Biotech Daily

Tuesday November 25, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CLINUVEL UP 8%, OPTISCAN DOWN 15%**

*** DIMERIX SHELVES IPO, PREPARES TO TREAT 1st KIDNEY PATIENT**

*** BENITEC LODGES APPEAL TO EUROPEAN PATENT DECISION**

*** MESOBLAST WELCOMES JAPAN STEM CELL ACT**

*** PHYLOGICA WINS EUROPEAN PHYLOMER LIBRARY PATENT**

*** SAFETY MEDICAL $5m FOR 3D MEDICAL IMAGING BACK-DOOR LISTING**

*** BVF PARTNERS, MARK LAMPERT TAKE 13% OF CIRCADIAN**

*** PACKER & CO INCREASES, DILUTED TO 9% OF CIRCADIAN**

*** ORTHOCELL 36% OPPOSE DIRECTOR MATTHEW CALLAHAN OPTIONS**

*** UP TO 12% DISSENT AT AVEXA AGM**

*** INVESTORS UNDERWRITE CYNATA'S EXPIRING OPTIONS**

*** BIOPROSPECT TO BECOME MEDIBIO, 'MATERIAL AGREEMENT' TRADING HALT**

*** GENETIC TECHNOLOGIES LOSES CEO ALISON MEW**

*** PROBIOTEC TO LOSE FOUNDING CEO WAYNE STRINGER**

MARKET REPORT

The Australian stock market fell 0.5 percent on Tuesday November 25, 2014 with the S&P ASX 200 down 27.0 points to 5,334.8 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and three were untraded.

Clinuvel was the best, up 35 cents or 8.4 percent to $4.50 with 38,893 shares traded. Starpharma climbed 6.25 percent; Avita was up 5.6 percent; Analytica was up 3.45 percent; Antisense and Psivida rose more than two percent; Alchemia and Resmed were up more than one percent; with Benitec up 0.7 percent.

Optiscan led the falls, down 1.2 cents or 15.4 percent to 6.6 cents with five million shares traded. Both GI Dynamics and Uscom lost 10 percent; Acrux fell 9.3 percent; Living Cell was down 5.1 percent; Admedus, Anteo and Biotron fell more than four percent; Cellmid, Medical Developments and Tissue Therapies were down more than three percent; IDT, Nanosonics, Oncosil, Phosphagenics and Prima shed more than two percent; Impedimed Mesoblast and Sirtex were down one percent or more; with Cochlear, CSL and Osprey down by less than one percent.

DIMERIX BIOSCIENCE

Dimerix expects to treat its first phase II proof-of-concept chronic kidney disease patient with its DMX200 combination drug by the end of 2014.
Dimerix executive chairman Dr James Williams said that the company had shelved its proposed initial public offer and was proceeding with a two-part trial, initially treating 10 to 15 patients for nephrotic syndrome, and evaluating them prior to approaching the US Food and Drug Administration to discuss an investigational new drug application for the second part of the trial (BD: Jun 4, Sep 29, 2014).
Dr Williams said that the combination of irbesartan and propagermanium was synergistic with the combination more effective than the component parts.
Irbesartan has been marketed as Avapro and propagermanium as Serocion.
Dr Williams said that the mechanism of action was to block two separate receptors, but the two molecules also interacted positively with each other.
Dr Williams said that the patient recruitment had begun at Melbourne's Austin Hopsital and the first patient was expected to be dosed by the end of the year, initially three times daily for one month and then escalating to higher doses and for longer durations.
He said the company was expecting to see a response within three months and complete the first part of the trial by mid 2015 and take the data to a meeting with the FDA.
Dr Williams said that the endpoint of the nephrotic syndrome trial was safety and a reduction of protein in patients' urine or proteinurea.
The second part of the 60 patient open-label trial would continue dose escalation and then apply a fixed dose regime.
Dr Williams said that the DMX200 combination reduced proteinurea with a measurable inflammatory response and protection of the kidney's podocyte filtration cells.
He said that the company had sufficient funds to complete the first part of the trial as well as pharmaco-kinetic and other pre-clinical studies to take a data pack to the FDA, but would need to raise more funds to complete the trial.
Dr Williams said that DMX200 was identified using its g-protein coupled receptor heteromer identification technology (GPCR-HIT) platform technology that determined synergistic reactions between g-protein coupled receptors.
He said that the technology had identified a preclinical pipeline of diabetic retinopathy, multiple sclerosis and cancer fatigue.
Dimerix is a public unlisted company.

BENITEC BIOPHARMA

Benitec says it has filed a statement of appeal with the European Patent Office against the Office's revocation of the Graham EP patent 1555317 (May 23, Sep 22, 2014).
Benitec chief executive officer Dr Peter French said that Benitec and the Commonwealth Scientific and Industrial Research Organisation worked closely on the statement and were confident that it provided strong grounds for the Graham patent to be reinstated in Europe.
Dr French said that while Benitec and the CSIRO continued worked together to protect the foundation patents, Benitec was building its own intellectual property portfolio to protect its position in ddRNAi in general and in the pipeline programs under development.
Benitec said that the next Graham patent opposition, from Germany's BASF SE, for European patent 1624060 would be heard in Rijswijk, Netherlands, in early 2015.
Benitec counsel Sakura Holloway said the key difference between the two patents was the length of the expressed RNA but many of the arguments developed in the appeal for were relevant to the second Graham patent, with positive outcomes expected in both.
Benitec was up half a cent or 0.7 percent to 74.5 cents.

