



Biotech Daily

Monday May 25, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PRIMA UP 32%, PATRYS DOWN 14%**
- * **REGENEUS READY FOR PHASE I RGS4K TUMOR IMMUNOTHERAPY**
- * **AIRXPANDERS \$36.5m IPO FOR BREAST RECONSTRUCTION DEVICE**
- * **IQ3 RELATED-PARTY CRC IPO**
- * **PRIMA, DATABASE INTEGRATIONS COMMERCIALIZE CVAC SOFTWARE**
- * **BENITEC CONTRACTS OMNIA FOR TT-034 TRIAL MATERIAL**
- * **CYNATA RECEIVES \$281k FEDERAL R&D TAX REFUND**
- * **QRX IN VOLUNTARY ADMINISTRATION**
- * **TISSUE THERAPIES TO LOSE 12-YEAR CHAIRMAN ROGER CLARKE**
- * **DR ELAINE SAUNDERS, DR MEGAN BALDWIN BIO-MELBOURNE GONGS**
- * **BIONICS INSTITUTE, PROF MARK DODGSON INNOVATION LECTURE**

MARKET REPORT

The Australian stock market climbed 1.0 percent on Monday May 25, 2015 with the S&P ASX 200 up 56.8 points to 5,721.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 12 were unchanged and two traded unchanged.

Prima was the best, up 2.9 cents or 31.9 percent to 12 cents with 80.0 million shares traded, followed by GI Dynamics up 11.5 percent to 14.5 cents with 464,978 shares traded.

Benitec climbed 7.8 percent; Viralytics was up 6.1 percent; Antisense and Atcor rose more than four percent; Circadian was up 3.3 percent; Genetic Technologies, Mesoblast and Starpharma rose two percent or more; Bionomics, Clinuvel, CSL, Resmed and Tissue Therapies were up one percent or more; with Impedimed up 0.55 percent.

Patryst led the falls, down 0.2 cents or 14.3 percent to 1.2 cents with 4.5 million shares traded. Universal Biosensors lost 7.8 percent; Anteo and Oncosil fell more than four percent; Admedus shed 2.7 percent; Acrux, Actinogen, Living Cell, Psivida, Resmed and Sirtex were down more than one percent; with Cochlear and Nanosonics down by less than one percent.

REGENEUS

Regeneus says it has ethics approval for a 21-patient, open label, first in-human, phase I dose escalating study of its RGS4K vaccine for advanced cancers.

Regeneus said that the single-centre Activate study at the St Leonards, Sydney-based private hospital the Northern Cancer Institute would evaluate the safety, tolerability and preliminary efficacy of RGS4K, which was produced from a patient's own cancer cells and combined with a proprietary immuno-stimulant to activate the immune system against the cancer cells to initiate a body-wide response.

The company said that the immune system's memory should recognize and respond to both existing and new tumors.

Regeneus said that in canine trials, working with the Bill Walsh Translational Cancer Research Laboratory at Royal North Shore Hospital, the vaccines created using a dog's own tumor, resulted in the majority of treated dogs outliving the average expected survival time for their particular type of cancer.

Regeneus chief executive officer John Martin said the company was "hopeful that the success we have seen with the vaccine in treating a wide variety of cancers in dogs translates to humans".

The company said that cancer immuno-therapies were a treatment option without many of the side effects of standard chemotherapy, interfering minimally with most chemotherapeutic drugs making them likely helping agents to traditional therapies.

Regeneus said that the RGS4K vaccine was simple to manufacture and contained no live cancer cells.

The company said it had established a tumor bank so a patient's stored tumor sample could be used to produce an autologous cancer vaccine for use in the trial.

In this trial, adult patients with a variety of advanced cancer types will be treated using this revolutionary technology.

Regeneus said that suitable patients would have their tumor removed and stored prior to first-line treatment and if the patient relapsed and there are no other useful treatment options available, they would have a personalized vaccine produced from excised tumor, which would be injected at staged intervals and the patients monitored for a response.

The company said that the principal investigators were University of Sydney's Northern Clinical School medical oncologists Prof Stephen Clarke and Prof Nick Pavlakis.

Prof Clarke said the aim would be for the cancer to be stabilized and the tumor to shrink, leading to an extended life expectancy for the patient, similar to the canine research results.

Regeneus said that the cancer vaccine technology was developed at the Bill Walsh Translational Cancer Research Laboratory which is part of the Kolling Institute of Medical Research and was the research arm of the Royal North Shore Hospital's Medical Oncology Department.

"It's exciting to see world-class innovative cancer research done at the Kolling Institute translated into clinical application as a potential new therapeutic cancer vaccine," Prof Clarke said.

Regeneus said it had the exclusive worldwide rights to develop and commercialize the vaccine technology for human and veterinary applications.

