



# Biotech Daily

Thursday September 21, 2017

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: DIMERIX UP 14%, ACTINOGEN DOWN 7%**
- \* **AVITA SIGNS \$30m BARDA PAEDIATRIC BURNS EXTENSION**
- \* **CARL ZEISS UNVEILS OPTISCAN IN-VIVO 'DIGITAL BIOPSY TOOL'**
- \* **COMPUMEDICS SIGNS \$1m GERMAN EPILEPSY MONITOR CONTRACT**
- \* **PROBIOTEC BUYS SOUTH PACK FOR \$8m CASH, 7.9m SHARES**
- \* **AUSTRALIAN PATENT FOR ORTHOCELL CELGRO REPAIR PLATFORM**
- \* **GENETIC TECHNOLOGIES D-I-Y BREVAGENPLUS BREAST CANCER TEST**
- \* **POLYNOVO REQUESTS CAPITAL RAISING TRADING HALT**
- \* **PSIVIDA \$14m AVAILABLE THROUGH FBR 'AT MARKET' FACILITY**
- \* **MACQUARIE UNI, CSIRO HOLD SYNTHETIC BIOLOGY CONFERENCE**

## MARKET REPORT

The Australian stock market fell 0.94 percent on Thursday September 21, 2017 with the ASX200 down 53.7 points to 5,655.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and eight were untraded. All three Big Caps fell.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 5.5 million shares traded.

Living Cell climbed 6.7 percent; Avita was up five percent; Prima improved 4.8 percent; Bionomics was up 3.2 percent; Starpharma rose 2.9 percent; Ellex, LBT, Neuren and Pharmaxis were up more than one percent; with Mesoblast up 0.4 percent.

Actinogen led the falls, down 0.4 cents or 6.8 percent to 5.5 cents with 26,000 shares traded.

Airxanders and Cellmid fell four percent or more; Factor Therapeutics and Sirtex lost more than three percent; Osprey shed 2.3 percent; Admedus, Cochlear, Compumedics, Impedimed, Nanosonics and Orthocell were down more than one percent; with Clinuvel CSL, Medical Developments, Pro Medicus and Resmed down by less than one percent.

## AVITA MEDICAL

Avita says the US Biomedical Advanced Research and Development Authority has expanded its burns research contract valued at about \$US24.3 million (\$A30.4 million). Avita said that the BARDA contract would fund clinical and health economics research in US paediatric burn care to September 2022.

In 2015, the company said it signed its first five-year BARDA contract worth up to \$US53.9 million then worth \$A76.99 million to provide more than 5,000 Recell wound treatment units (BD: Sep 30, 2015).

Today, Avita said that BARDA's goal was to build burn care preparedness, by securing effective medical countermeasures for burn injuries for use in case of a mass casualty. The company said that the base contract provided substantial support to the primary goals of US regulatory approval for the Recell spray-on skin device and establishing preparedness for a potential US mass burns casualty event.

Avita said that 30 percent of burns in the US were in patients under 16 years of age and children had limited skin availability with increases in morbidity associated with harvesting skin for conventional autografts.

The company said that two randomized control trials had been presented to the US Food and Drug Administration via the pre-submission process.

Avita said that one trial focuses on characterizing benefit from use of the Recell device to treat donor sites in patients aged one to 16 years and the other trial would aim to show decreases in time to healing and in the frequency of conventional autografting in patients of the same age range with second-degree burns.

The company said that the trials would run in parallel at up to 20 US burn centres.

Avita head of clinical development Andrew Quick said that the studies would “contribute substantially toward rounding out the story and enabling changes to burn care in everyday clinical practice”.

Avita was up 0.3 cents or five percent to 6.3 cents with 14.65 million shares traded.

## OPTISCAN IMAGING

Optiscan says that Carl Zeiss Meditec will unveil the live in-vivo Digital Biopsy Tool, based on Optiscan technology, at meetings in Europe and the US in October.

Optiscan chief executive officer Archie Fraser told Biotech Daily that the system was “Optiscan’s confocal microscope in a Carl Zeiss box”.

In a media release, Optiscan said that the Digital Biopsy Tool would be available for hands-on sessions at the European Association of Neurosurgical Societies meeting in Venice, Italy, October 1 to 5 and the Congress of Neurological Surgeons in Boston, Massachusetts, October 7 to 11, 2017.

