



Biotech Daily

Monday October 24, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BENITEC UP 40%; DIMERIX DOWN 9%**
- * **VICTORIA PREMIER DANIEL ANDREWS OPENS AUSBIOTECH CONFERENCE**
 - Monash Medicines Manufacturing Innovation Centre
 - Appoints Amanda Caples Lead Scientist, Dr Gareth Goodier Parkville Chair
 - CSL's Paul Perreault: 'Innovate, Focus On Patients, Or Leave'
 - Innovation & Science Australia's Bill Ferris On R&D Review
 - Federal \$7.4m For 14 MTP Connect Projects
- * **BENITEC \$5m+ NANT CANCER ddRNAi COLLABORATION**
- * **AMPLIA LICENCES (ALCHEMIA) CTX FOCAL ADHESION KINASE DRUGS**
- * **ITL TO LAUNCH DONORCARE NEEDLE GUARD 2**
- * **INVITROCUE, GENOME INSTITUTE COLORECTAL CANCER COLLABORATION**
- * **TGA CANCELS GI DYNAMICS ENDOBARRIER LISTING, TRIAL CONTINUES**
- * **AUSTRALIAN ETHICAL TAKES PROFIT TO 7% OF INNATE**
- * **GRAHAM DURBIN SUPERANNUATION TAKES 11.6% OF GENERA**
- * **RHINOMED LOSES CFO, COO JUSTINE HEATH**
- * **RACE APPOINTS PROF DOUGLAS SMITH CONSULTANT ADVISOR**
- * **ANALYTICA'S CHELSEA CORNELIUS WINS MTAA GONG**

MARKET REPORT

The Australian stock market fell 0.4 percent on Monday October 24, 2016 with the ASX200 down 21.8 points to 5,408.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Benitec was the best, up 3.7 cents or 39.8 percent to 13 cents with 2.5 million shares traded. Compumedics and Oncosil were up more than four percent; Avita was up 3.85 percent; Cellmid, Mesoblast and Osprey rose more than two percent; Acrux, Impedimed, Pharmaxis and Pro Medicus were up more than one percent; with Sirtex up 0.3 percent.

Dimerix led the falls, down 0.1 cents or 9.1 percent to one cent with 7.6 million shares traded. Bionomics fell seven percent; Cochlear and IDT lost more than four percent; Admedus shed 3.7 percent; Actinogen, Medical Developments, Neuren, Orthocell and Uscom fell two percent or more; Anteo, Atcor, CSL, Ellex, Factor Therapeutics, Polynovo and Reva were down more than one percent; with Clinuvel, Cyclopharm, Nanosonics, Resmed, Starpharma and Viralytics down by less than one percent.

AUSBIOTECH, VICTORIA GOVERNMENT, MIPS

Victoria Premier Daniel Andrews opened Ausbiotech's 2016 conferences announcing the Medicines Manufacturing Innovation Centre and two key appointments.

Mr Andrews welcomed delegates to the conference, praising the State's successes in biotechnology and current programs to support the sector.

Mr Andrews announced a \$4 million investment in the Medicines Manufacturing Innovation Centre to be led by Monash University and supported by Glaxosmithkline for "a world class medicines manufacturing centre to help Victoria's pharmaceutical industry create new products, grow exports and develop skills".

Mr Andrews said that Department of Economic Development, Jobs, Transport and Resources' Dr Amanda Caples had been appointed as Victoria's lead scientist and that Dr Gareth Goodier had been appointed Executive Chair of the Melbourne Biomedical Precinct in Parkville.

A media release from Mr Andrews said that the Medicines Manufacturing Innovation Centre would "provide Victoria's medicines manufacturers with access to specialist scientific capabilities to solve technical challenges and encourage investment in research and development, high-tech manufacturing, skills development and collaboration ... [and] offer internships with manufacturing companies to provide students with industry experience".

"Since 2010, more than 85 Monash [University] students have gained industry experience through internships at [Glaxosmithkline], all gaining employment within six months of graduation, the media release said.

