



Biotech Daily

Friday November 14, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OPTISCAN UP 56%, NEUREN DOWN 8%**
- * **PROTEOMICS IPO TO RAISE UP TO \$6m**
- * **GSK INVESTS \$31m IN BORONIA BLOW-FILL-SEAL MANUFACTURING**
- * **ACRF GRANTS \$9m TO FOUR INSTITUTIONS**
- * **UK APPROVES VIRALYTICS PHASE I CAVATAK BLADDER CANCER TRIAL**
- * **CARL ZEISS PAYS OPTISCAN \$258k FOR ENDO-MICROSCOPE SHEATH**
- * **REGENEUS AUSTRALIAN PATENT FOR FAT STEM CELLS FOR ACNE**
- * **FLEXTRONICS TO EXPAND UNILIFE PRODUCTION**
- * **UP TO 15% OPPOSE IMMURON PLACEMENT CAPACITY, AGAIN**
- * **UP TO 20% OF PRIMA OPPOSE 24m DIRECTOR 'PERFORMANCE RIGHTS'**
- * **NZ PIE FUNDS TAKE 7% OF MEDICAL AUSTRALIA**
- * **SIMAVITA APPOINTS CRAIG HOLLAND DIRECTOR**

MARKET REPORT

The Australian stock market rose 0.21 percent on Friday November 14, 2014 with the S&P ASX 200 up 11.6 points to 5,454.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and three were untraded.

Optiscan was the best, climbing as much as 2.2 cents or 64.7 percent to 5.6 cents, before closing up 1.9 cents or 55.9 percent at 5.3 cents with 4.8 million shares traded, followed by Anteo up 13.6 percent to 12.5 cents, with 2.9 million shares traded. Genetic Technologies climbed 7.7 percent; Nanosonics was up 6.4 percent; Tissue Therapies was up five percent; Admedus and Clinuvel were up more than four percent; Impedimed and Medical Developments were up more than three percent; Viralytics rose 1.7 percent; with CSL and Sirtex up by less than one percent.

Neuren led the falls, down one cent or 8.3 percent to 11 cents with 10.5 million shares traded. Prana fell 7.7 percent; Ellex lost 6.25 percent; Benitec, Prima and Psivida fell more than five percent; Biotron fell 4.8 percent; Avita, Bionomics, Starpharma and Universal Biosensors shed more than two percent; Alchemia, Antisense, GI Dynamics and Mesoblast were down one percent or more; with Cochlear and Resmed down less than one percent.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it hopes to raise \$4 million to \$6 million in its initial public offer at 20 cents a share, to list on the ASX and expand its existing protein analysis-based business. In Melbourne to present to investors for the offer, Proteomics managing director Dr Richard Lipscombe and chairman Terry Sweet told Biotech Daily that the Perth, Western Australia-based company had revenues of about \$1 million a year from its existing analytical services and consultancy business.

Dr Lipscombe said that the company had an internally-developed, single platform technology, which enabled “industrial scale analyses of proteins”.

Dr Lipscombe said that the technology supported the provision of services and consultancy work as well as the development of new diagnostics and new therapies and the capital raising was intended to support all three arms of the business.

He said that Proteomics had a partnership with the University of Western Australia for the company’s first diagnostic, a test for diabetic kidney disease, and was in discussions with diagnostic companies and laboratories to roll-out the test.

Dr Lipscombe said that the company did not intend to conduct any clinical trials, undertaking protein diagnostic work and licencing tests and therapeutics to biotechnology and pharmaceutical companies to further develop.

He said that the company had signed an agreement with the Princeton, New Jersey-based contract research organization Inventiv Health Clinical.

“We do the front end testing and they do the back end,” Dr Lipscombe said.

Dr Lipscombe said that Proteomics had accreditation to conduct analyses and had targeted the bio-similar market where companies in India and several other countries were in need of drug characterization data for data packs for regulatory approval.

Dr Lipscombe said that recently the US Food and Drug Administration had announced that it required more analytical testing which would benefit his company.

Dr Lipscombe said that if Vioxx had a companion diagnostic when it was first launched it might have been saved much of the safety and regulatory trouble it later faced.

In a presentation for the offer, Proteomics said that along with Mr Sweet and Dr Lipscombe, the other directors were co-founder Dr Bill Parker and John Dunlop, with Chuck Morrison the head of business development.

The Proteomics offer opened on November 3 and will close on November 28, with the company hoping to list on the ASX under the code PIQ by December 16, 2014.

Mr Sweet said that in four months a “loyalty option” program would offer a one-for-four option issue at one cent per option exercisable at 20 cents an option within three years.

The prospectus is available at: <http://www.proteomicsinternational.com/prospectus/>.

GLAXOSMITHKLINE AUSTRALIA

Glaxosmithkline says it will invest \$31 million in “next generation manufacturing technology” at its Boronia site in Melbourne’s eastern suburbs.

Glaxosmithkline said that the expansion would include the introduction of the latest high speed blow-fill-seal machinery developed for advanced aseptic packing of sterile pharmaceutical liquids.

