \* **ALCIDION, MONASH NEGOTIATING MIYA CLINICAL TASK MANAGEMENT**
- \* **ADMEDUS TO SUPPLY ADAPT TISSUE TO 4C FOR MITRAL VALVE REPAIR**
- \* **PRIMA, MONASH WIN \$360k ARC GRANT FOR LAG-3**
- \* **IMUGENE DOSES 1<sup>st</sup> HER-VAXX GASTRIC CANCER PATIENT**
- \* **MTP CONNECT, INDIA TO COLLABORATE ON LIFE SCIENCES**
- \* **US PATENT FOR OPTHEA OPT-302 FOR EYE DISEASES**
- \* **CLINICAL GENOMICS WINS J&J EUREKA PRIZE FOR CANCER TEST**
- \* **OBJ TO LOSE CHAIRMAN GLYN DENISON**
- \* **CHO GROUP TAKES CONTROL OF INVION, LIGHT THERAPY FOR CANCER**
- \* **AVITA APPOINTS ERIN LIBERTO CHIEF COMMERCIAL OFFICER**

## MARKET REPORT

The Australian stock market was up 0.79 percent on Thursday August 31, 2017 with the ASX200 up 44.8 points to 5,714.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and three were untraded. All three Big Caps rose.

Starpharma was best, up 13 cents or 14.3 percent to \$1.04 with 992,813 shares traded. Prima climbed 9.1 percent; ITL was up 8.1 percent; Nanosonics and Polynovo were up more than seven percent; Actinogen improved 4.8 percent; Bionomics and Clinuvel were up more than three percent; with Admedus and Osprey up more than two percent.

Dimerix led the falls, down 0.1 cents or 10 percent to 0.9 cents with 630,000 shares traded. Avita lost 7.25 percent; Compumedics was down six percent; Prana fell 5.4 percent; Cellmid fell four percent; Reva was down 3.1 percent; with Cyclopharm and Oncosil down more than two percent.

## COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says with Monash University its M2 to support the biotechnology industry.

In a media release, the CSIRO said that with Monash University and Monash Health Translation Precinct it had launched M2 at its biomedical materials translation facility in Clayton to provide facilities for all aspects of research and development.

CSIRO manufacturing director Dr Keith McLean said that M2 “leverages some of Australia's best [medical technology] expertise, experience and equipment”.

“When a company comes to us we can use CSIRO and [Monash Health Translation Precinct] facilities to develop and analyze production scale prototypes, whilst the Monash Biomedical Imaging facility can provide advanced pre-clinical and clinical testing and imaging,” Dr McLean said.

The media release said that the Minister for Industry, Innovation and Science Senator Arthur Sinodinos officially launched the M2 precinct.

CSIRO said that Australia had more than 500 companies working in the medical technologies and pharmaceuticals sector, many of which were small and medium enterprises, which could “struggle to make the expensive, time consuming transition from prototype to clinically tested product”.

The Organisation said that M2 would provide “a research ecosystem to transition new discoveries from the bench to prototyping, pre-clinical testing, industry evaluation and commercialization”.

Monash University provost and senior vice-president Prof Marc Parlange said the This initiative would “deliver real health benefits to all Australians”.

CSIRO said that M2 was supported by a Federal Science and Industry Endowment Fund.

## ADMEDUS

Admedus says that revenue for the year to June 30, 2017, was up 57.8 percent to \$22,324,000 with net loss after tax down 49.6 percent to \$12,676,000.

Admedus said that its Adapt Cardiocel and Vascucel sales were up 30.2 percent to \$6.9 million driven by the roll-out in North America, Europe, the Middle East and North Africa and Asia, with the hospital supply infusion division up 74.2 percent to \$15.4 million.

Admedus said that net tangible asset backing per share was up 7.8 percent to 6.9 cents, with basic loss per share down 61.6 percent to 4.83 cents and cash and cash equivalents of \$11,260,657 at June 30, 2017 compared to \$8,813,119 at June 30, 2016.

Admedus was up 0.5 cents or two percent to 25 cents.

## CLINUVEL

Clinuvel says revenue for the year to June 30, 2017, was up 164.6 percent to \$16,984,536 with last year's \$3,153,718 loss turned to a \$7,114,286 maiden profit.

Clinuvel said that European revenue from Scenesse for erythropoietic protoporphyria was up 357.5 percent to \$11,886,000 compared to the previous year's \$2,598,000, with sales in Italy and Switzerland under special access schemes up 33.8 percent to \$4,834,000 compared to the previous year's \$3,614,000.