"Victoria is leading the country as the centre of biotechnology, pharmaceuticals and medical technologies," Mr Andrews said.

"These industries are vital for our state's future, that's why we're actively driving them to grow the economy and create Victorian jobs," Mr Andrews said.

Mr Andrews told the conference that the Medicines Manufacturing Innovation Centre would be led by the Monash Institute of Pharmaceutical Sciences.

Mr Andrews said that Victoria had a low-risk, competitive environment for investment in life sciences with more than 50 percent of ASX-listed biotech companies headquartered in Melbourne, employing 21,000 Victorians and with CSL "in many respects a perfect example".

Mr Andrews said that the State provided "access to the brightest minds and the best scientists ... [who had] attracted 40 percent of all research fund to Victoria.

"We are pooling our collective energies to change and save lives".

Mr Andrews said that to do so could not be done in isolation.

"It requires collaboration and partnerships," Mr Andrews.

Ausbiotech chief executive officer Glenn Cross said that with more than 1,700 delegates from 38 countries and more than 255 speakers at the three parallel conferences, it was "the largest gathering of the Australian life sciences community ever".

Mr Cross said that the International Biotechnology Symposium and Exhibition would run from today to Thursday October 27, with the Ausbiotech Conference from today until Wednesday October 26 and the Australia Biotech Invest meeting on October 26 and 27, 2016.

Mr Cross said that Ausbiotech had more than 30 partners for the meeting led by the Victoria Government and CSL.

[CSL](#)

CSL chief executive officer Paul Perreault says that companies that fail to innovate and don't look through the prism of the patient should leave the industry.

In the opening address to the Ausbiotech Conference, Mr Perreault spoke about his company's history and the need for constant innovation, both in terms of drug research and company systems.

Under the title '100 years old and just getting started' Mr Perreault said that there were a range of disruptors to the status quo from changes in demography to competition, Brexit, elections, including the US election and health care reform.

"Unless you are innovating you should get on with planning your exit from the industry," Mr Perreault said. "We are constantly looking for ways to innovate, not just the science, but the structures and systems."

Mr Perreault said that companies needed to look beyond their horizons and "look for white space where your competitors are not".

Mr Perreault said that when the Commonwealth Serum Laboratories was established by the Federal Government in 1916, at the same time as Commonwealth Scientific and Industrial Research Organisation and The Walter and Eliza Hall Institute of Medical Research, its mission was to bring medicines to Australia and today its mission was to export medicines developed in Australia to the rest of the world.

He said that CSL's structure was hub and spokes, with the hub at Bio21 and the Parkville headquarters and the spokes reaching to its operations in the US, Germany and Switzerland.

Mr Perreault said that CSL expected to "double the number of scientists in the next few years" and if CSL was based in the US it would have to compete with Pfizer, Glaxosmithkline and Johnson & Johnson for graduates from the leading universities, but being based in Australia gave CSL an edge in finding talented staff.

Mr Perreault said that the \$1.25 million CSL Centenary Fellowships were deliberately designed for mid-career scientists as five year funding arrangements because that "allows scientists to do research rather than write grant proposals".

"We will award two fellowships a year over the next 10 years," Mr Perreault said.

"We have to give back and foster the people who do the research," he said.

Mr Perreault said that following privatization in 1994, CSL acquired the Swiss Red Cross in 2000 and Nabi Plasma in 2001 to expand the plasma supply later buying Aventis Behring in 2004 which was transformational for CSL, providing commercial access to the world and last year acquired the Novartis influenza business.

"These businesses were all in business that we know," Mr Perreault said.

"Some companies don't know what they're buying," Mr Perreault said.

"You have to pick the right things," he said.

Mr Perreault said that in terms of disruption no one predicted that a mobile telephone application could provide an electro-cardiogram and deliver it to a patient's cardiologist.

"We need visionaries to see 15 years ahead," Mr Perreault said.

But he said that it always came back to patients.