The company said that Carl Zeiss had begun preparations for regulatory approvals.

Mr Fraser told Biotech Daily that he expected the system to have “regulatory approvals early next year” with payments from Carl Zeiss for buying the systems from Optiscan.

“There are more than one million neurosurgery procedures conducted in the US alone, each year,” Mr Fraser said.

Optiscan said that it had “a long-standing collaboration agreement [with Carl Zeiss] focused on the integrated development of a miniaturized confocal imaging probe based system, specifically designed for in-vivo real time digital imaging for clinical use in neurosurgery”.

“This is a significant milestone for the commercialization of the Optiscan-patented technology into a major clinical application,” the company said.

Optiscan was up 0.2 cents or 2.4 percent to 8.4 cents.

## COMPUMEDICS

Compumedics says has signed a \$1 million contract to supply neurological monitoring systems to the Bielefeld-Bethel, Germany-based Krankenhaus Mara epilepsy centre. Compumedics said it would ship systems to the Bethel epilepsy centre in stages to June 30, 2019 and described the centre as “one of Europe’s leading centres for treating and rehabilitating people with epilepsy”.

The company said that Bethel was the largest epilepsy hospital in Germany with 130 beds and 35 rehabilitation places for in-patient treatment.

Compumedics said that in 2016, 2,811 in-patients were treated, more than 100 epilepsy surgeries were performed, 17 of them after intra-cranial studies.

Bethel clinical director Prof Christian Bien said the primary reasons for buying the Compumedics’ systems “over four other internationally recognised vendors were the transparency and flexibility of Compumedics’ systems, particularly the ability to record, distribute and store high quality video and [electro-encephalogram] signals”.

“Also important were the knowledge and responsiveness of Compumedics staff, as well as the company’s on-going commitment to working with key customers on innovative new solutions to improve patient outcomes and efficiencies within the clinical centre,” Prof Bien said.

Compumedics executive chairman Dr David Burton said the contract for its neurological monitoring technology included the Graef product platform.

“Compumedics was able to achieve this win against robust local and international competition in Germany, so this is a significant reference site for the company in the critical German and wider European market,” Dr Burton said.

Compumedics fell 0.5 cents or 1.35 percent to 36.5 cents.

## PROBIOTEC

Probiotec says it will acquire Sydney’s South Pack Laboratories (Aust) Pty Ltd for \$8 million in cash and 7.9 million shares.

Probiotec said that South Pack was a pharmaceutical and food additive contract packer.

The company said \$1 million of the cash payment would be deferred for one year and a further \$1 million deferred for two years, with 50 percent of the issued shares to be issued to an entity associated with South Pack chief executive officer Tony Gian subject to escrow with half released after one year and the balance released after two years, subject to certain conditions.

Probiotec said the vendors would be entitled to an additional cash payment of \$1 million subject to a minimum earnings hurdle for the first year and a further \$1 million in cash subject to a higher minimum earnings hurdle for the second year.

The company said that the initial cash payment of \$6 million would be funded through an increase in its current debt facilities, with the deal expected to be completed in October 2017, subject to conditions.

Probiotec said South Pack would continue to operate within its current production facility, which was being upgraded to increase capacity and capabilities and the business would continue to be led by the existing management team.

Probiotec managing-director Wes Stringer said the acquisition was “the continuation of the company’s business strategy of increasing its manufacturing capabilities and scale”.

“This acquisition is consistent with our stated strategy that Probiotec would look to grow its core business units, with contract manufacturing being our largest segment,” Mr Stringer said.

Probiotec was up two cents or 3.9 percent to 53 cents.

## ORTHOCELL

Orthocell says it has been granted a further Australian patent for its Celgro collagen medical device platform for soft tissue regeneration and repair applications.

Orthocell said that the patent, entitled 'Method for Producing a Collagen Membrane and Uses Thereof' provided additional intellectual property protection for its Celgro product platform until June 12, 2032.

The company said that Celgro was manufactured at its quality controlled facility in Perth, Western Australia, using its SMRT tissue engineering process, developed with its chief scientific officer Prof Ming-hao Zheng and the University of Western Australia.

Orthocell said that Celgro was "a customizable, fit-for-purpose collagen medical device with numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue in growth and repair".