The company said that last years diluted loss per share of 7.0 cents was turned to a diluted earnings per share of 14.3 cents at June 30, 2017, tangible assets per share increased 39.5 percent to 53 cents, and the company had with \$23,752,312 in cash and cash equivalents at June 30, 2017, compared to \$13,844,703 at June 30, 2016.

Clinuvel climbed 27 cents or 3.9 percent to \$7.27.

### SUDA

Suda says that revenue for the year to June 30, 2017, was up 23.0 percent to \$7,221,000 with net loss after tax down 45.9 percent to \$1,238,000.

Suda said that the revenue primarily came from a 16 percent increase in revenue from its wholly-owned subsidiary Westcoast Surgical and Medical Supplies, as well as a payment from Eddingpharm for a licence to its Zolpimist in China and a fee for formulation services from Pfizer Consumer Health.

The company said that net tangible asset backing per share fell 41.7 percent to 0.14 cents, with diluted loss per share down 45.0 percent to 0.11 cents, and cash and cash equivalents of \$1,769,812 at June 30, 2017 compared to \$2,448,771 at June 30, 2016. Suda was up 0.1 cents or 4.55 percent to 2.3 cents with 2.8 million shares traded.

### CELLMID

Cellmid says revenue for the year to June 30, 2017, was up 20.6 percent to \$5,560,121 with net loss after tax up 27.8 percent to \$4,470,136.

Cellmid chief executive officer Maria Halasz told Biotech Daily that licence fees and royalties for its midkine diagnostics fell 28.2 percent to \$147,520 but sales of its Advangen hair loss products climbed 44.1 percent to \$4,496,338.

Ms Halasz said that the Japanese subsidiary was profitable for the second year in a row and she hoped the Australian Advangen division would be profitable next year.

Ms Halasz said that profits from the hair loss products and consumer health would be used for research and development of the midkine assets.

Cellmid said that diluted loss per share was up 15.8 percent to 0.44 cents at June 30, 2017, net tangible assets per share were down 11.1 percent to 0.24 cents and it had in cash and cash equivalents at June 30, 2017, compared to \$2,686,329 at June 30, 2016. Cellmid fell 0.1 cents or four percent to 2.4 cents.

### MEDLAB CLINICAL

Medlab says that revenue for the year to June 30, 2017 was up 69.7 percent to \$4,446,533, with net loss after tax up 2.8 percent to \$3,828,185.

Medlab said that revenue from sales of its probiotic and food additive products was up 117.9 percent to \$3,272,926.

The company said it was investigating the use of cannabis for nausea and vomiting related to cancer pain as well as developing its Nanostat to provide lower doses of statins.

Medlab said that diluted loss per share fell 7.0 percent to 1.98 cents at June 30, 2017, with cash and equivalents of \$1,497,600 at June 30, 2017 compared to \$801,368 at June 30, 2016.

Medlab was up 0.5 cents or 0.7 percent to 72.5 cents.

### ATCOR MEDICAL

Atcor says revenue for the 12 months to June 30, 2017 fell 13.85 percent to \$4,327,283, with net loss after tax down 9.2 percent to \$4,363,571.

Atcor said that net tangible asset backing per share fell 62.5 percent to 0.6 cents, diluted loss per share fell 16.7 percent to 2.0 cents and the company had cash and equivalents of \$677,917 at June 30, 2017 compared to \$1,773,950 at June 30, 2016.

Atcor was unchanged at 2.9 cents.

## IMMURON

Immuron says revenue for the year to June 30, 2017, was up 39.5 percent to \$1,396,197 with net loss after tax up 21.0 percent to \$6,764,137.

Immuron said that sales of the travellers' diarrhoea preventative product Travelan had increased.

The company said that diluted loss per share fell 12.3 percent to 6.4 cents at June 30, 2017 and net tangible assets per share fell 18.0 percent to 5.056 cents and it had \$3,994,924 in cash and cash equivalents at June 30, 2017, compared to \$2,290,639 at June 30, 2016.

Immuron was unchanged at 19.5 cents.

## ALCIDION GROUP

Alcidion says that Melbourne's Monash Health has awarded it preferred vendor status for its Miya Smartpage Clinical task management product.

Alcidion said that the terms of the contract were being negotiated, which was expected to be finalized by October with the Miya Smartpage Clinical software system expected to be operational by the end of 2017.

The company said that Monash Health included two major public hospitals Monash Medical Centre and Monash Children's as well as four smaller hospitals.

Alcidion said that the Miya Smartpage Clinical provided "instant, two-way messaging, to support clinical supervision, task sharing and fast clinical handover".

The company said the system streamlined workflows, integrated clinical summaries and patient data, providing care team productivity and benefits to patient safety.

Alcidion said the system was "of very high value overnight when clinical staffing levels are at the minimum but the patient load is much the same as during peak staffing times".