"Patients are the over-arching prism of what biotechs and pharmas should be looking through," Mr Perreault said.

Mr Perreault said that drugs were necessary and non-discretionary and patients were often treated symptomatically compared to the underlying disease.

"Listen to the patient community to find the white space," Mr Perreault said, describing the concept as "patientcentricity".

"Patient lives depend on the work we do," Mr Perreault said. "If that doesn't do it for you, go find a different industry."

AUSBIOTECH, FEDERAL GOVERNMENT

The chair of Innovation and Science Australia, Bill Ferris, said that the review of the R&D Tax Incentive found that the program was good but not great and could be improved. Mr Ferris told a packed room for the first Ausbiotech session on the Federal Government's National Innovation and Science Agenda that rorts had been uncovered, including some which were currently before the courts.

Mr Ferris said that Prime Minister Malcolm Turnbull was committed to the National Innovation and Science Agenda as a core belief with bipartisan support.

He said that Innovation and Science Australia was tasked with developing an Innovation and Science Plan 2030 and that apart from the R&D Tax review there had been a tax break-through for angel investors, along with co-investment based \$250 million Biomedical Translation Fund, "landing pads" and support for science, technology, engineering and mathematics.

Mr Ferris said that the 1.5 percent cut to the 45 percent R&D Tax Incentive was "not a surprise" despite the Greens and Labor previously blocking the measure.

Mr Ferris said that the review "did opine" on the issue and it was not made retrospective as originally planned, but the 1.5 percent cut to the program was "outside the review".

Mr Ferris said the fewer than 30 companies would be affected by the \$2 million R&D Tax Incentive cap.

Biotech Daily previously reported that 72 R&D Tax Incentive payments were less than \$2 million and 39 payments were more than \$2 million (BD: Sep 28, 29, 2016).

Mr Ferris referred to the incentive as "a tax subsidy" and said there were other programs that would compensate that loss, including the Biomedical Translation Fund.

He said that the review was within a context and was not just the six recommendations and industry could comment on the review.

Submissions close on October 28, 2016.

FEDERAL GOVERNMENT, MTP CONNECT

The Federal Government and the Medical Technologies and Pharmaceuticals Industry Growth Centre say they will provide \$7.4 million for 14 projects.

A media release from the Minister for Industry, Innovation and Science Greg Hunt said the Federal Government would invest the \$7.4 million over two years through MTP Connect "in dollar-matched, industry-led projects to boost competitiveness and productivity".

"These projects could also leverage as much as \$32 million of industry partner funds," the media release said.

MTP Connect said it received 38 applications from industry, research organisations and universities to share in the funding available, with a proposed \$90 million of matched funding coming from the sector.

MTP Connect said that it selected the projects that would deliver results on a national scale, have sector-wide impact and were aligned with its sector growth priorities.

The media releases said that the successful applicants were: the Australian Academy of Technological Sciences; The Bridge Program; Small Technologies Cluster Australia; Murdoch Children's Research Institute; Monash University with Commonwealth Scientific and Industrial Research Organisation; Melbourne's St Vincent's Hospital; Ausbiotech; Monash University; Cancer Therapeutics co-operative research centre (CTX); Clinical Oncology Society of Australia; Vaxine Pty Ltd; Flinders University of South Australia; the Centre for Entrepreneurial Research and Innovation; and Queensland University of Technology.

Full details are at: http://www.mtpconnect.org.au/Story?Action=View&Story_id=19.

BENITEC BIOPHARMA

Benitec says it will collaborate with Nantventures on a phase II gene-silencing asset for a solid tumor-based indication and appoint Dr Jerel Banks as a director.

Benitec said that it would place 19.99 percent of its shares worth \$2,622,871 to the Los Angeles, California-based Nant Capital LLC, an investment entity associated with Nantventures, and Dr Banks was Nantventures chief investment officer.

The company said that Nantventures was founded by Dr Patrick Soon-Shiong and was the private investment arm of Nantworks and California Capital.