The company said that Celgro improved tissue in-growth and repair in clinical studies using the device to augment repair of the shoulder rotator cuff tendon, to guide bone regeneration in the jaw and to assist in the re-joining of severed, or damaged peripheral nerves.

Orthocell fell half a cent or 1.5 percent to 33.5 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies says it will transition the Brevagenplus breast cancer test to an electronic commerce-based system.

Genetic Technologies said that consumers would be able begin the test through the platform at its US subsidiary Phenogen Sciences' website at: [www.brevagenplus.com](http://www.brevagenplus.com).

Genetic Technologies chief executive officer Eutillio Buccilli said that since the launch of Brevagenplus the company had been "steadfast in exploring the optimal methodology to effectively market the product without comprising resources".

"Our recent shift to a patient self-pay program coupled with the on-going operational strategic review served as catalysts to transform the commercial program into a pure [electronic] commerce system enabling us to manage in totality, a streamlined organisation that is conserving capital without comprising commercial activities".

In March, Genetic Technologies said it would charge patients directly \$US349 per test compared to \$US2,795 to insurance companies for its Brevagenplus breast cancer risk assessment (BD: Mar 31, 2017).

The company said from April 1, 2017, it would move from reimbursement through insurers to direct patient self-pay because gaining adequate payment had become increasingly difficult using a traditional payment model and payment was "an acknowledged issue for ... companies selling molecular diagnostics and seeking reimbursement from insurers through a current procedural terminology miscellaneous code".

Today, Genetic Technologies said that consumer initiated testing through the website provided testing under the guidance and management of a remote physician using guideline driven protocols to ensure a two-way patient physician relationship was established; appropriate informed consent was obtained; results were interpreted correctly; abnormal results were flagged responsibly and communicated in a way to drive action; state guidelines were being met for the ordering of laboratory tests; next steps were provided; and the individual is triaged to local care when appropriate.

The company said that consumer initiated testing complemented by direct-to-consumer advertising could reach two primary audiences through various channels and mediums. Genetic Technologies was unchanged at 0.7 cents.

## POLYNOVO

Polynovo has requested a trading halt “pending an announcement regarding a likely capital raising”.

Trading will resume on September 26, 2017 or on an earlier announcement.

Polynovo last traded at 28.5 cents.

## PSIVIDA

Psivida says it has used \$US8,892,571 (\$A11,154,527) of its \$US20,000,000 “at market” draw-down facility with the Arlington, Virginia-based FBR Capital Markets.

In February, Psivida said it had a \$US20,000,000 “at market” draw-down facility with FBR and had lodged a “shelf registration” to raise up to \$US75,000,000 with the US Securities and Exchange Commission (BD: Feb 9, 2017).

Today, Psivida said it had \$US11,107,429 (\$A13,943,308) of its US shares available under the agreement.

The company said the funds would be used for “the continued research and clinical and pre-clinical development of our product candidates, commercialization of our product candidates, if approved, and for other general corporate purposes”.

Psivida was unchanged at \$1.56.

## COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION, MACQUARIE UNIVERSITY

Macquarie University and the Commonwealth Scientific and Industrial Research Organisation are holding a two day ‘synthetic biology’ conference in Sydney.

A media release from Macquarie University said that the conference today and tomorrow September 21 and 22, 2017 would review synthetic biology “as a priority research area with the capacity to shape Australia’s future”.

A spokesperson for the University told Biotech Daily that synthetic biology was “the application of engineering principles to biology and involves the design and construction of biological systems and devices, for useful purposes”.

A joint Macquarie University and CSIRO media release said that synthetic biology was “one of the fastest-growing sciences in the world, a \$US150 billion industry set to drive innovation in the areas of manufacturing, human health, agriculture and protecting ecosystems”.

The University said that synthetic biology was “a foundational science to a number of other industries and areas, capable of generating significant societal benefits and commercial opportunities, such as speeding up the process of pharmaceutical development, reversing complex problems in ecosystems, and even repurposing dangerous chemicals and gasses for positive use”.

Macquarie University said that research deputy vice-chancellor Prof Sakkie Pretorius made synthetic biology a research priority in 2014 and joined the Global Flagship Yeast 2.0 project.

The University said that in 2016 CSIRO launched the Synthetic Biology Future Science Platform as one of six blue-sky research platforms with the potential “to help reinvent and create new industries for Australia”.

More information on the conference is at: <https://synbioaustralasia.org/sba2017/>.

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