The company said the software allowed instant responses from clinicians, with read receipts and full audit trail management, so that staff know their requests have been implemented.

Alcidion said it included a trial of the Miya Smartpage Orderly module in its offer, to provide ward-based electronic ordering, eliminating the need for dispatchers and the associated faxes and telephone calls, with all requests, delays and cancellations openly visible real time with no confusion over whether a task had been ordered or completed.

Alcidion was unchanged at 5.4 cents.

## ADMEDUS

Admedus says it has an exclusive supply agreement for its Adapt bovine tissue with the Brooklyn Park, Minnesota-based 4C Medical Technologies.

Admedus said that 4C Medical would use the Adapt process tissue in its trans-catheter mitral regurgitation treatment technology that "preserves the native mitral valve and left ventricle using a supra-annular, atrial-only fixation technology".

The company said that the 4C technology "eliminates known issues of current trans-catheter mitral valve replacement technologies which rely on placement and fixation in the native mitral annulus and left ventricle".

Admedus said that the functioning valve apparatus of the 4C implant would use its Adapt tissue engineering process for the functioning leaflet component.

Admedus chief executive officer Wayne Paterson said that the supply agreement would "give Admedus access to a significant new revenue stream".

### PRIMA BIOMED

Prima says it has won a \$360,000 Australian Research Council Linkage Project grant with Monash University for the use of LAG-3 in immune responses.

Prima said Monash University's Prof Jamie Rossjohn would conduct a three-year study entitled 'Investigating the structure of a T-cell immune checkpoint molecule' to assess T-cell receptors and their role in the immune system and provide insights into the LAG-3 function and how it controls T-cell signalling.

The company said the study could lead to the development of new T-cell immunomodulatory agents.

Prof Rossjohn said the study would help further understand the way that LAG-3 controls T-cell signalling, which was important for both cancer and autoimmunity.

Prima was up 0.2 cents or 9.1 percent to 2.4 cents with 11.0 million shares traded.

### IMUGENE

Imugene says it has begun dosing the first of up to 18 patients in its phase Ib combination with chemotherapy trial of its HER-Vaxx immunotherapy for gastric cancer.

Last year, Imugene said it had begun its phase Ib/II clinical study of HER-Vaxx for gastric cancer with gastric cancer patients to be screened and enrolled at eight sites in Asia, including Hong Kong, Thailand and Taiwan (BD: Nov 7, 2016).

Imugene said the phase Ib trial was an open-label, multicentre, dose-escalation study, designed to assess the safety, tolerability and immunogenicity, which would show how well the vaccine was directing production of HER2 antibodies in patients.

The company said the combination HER-Vaxx and chemotherapy trial would interrogate three dose levels and evaluate the booster schedule to help determine the optimal recommended dosing for the phase II study.

Imugene said that the 68-patient, open-label phase II study would recruit patients with metastatic gastric cancer overexpressing HER2 with patients randomized to either HER-Vaxx plus chemotherapy or chemotherapy alone.

Imugene was unchanged at 1.4 cents with 2.3 million shares traded.

### MTP CONNECT

The Medical Technologies, Biotechnologies and Pharmaceuticals Industry Growth Centre (MTP Connect) says it will collaborate with India in life sciences.

MTP Connect said that it had signed a memorandum of understanding with the Confederation of Indian Industry to collaborate on the medical technology, biotechnology and pharmaceutical sectors in India and Australia.

The Federal Government funded MTP Connect said that North America and Europe were the most significant markets but the groupings of Brazil, Russia, India, China and South Africa (BRICS) and the Association of Southeast Asian Nations (ASEAN) were "rapidly increasing in buying power" with North America predicted to lose its 'largest healthcare market' title to the Asia Pacific in the next decade.

The organization said Australia had "an opportunity to capitalize on the export, investment and job creating potential of its medical research and technology sector to India and further strengthening the relationship with India will help enable us to achieve that".

MTP Connect said the agreement would bring the two organisations together to support inbound and outbound missions, exchanging information, introductions and market support in both countries, as well as joint events and projects.



## OPTHEA

Opthea says it has been granted a US patent for its OPT-302 soluble vascular endothelial growth factor-3 (VEGF-3) trap molecule for eye diseases.

Opthea said that the patent, entitled 'VEGFR-3 ligand binding molecules and uses thereof' was granted in the name of its wholly-owned subsidiary Vegenics Pty Ltd and would provide coverage until February 13, 2034.

The US Patent and Trademark Office website said that the invention was "directed to VEGFR-3 ligand binding molecules and uses thereof to modulate angiogenesis and/or lymphangiogenesis".

"A glycosylation sequon of wildtype VEGFR-3 has been modified to eliminate glycosylation in the ligand binding molecules," the USPTO said.