Benitec said it would lead clinical development and preclinical evaluation of several assets and chief executive officer Greg West said the collaboration was “a very significant strategic engagement” returning the company to the clinic using its DNA-directed RNA-interference (ddRNAi) technology with Nantventures and “benefit from a strong shareholder who will be supportive and knowledgeable in our technologies”.

The company said it would issue Nant Capital 29,305,819 shares or 19.99 percent of its issued capital for a post-issue holding of 16.67 percent, priced at 8.95 cents a share and seek shareholder approval to issue Nant a further 29,305,819 shares, taking its holding to 28.57 percent with the funds to be used for the collaboration and existing programs.

The company said it would work with Nantworks to finalize a research and development plan and budget with a targeted date for an agreement by December 30, 2016.

Dr Banks said that Benitec had made “solid progress in an important area of scientific research and development that has the potential to improve the standards of care across many clinical indications for which the unmet need remains significant”.

“Our investment in Benitec demonstrates our long-term interest and confidence in the Benitec technology and vision for the business as it strives to find innovative single administration treatments for human disease using gene therapy,” Dr Banks said.

Benitec was up 3.7 cents or 39.8 percent to 13 cents with 2.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it will licence two early-stage oncology drug candidates targeting focal adhesion kinase from Cancer Research Technology, formerly licenced by Alchemia.

Amplia said the drug candidates targeted fibrosis and immune-oncology and were first developed by the Australian Cancer Therapeutics co-operative research centre (CTX).

In 2014, Alchemia licenced the focal adhesion kinase (FAK) inhibitor candidates from London's Cancer Research Technology for cancer (BD: Mar 5, 2014).

Today, Amplia co-founder and chief executive officer Dr Chris Burns said that “FAK is a target that is generating significant big pharma interest as a way of increasing the efficacy of existing immune-oncology products in a wide range of cancers”.

Amplia said that FAK was a non-receptor tyrosine kinase which played an important role in the development and spread of many malignancies, had emerged as a promising target in cancer therapy and might have an important role in the proliferation of immune cells in cancer, potentially amplifying the efficacy of other immune-oncology drugs in combination.

Amplia co-founder Dr Christian Behrenbruch told Biotech Daily the financial terms were “not disclosed but the term sheet was a commercially competitive term sheet and there was significant interest in the assets”.

“The FAK assets, originally developed by the highly-successful Cancer CRC, are extremely promising molecules that were crying out to be developed following the implosion of Alchemia,” Dr Behrenbruch said. “We expect to have completed an initial financing by end-year, in order to take these exciting assets into the clinic.”

Amplia is a private company.

ITL

ITL says it will launch its Donorcare Needle Guard 2 at the American Association of Blood Banks meeting in Orlando Florida, October 22 to 25, 2016.

ITL said that the first generation Donorcare Needle Guard had been on sale for more than 15 years selling more than 200 million units in more than 50 countries and the Donorcare Needle Guard 2 provided “robust functionality with enhanced features including visual confirmation that the needle is safely locked in place, along with an audible click”.

The company said the Donorcare Needle Guard 2 allowed safe, fast needle withdrawal, shielding whole blood collection needles and providing users a high level of protection from potential biohazard exposure and needle-stick injury, was simple, user-friendly, required minimal training and manufacturers could pre-attach them to blood bag tubing. ITL executive chairman Bill Mobbs said it was “very rewarding to take a global industry standard product up to the next level”.

“As with all of our innovative products, Donorcare Needle Guard 2 was designed with end-user input from the beginning and we feel confident this product will be as successful as its predecessor,” Mr Mobbs said.

ITL was unchanged at 22.5 cents.

INVITROCUE

Invitrocue says it has a collaboration with the Cancer Therapeutics and Stratified Oncology Group at the Genome Institute of Singapore.

Invitrocue said that it and the Genome Institute would jointly conduct a pilot feasibility study using Invitrocue's cell-based three-dimensional scaffolding technology (Onco-PDO) to culture colorectal cancer organoids.