The company said that blow-fill-seal manufacturing had been a focus for the Boronia facility for 25 years, with the site providing developed and emerging markets with high quality, low cost pharmaceutical products.

Glaxosmithkline said the new machine would be dedicated to the manufacture of Ventolin (salbutamol sulfate) nebulas for asthma, would meet increased demands from emerging markets in China, Turkey and Brazil and was expected to be operational in January 2016.

AUSTRALIAN CANCER RESEARCH FOUNDATION

The Australian Cancer Research Foundation has provided \$9 million in grants to four institutions taking the total in grants over 30 years to more than \$100 million.

The Foundation said that the University of Queensland Centre for Advanced Imaging was awarded \$2.5 million to purchase hybrid digital imaging technology for both humans and companion animals with cancer.

The Foundation said that Melbourne's Walter and Eliza Hall Institute was granted \$2.5 million to build a breakthrough technologies laboratory to analyze genetic mutations that drive cancers at the individual cell-level.

The ACRF said that the University of Sydney Central Clinical School was awarded \$2.5 million for radiotherapy technology to increase cure-rates while decreasing the cost and side effects of radiotherapy.

The Foundation said that the Sydney Children's Cancer Institute was awarded \$1.5 million to develop a national precision medicine platform to individualize the therapy for high-risk children that had relapsed from current treatments and provide new treatment alternatives.

VIRALYTICS

Viralytics says it has final UK approval for its two-part, phase I trial of Cavatak for non-muscle invasive bladder cancer or superficial bladder cancer.

Viralytics said that the UK Medicines and Healthcare Products Regulatory Agency approved the open-label, dose-escalation study in up to 50 patients, designed to evaluate the safety and tolerability of Cavatak (Coxsackievirus 21) administered alone, as well as in combination with the standard chemotherapy, mitomycin C, in patients with non-muscle invasive bladder cancer.

The company said the trial was expected to begin by April 2015 and investigators would examine the pharmaco-dynamics of Cavatak as well as document any evidence of anti-tumor activity.

Viralytics said that the Cavatak in non-muscle invasive bladder cancer (Canon) study, would be undertaken by University of Surrey Cancer Research Institute director Prof Hardev Pandha as part of the Institute's collaboration investigating Cavatak's oncolytic activity in bladder cancer.

The company said that the first part of the trial (VLA012A) would evaluate safety and tolerability of Cavatak alone in up to 20 patients as well as pharmaco-dynamics, with the second part of the trial (VLA012B) in up to 30 patients, investigating the safety and tolerability of Cavatak in combination with mitomycin C and establish a recommended phase II dose.

Viralytics said that biopsies of tumor tissue would be taken in both the first and second stage of the trial to assess the response to Cavatak administration.

The company said that its cancer immunotherapy, based on a cold virus that preferentially infected and attacked cancer cells, in combination with mitomycin C "synergistically enhanced the cancer-killing activity in bladder cancer cell lines".

"Based on the significantly increased oncolytic activity of the Cavatak [and] chemotherapy combination observed in bladder cancer cell cultures, we are excited to further explore this treatment in human trials," Prof Pandha said.

Viralytics chief executive officer Dr Malcolm McColl said the approval was "a significant milestone".

Dr McColl said that Viralytics was developing Cavatak as a treatment for a variety of cancers, including late-stage melanoma, prostate and lung cancer.

Viralytics was up half a cent or 1.7 percent to 30 cents.

OPTISCAN

Optiscan says it has received a milestone payment of EUR180,000 (\$A257,842) from Carl Zeiss for its endo-microscope disposable sterility sheath development.

Optiscan said that the payment marked “the critical downstream progression of this project following the successful completion of testing announced in August” (BD: Aug 27, 2014).

The company said that the sheath development upheld its “philosophy of a no compromise development of the highest quality, functional and enduring products”.

Optiscan said that the sheath would be integrated with its stand-alone rigid endo-microscopy system for neurosurgery, providing real time, high resolution tissue imaging at a cellular level.

The company said that it was refining its US Food and Drug Administration submission.

Optiscan climbed 1.9 cents or 55.9 percent to 5.3 cents with 4.8 million shares traded.

REGENEUS

Regeneus says the Australian Patent Office has granted a patent entitled ‘Therapeutics for skin conditions’ protecting its stem cell secretions technology for acne.

Regeneus, which derived its stem cells from adipose or fat tissue, said it was its first patent granted in Australia.

The company said that its secretions technology used the molecules, including cytokines and growth factors, that were secreted by mesenchymal stem cells and it had developed technology and protocols for the production of secretions from mesenchymal stem cells.

Regeneus said that the therapeutic value of mesenchymal stem cells was due to the secretions and that when the secretions were applied to skin, there was a localized anti-inflammatory effect, an acceleration of healing and a reduction in scarring.

The company said it had produced a cream which was under investigation and safety testing that incorporated the cell secretions and was exploring partnering options for the commercialization of the secretions technology.

Regeneus chief scientific officer Prof Graham Vesey said that “a number of our patents are in the final stages of being granted in Australia and are progressing through the overseas examination process”.