Opthea said that the patent covered OPT-302 and its use to treat disorders involving neo-vascularisation, including eye diseases such as wet age-related macular degeneration and diabetic macular oedema.

The company said that corresponding patent applications were pending in 17 other countries and had been granted in South Africa.

Opthea said it was planning to investigate OPT-302 in a 350-patient phase IIb wet age-related macular degeneration trial, along with two phase IIa trials, one in diabetic macular oedema and the other in wet age-related macular degeneration patients previously treated with anti-VEGF-A therapy with a sub-optimal clinical response.

Opthea fell one cent or 1.45 percent to 68 cents.

## CLINICAL GENOMICS

Clinical Genomics says its Colvera "liquid biopsy" blood test for colorectal cancer has won the Johnson & Johnson Eureka Prize for Innovation in Medical Research.

Clinical Genomics said the test was co-developed with the Commonwealth Scientific and Industrial Research Organisation and Adelaide's Flinders Medical Centre to identify early cancer relapse following colorectal cancer surgery.

The company said that the blood test "sensitively and accurately detects tumor DNA" assisting doctors to improve survival rates after surgery by detecting recurrence of the disease earlier and more accurately.

Clinical Genomics chief executive officer Dr Larry LaPointe said that colorectal cancer outcomes improved with early detection "but currently available monitoring tests frequently fail to detect disease at a point when clinical intervention can be effective". "This failure is a key reason why mortality from colorectal cancer is so high," Dr LaPointe said.

"Colvera is a new test that can detect molecular changes in circulating tumor DNA associated with cancer development," Dr LaPointe said.

"Colvera provides physicians with actionable information that can trigger further clinical assessment ... to improve survival," Dr LaPointe said.

Clinical Genomics is a private company.

## OBJ

OBJ says that chairman Glyn Denison will retire from having reached the age of 65 years. OBJ said that Mr Denison would remain a director pending the appointment of a replacement.

The company said that it would seek an experienced director with industry experience to "guide the market development activities".

OBJ was up 0.4 cents or 9.5 percent to 4.6 cents with 1.4 million shares traded.

## INVION

Invion says it will licence “new generation photo dynamic therapy” for cancers from the Hong Kong’s Cho Group for \$5.5 million in shares at 0.2 cents a share.

Invion has a market capitalization of \$2,911,931.

Invion said that it would be the exclusive distributor and licensee in Australia and New Zealand for the technology and would conduct research and development of the technology, initially targeting prostate cancer and the Cho Group would provide non-dilutive funding for the trials.

The company said the Cho Group would underwrite a non-renounceable pro rata rights offer to raise \$2.5 million for working capital and the costs of the transaction.

In April, Invion said it had a “strategic alliance” with the Cho Group, investing \$656,682 for shares at 0.3 cents each to take a 15.03 percent stake in the company, appoint two directors and the funds to be used for working capital as it continued to market the sale or out-licence of its respiratory assets and sought, with the Cho Group, to identify new assets for its pipeline. (BD: Apr 18, 2017).

Today, the company said that new generation photo dynamic therapy (NGPDT) was “a new generation photo-sensitizer derived from chlorophyll which [was] hypothesized to identify and selectively accumulate within solid cancerous tumor tissues”.

Invion said that specific whole-body light and internal laser delivery methods were targeted to activate the absorbed photo-sensitizer within both surface and deep seated tumors.

Invion interim executive chair Dr Greg Collier said the transaction “represents a series of positive outcomes for Invion”.

“Invion has the opportunity to commercialize in Australia and New Zealand products and services for the non-invasive treatment of all solid cancers,” Dr Collier said.

“The R&D Services Agreement leverages Invion’s expertise in clinical development and provides the company with non-dilutive funding to develop this asset as part of a global development strategy for the product,” Dr Collier said.

“The company will also continue to identify and assess new advanced clinical opportunities to expand its business prospects,” Dr Collier said.

Invion fell 0.05 cents or 20 percent to 0.2 cents.

## AVITA MEDICAL

Avita says it has appointed Erin Liberto as its chief commercial officer effective from August 28, 2017.

Avita said that Ms Liberto would be responsible for the execution of the company’s commercial strategy including development of sales, reimbursement and marketing.

The company said that Ms Liberto was most recently Allergan’s head of topical dermatology marketing, where she oversaw more than \$US650 million of business revenue, doubled the domestic Skinmedica growth rate and gained the number one share position for Aczone for acne.

Avita said the previously Ms Liberto was US marketing director at Johnson & Johnson’s Biosense Webster.

Avita fell 0.5 cents or 7.25 percent to 6.4 cents with 1.5 million shares traded.