Regeneus fell one cent or 7.4 percent to 12.5 cents.

AIRXPANDERS INC

Airxpanders says it expects to raise \$36.5 million in a fully-underwritten initial public offer at 50 cents per Chess depositary interest (CDI) for its breast reconstruction device.

The Delaware-incorporated and Paolo Alto, California-based Airxpanders said that following the offer, underwritten by Canaccord Genuity and expected to close on June 9, 2015, it would have a market capitalization of about \$113 million and have the equivalent of 225,176,142 CDIs on offer, with each US share equivalent to three Australian CDIs.

The company said that Aeroform tissue expander was used in breast reconstruction procedures following mastectomy to expand and stretch the skin and underlying muscle prior to the placement of a permanent breast implant.

Airxpanders said that tissue expansion through traditional saline-based expanders was described as an unpleasant, painful and time-consuming procedure, with patients needing to regularly attend the surgeon's office over a period of weeks or months to receive a series of saline injections through the breast region and into the tissue expander.

The company said that its Aeroform tissue expander was needle-free and activated by a patient-controlled wireless remote control unit and in clinical trials and commercial settings with Australian and US breast reconstruction surgeons Aeroform had been successfully used in more than 350 patients, providing needle-free, faster and less painful tissue expansion with a significantly reduced need for surgeon office visits.

Airxpanders said that Aeroform had Australian and European regulatory approval and a 150-patient, US Food and Drug Administration-approved, prospective, randomized, controlled, pivotal trial under an investigational device exemption, began in 2012.

The company said that the Xpand trial's "highly encouraging" preliminary results were published in May 2014, with final trial results expected in the middle of 2015 and it expected FDA clearance by the end of 2015.

Airxpanders said it aimed to commercialize Aeroform in the US in 2016 and its use was covered by existing reimbursement regimes in both Australia and the US.

The company said that the addressable market for tissue expanders was about 350,000 units a year.

Airxpanders chief executive officer Scott Dodson said that his company believed that "every woman deserves a comfortable, efficient breast reconstruction journey and the highest quality of life possible following a mastectomy and that Aeroform is the best innovation in tissue expanders in decades".

"As a result, we consider that Aeroform provides an attractive and compelling new alternative for this important patient group in a significant market," Mr Dodson said.

A copy of the prospectus is available at: <https://www.airxpandersipo.com/offer/home/>.

IQ3 CORP

IQ3 says its mandate to act as lead manager, corporate advisor and to raise capital for Clinical Research Corporation Pty Ltd has been extended to its initial public offer.

IQ3 said it would act as the lead manager and corporate advisor for the offer, conduct the capital raising and manage the offer's underwriting for Clinical Research Corporation, which was declared as a related party in the IQ3 prospectus (BD: Apr 23, 2015).

IQ3 chief executive officer Dr George Symmalis said that the Clinical Research Corporation business "goes well beyond a typical [contract research organization] and extends a solid and crystal clear value proposition to the medical affairs business units within the Australian bio-pharmaceutical industry".

IQ3 did not provide any further details regarding the offer.

IQ3 fell 3.5 cents or 6.3 percent to 52 cents.

[PRIMA BIOMED](#)

Prima says the Alpharetta, Georgia-based Database Integrations will commercialize its Ican CVac cellular therapy software platform for use in other cellular therapies.

Prima said that Ican was designed by Database Integrations to its specifications and commissioned in 2011 to handle, in a scalable architecture and with a high level of automation, all the electronic records and electronic signatures associated with labelling, manufacturing operations, distribution, logistics, communications and scheduling for immuno-cellular therapies like CVac.

In February, Prima closed its 10-year CVac program (BD: Feb 27, 2015).

Prima head of investor relations Stuart Roberts told Biotech Daily that if Database Integrations was able to commercialize the Ican system for other cellular therapies Prima would be entitled to a profit share and royalties.

The company said that Ican significantly contributed to making CVac an efficient and relatively low cost cellular therapy.

Prima said the two companies would work together to seek sub-licencees for the system.

Prima chief executive officer Marc Voigt said Database Integrations had been "a very reliable and knowledgeable partner for us as we took CVac from bench-top into mid-stage clinical trials, even though our people were in widely distributed time zones".

Database Integrations chief operating officer Jackie Littlefield said that "with cellular therapy being a new area of modern medicine and developers of new therapies now cognizant of the need to automate the complex processes as much as possible, we see potential for Ican to become an industry standard".

Prima climbed 2.9 cents or 31.9 percent to 12 cents with 80.0 million shares traded.

[BENITEC BIOPHARMA](#)

Benitec says the Rockville, Maryland-based Omnia Biologics will manufacture clinical material for its phase I/IIa trial of TT-034 for hepatitis C.