“Our patent applications cover our product pipeline that includes our allogeneic and autologous stem cell products,” Prof Vesey said.

“The patent that has been granted is specific for the topical treatment of acne, however, we have additional patent applications in the pipeline that cover the use of the secretions technology for other skin conditions,” Prof Vesey said.

“A number of our patent applications were the subject of oppositions by companies in our sector ... [but] these oppositions have now been resolved and we expect these patents to be granted in the near future,” Prof Vesey said.

Regeneus was up 1.5 cents or 9.7 percent to 17 cents.

UNILIFE CORP

Unilife says it has an agreement with the San Jose, California and Singapore-based Flextronics to expand the production capacity and scale-up capability of its products.

Unilife said Flextronics would “support accelerating commercial demand from a multitude of pharmaceutical customers” for its injectable biologics, drugs and vaccines.

The company said that along with its own manufacturing facilities in York, Pennsylvania, Flextronics would be a secondary source of supply to Unilife and its customers.

Unilife was up 3.5 cents or 6.2 percent to 60 cents.

IMMURON

For the second year in a row, Immuron faced dissent against its additional share issue capacity.

Last year Immuron faced 26.1 percent dissent against the additional share issue capacity as well as a lower level of opposition to stock issues to directors and associated companies (BD: Dec 2, 2013).

Today the only strong opposition was against a resolution to approve additional capacity to issue shares with 207,298,321 votes (15.4%) against and 1,136,704,481 votes (84.6%) in favor.

All other resolutions, including a 40 to one consolidation and the remuneration report were passed with significantly wider margins.

Immuron's most recent Appendix 3B new issue announcement said the company had 2,995,662,120 shares on issue, meaning that the votes against the placement capacity amounted to 6.9 percent of the company, up from last year's 6.4 percent dissent, sufficient to requisition extraordinary general meetings.

Three resolutions issuing 8,750,000 shares to Grandlodge, 1,875,000 shares and 10,000,000 options to director Daniel Pollock and 10,000,000 options to director Stephen Anastasiou were each opposed by 60,145,128 votes with more than 189 million votes in favor.

In May, Grandlodge Pty Ltd and the Anastasiou Superannuation Fund became substantial shareholders in Immuron with the acquisition of 168,326,929 shares or 16.56 percent of the company (BD: May 7, 2013).

The remuneration report was opposed by 2.9 million votes with 238.12 million in favor, while resolutions to issues 2,604,167 shares and 20,000,000 options to chairman Dr Roger Aston, along with 5,000,000 shares and 10,000,000 options to the CFO Solution and the election of directors Mr Pollock and Mr Anastasiou were passed overwhelmingly. Immuron chief executive officer Amos Meltzer told Biotech Daily that the share and option issues were in lieu of cash.

Immuron was unchanged at 0.6 cents with 2.75 million shares traded.

PRIMA BIOMED

Up to 20.45 percent of Prima's annual general meeting voted against the grant of 24,044,117 'performance rights' and the issue of 900,000,000 placement shares. Prima said that 20,319,278 votes (20.45%) opposed the issue of 7,720,588 'performance rights' to director Pete Meyers "in lieu of cash remuneration for director's fees" with 79,040,546 votes (79.55%) in favor.

The issue of the 900,000,000 placement shares was opposed by a similar margin as was the issue of 16,323,529 performance rights to chief executive officer Marc Voigt and the approval of the placement capacity.

Other resolutions, including the remuneration report and the election of directors were passed by wider margins.

The company's most recent Appendix 3B new issue announcement said that Prima had 1,228,709,341 shares on issue, meaning that the largest opposition vote against Mr Meyers' rights of 20,319,278 shares amounted to 1.65 percent of the company, not sufficient to requisition extraordinary general meetings.

Prima fell 0.2 cents or 5.1 percent to 3.7 cents.

MEDICAL AUSTRALIA

The Auckland, New Zealand-based Pie Funds Management says it has become a substantial shareholder in Medical Australia with 10,092,190 shares (7.38%).

The substantial shareholder notice said that Pie Funds acquired the shares between October 3 and November 12, 2014 at prices between six and 10.5 cents.

Medical Australia was up 0.1 cents or 1.4 percent to 7.1 cents.

SIMAVITA

Simavita says it has appointed Craig Holland as an independent, non-executive director, effective immediately.

Simavita said that Mr Holland would also be appointed as chairman of the audit and risk committee.

The company said that Mr Holland was a former senior partner of the accounting firm Deloitte and was Deloitte Private's chief operating officer prior to his retirement in 2012 to pursue private business interests in the aged care sector.

Simavita said that Mr Holland was an executive director and owner of the Menarock Aged Care Services Group, which owned and operated 480 beds in nine facilities in Victoria and New South Wales and was a director of the Good Guys retail group, Kaldor Public Art Projects and Tarrawarra Museum of Art in Healesville Victoria.

The company said that Mr Holland held a Bachelor of Economics from Monash University and a Masters in Taxation from the University of New South Wales.

Simavita fell one cent or 1.7 percent to 57 cents.