The company said the study aimed to grow and culture colorectal cancer organoids and once cultured, drugs would be applied through its high-throughput screening to ascertain effectiveness in treating colorectal cancer as a personalized guide to clinical intervention.

Invitrocue executive director Dr Steven Fang said that oncologists would be able to assess which drugs will have the greatest benefits for patients before they were administered, “a potential game changer in cancer treatment”.

Invitrocue was unchanged at seven cents.

GI DYNAMICS

GI Dynamics says that the Australian Therapeutic Goods Administration has cancelled the Endobarrier listing on the Australian Register of Therapeutic Goods (BD: Sep 14, 2016).

GI Dynamics said the TGA stated that it “failed to provide adequate evidence of compliance with certain provisions of the TGA Essential Principles within the required 20 working days” and cancellation took effect on October 12, 2016.

The company said it was not permitted to supply the Endobarrier device in Australia for use outside approved trials, but this did not constitute a recall, nor was the action a result of any direct safety concerns associated with the Endobarrier.

GI Dynamics said that all implanted patients could continue therapy subject to on-going evaluation and monitoring by their healthcare professionals and enrollment would continue for a current on-going randomized controlled trial on non-alcoholic steato-hepatitis that had been enrolling patients for 14-months, and it would continue supporting the trial.

GI Dynamics said that Australian revenue from Endobarrier sales comprised about 15 percent of worldwide revenue, but it would not appeal the TGA decision.

GI Dynamics fell 0.1 cents or 4.55 percent to 2.1 cents.

[INNATE IMMUNOTHERAPEUTICS](#)

Australian Ethical Investment says it has reduced its substantial shareholding in Innate from 18,730,924 shares (8.43%) to 16,291,784 shares (7.34%).

Australian Ethical said it sold shares between October 12 and 21, 2016 with the most recent sale 101,260 shares for \$73,454 or 72.5 cents a share.

In July, Australian Ethical bought and sold shares in Innate, with the largest acquisitions 4,503,867 shares for \$1,125,967 or 25 cents a share (BD: Jul 21, 2016).

Innate was up one cent or 1.4 percent to 73 cents.

[GENERA BIOSYSTEMS](#)

The Hunters Hill, Sydney-based Durbin Superannuation has increased its holding in Genera from 10,541,283 shares (10.58%) to 11,637,068 shares (11.58%).

The notice, signed by director Graham Durbin, did not disclose the cost of the shares, as required under the Corporations Act 2001.

Previous substantial shareholder notices from Mr Durbin also increased his holding without disclosing the cost of the shares (BD: Mar 3, 2015; Mar 3, 2016).

Genera was unchanged at 22 cents.

[RHINOMED](#)

Rhinomed says that chief financial officer and chief operating officer Justine Heath has resigned.

Rhinomed said that Ms Heath had been with the company for 18 months and it would begin a search for a chief financial officer and chief operating officer.

Rhinomed fell 0.1 cents or 5.3 percent to 1.8 cents.

[RACE ONCOLOGY](#)

Race says it has signed a consulting agreement with Prof Douglas Smith to advise on the clinical positioning and utility of Bisantrone for acute myeloid leukaemia.

Race said that Prof Smith was a professor of oncology at the Baltimore, Maryland-based Johns Hopkins Hospital and the hospital's Sidney Kimmel Comprehensive Cancer Centre.

The company said that Prof Smith held a Doctor of Medicine from the Medical College of Pennsylvania in Philadelphia and his research focused on leukaemia,

Race was up 1.5 cents or 6.4 percent to 25 cents.

[ANALYTICA](#)

Analytica says its product development manager Chelsea Cornelius has won the Medical Technology Association of Australia's outstanding achievement award.

Analytica said the award recognized "an individual who has contributed in a significant and outstanding way to the development of medical technology that improves patient outcomes and excellence".

Analytica was up 0.1 cents or 12.5 percent to 0.9 cents with 6.3 million shares traded.