Benitec manufacturing vice-president Dr Claudia Kloth said that Omnia had a well-established manufacturing process for adeno-associated virus-based products comparable to that used to produce the material used for the TT-034 trial.

Benitec chief executive officer Dr Peter French said that the existing process for clinical material in the TT-034 trial was "adequate for our immediate requirements, [but] the process is not scalable".

"To supply the large markets Benitec is aiming for such as in hepatitis C and B, the company is moving to establish its own large-scale manufacturing process in collaboration with third parties and we will make further announcements about those developments as they occur," Dr French said.

Benitec climbed six cents or 7.8 percent to 82.5 cents.

[CYNATA THERAPEUTICS](#)

Cynata says it has received \$281,464 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cynata said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2014.

Cynata was up one cent or 1.1 percent to 95 cents.

QRX PHARMA

QRX says that Timothy Heesh and Amanda Lott of TPH Insolvency have been appointed as joint and several administrators.

The company said that director Dr Richard Treagus and Bruce Hancox reviewed the company halting all development of the Moxduo portfolio of products (BD: Aug 14, 2015). QRX said the directors examined what value could be recovered from the assets, but without results.

The company said its current funds were “insufficient to contemplate any form of future development of the QRX portfolio or take advantage of other business opportunities” and to move forward in any way would require additional capital.

QRX said the directors became aware of “certain historical matters that in our opinion may expose the company to liabilities arising from potential litigation”.

“Consequently we have reached a view that we are unable to introduce third party capital into QRX without disclosing this contingent liability, which in our view significantly increases the potential investment risk,” the directors said.

QRX last traded at 2.8 cents.

TISSUE THERAPIES

Tissue Therapies says that former chairman Roger Clarke will resign as a director effective on May 31, 2015.

Following extensive delays in European approval for Tissue Therapies Vitrogro wound therapy, chief executive officer Dr Steven Mercer left the company and Mr Clarke stepped down as chairman, replaced on an interim basis by Dr Cherrell Hirst (BD: Apr 7, 2015) .

Today Tissue Therapies said that Mr Clarke became the chair at listing and “provided strong leadership throughout [the company’s] journey to date and in addition provided considerable support as an investor”.

“The Board expresses its sincere thanks to Roger for his very significant contribution over the many years since 2003,” Dr Hirst said.

“He has supported [Tissue Therapies] through his leadership, his considerable experience and wisdom and his commitment of time and effort as well becoming a significant investor,” Dr Hirst said.

Tissue Therapies was up 0.1 cents or 1.5 percent to 6.9 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that Dr Elaine Saunders and Dr Megan Baldwin have won its inaugural women in leadership awards.

The Network said that Blamey Saunders chief executive officer Dr Saunders won the 2015 Women in Leadership Award and Circadian chief executive officer Dr Baldwin won the 2015 Emerging Women in Leadership Award.

Bio-Melbourne chief executive officer Dr Krystal Evans said the two were selected “because of their leadership in their fields of expertise, the contributions to the industry, their roles as mentors and to recognize those women who take strategic risks, tenaciously pursue goals and have made outstanding contributions to innovation in the industry”.

BIONICS INSTITUTE

The Bionics Institute says University of Queensland professor of innovation studies Prof Mark Dodgson will deliver the 2015 public lecture, next week, June 3, 2015.

The Institute said that Prof Dodgson would discuss the need for successful economies to innovate continually at the lecture to be held at the Melbourne Museum.

"For Australia to be internationally competitive we need to be extremely smart and exceptionally well connected in what and how we innovate," Prof Dodgson said.

"At present we are neither," Prof Dodgson said.

"Our efforts are relatively small scale and highly vulnerable and we suffer a chronic lack of leadership in the area," Prof Dodgson said. "Our poor connections between business and research are a particular concern."

"This lecture outlines the scale of the problem and discusses the business strategies and government policies necessary for innovation to flourish in a modern productive Australian economy," Prof Dodgson said.

The Bionics Institute said that Prof Dodgson was a visiting professor at Imperial College London, had researched innovation in more than 60 countries and produced 12 books and more than 100 articles on the subject.

The Institute said that Prof Dodgson was formerly a director of Nestlé Australia, Thiess, and advised companies and government agencies on innovation strategies.

The Bionics Institute said that Victoria Parliamentary Secretary for Medical Research Frank McGuire would open the lecture at the Melbourne Museum, Nicholson St., Carlton, on June 3, 2015 at 5:30pm for refreshments, with the lecture for 6pm to 7pm.

For more information go to: www.bionicsinstitute.org or contact Berenice Hale by telephone on +613 9667 7513.

The Institute said that the lecture was free, but seating was limited. RSVP to kcampitelli@bionicsinstitute.org by May 27, 2015.