MESOBLAST

Mesoblast says that Japanese legislation establishing a framework for expedited approval for regenerative medical products takes effect today.

Mesoblast chief executive Prof Silviu Itescu said that the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act allowed for conditional approvals and the company intended to seek expedited approvals for its stem cell product candidates using clinical data generated to date, its intellectual property and manufacturing know-how.

Mesoblast said that the Act allowed for conditional product approvals based on existing phase II results demonstrating probable efficacy and safety with bridging studies in Japanese patients, allowing sales of each product candidate for up to seven years.

The company said that conditionally approved products would be covered by health insurance and the approvals covered allogeneic cell therapy product candidates manufactured outside Japan, with full approval expected to require further studies.

The company said the Act would enable its cell therapy candidates to be available sooner to patients and achieve nearer term revenues in Japan ahead of other major jurisdictions.

Mesoblast said it had completed prioritization of lead product candidates based on assessment of commercial opportunity and feasibility in Japan and would leverage existing phase II clinical trial results for its leading product candidates.

The company said it had engaged with product development and commercialization experts in Japan and begun dialog with the Japanese regulatory authority and was in discussions with existing and potential commercialization partners.

Mesoblast fell four cents or one percent to $4.10 with 579,616 shares traded.

PHYLOGICA

Phylogica says it has been allowed a European patent application for synthetic Phylomer libraries, extending its core intellectual property claim until 2027.

Phylogica said that Phylomers were peptides derived from nature that bound to disease-associated target proteins to block interactions that promoted multiple diseases such as infectious diseases, cancer, autoimmune and heart disease.

The company said that a synthetic Phylomer library picked the best quality peptides, particularly those that had evolved over billions of years for the ability to bind targets, greatly reducing the number required to generate disease-specific binders, from billions of peptides for a conventional library to potentially less than 100,000 candidates.

The company said the ability to miniaturize a synthetic Phylomer library made them “ideal for incorporation into next generation micro-sensors in diagnostics” and a synthetic Phylomer library could be used as a universal biosensor to screen patient samples from blood, urine or saliva to detect diseases such as diabetes, cancer or infections.

The company said that samples came into contact with the sensor, generating a binding signature characteristic of a particular disease, enabling rapid diagnosis.

Phylogica chief executive officer Dr Richard Hopkins said the European patent was a “major barrier-to-entry to potential competitors and ensures Phylogica has a stake-hold in the rapidly growing fields of diagnostics and personalized medicine”.

Phylogica said the core patent covered methods of designing synthetic Phylomer peptide libraries based on the identification of parts of natural proteins that were predicted to form structures independently in solution when isolated from the parent protein from which they were derived, as well as methods for maximizing the diversity of such structures represented in the library, and the corresponding patent had been granted in other jurisdictions including the US and Japan.

Phylogica was up 0.1 cents or 6.7 percent to 1.6 cents.

SAFETY MEDICAL PRODUCTS

Safety Medical says it hopes to raise a minimum of $3 million and up to $5,000,000 at five cents a share to acquire 3D Medical and rename the company 3D Medical.
Safety Medical said that 3D Medical had twin technology platforms of three-dimensional printing and holographic projection.
The company said that the public offer incorporated a priority offer of up to 40,000,000 shares to eligible shareholders of Capitol Health; 8,750,000 shares to the facilitators; and 175,000,000 shares to the vendors as part of the acquisition of all of the shares in 3D Medical, as well as 116,432,447 consideration options to 3D Medical vendors.
Safety Medical said that its business model had "historically been the development of the Securetouch syringe.
In 2012, Safety Medical said it would allow its syringe patents to lapse and would go gold mining in Brazil (BD: Jun 15, 2012).
Today the company said that following completion of the 3D acquisition, the focus would be to sell 3D anatomical models, hardware and software that delivered holographic images and other emerging technologies to radiology providers, hospitals, health insurance companies and surgeons.
Safety Medical said that the chairman was Peter Christie, with directors, Stephen Hewitt-Dutton and Simon Jenkins Director.
The company said it intended to appoint Matthew Morgan and Frank Pertile as directors and Mr Christie and Mr Jenkins will resign from the board.
Safety Medical said that the priority offer record date was December 1, the offer would open on December 2 and close on December 19, 2014.
The company said that a prospectus was available at: www.3dmedical.com.au or www.safemed.com.au.
Safety Medical was untraded at 0.4 cents.

CIRCADIAN

BVF Partners and Mark Lampert say they have become substantial shareholders in Circadian with 19,428,572 shares (13.12%).
The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert became substantial through participation in the company's $17.4 million placement and rights issue at 17.5 cents (BD: Oct 6, Nov 6, 2014).
In September BVF Partners and Mark Lampert increased their substantial holding in Viralytics to 22,931,933 shares (12.46%).having become substantial through the company's placement (BD: Mar 13, 14; Jun 11, Sep 10, 2014).
Circadian was untraded at 16 cents.

CIRCADIAN

Packer & Co of Cottesloe Western Australia has increased its substantial shareholding but been diluted in Circadian from 7,724,421 shares (17.07%) to 12,700, 488 shares (8.58%).
Packer & Co said it bought shares on-market and participated in the recent placement and rights issue.

ORTHOCELL

The Orthocell annual general meeting voted strong dissent against the grant of 400,000 options to director Matthew Callahan.
The resolution was opposed by 5,372,690 votes (36.3%), with 9,418,053 votes (63.7%) in favor, while resolutions to grant similar numbers of options to other directors were opposed by more than 730,000 votes but supported by more than 14 million votes, with the re-election of directors Mr Callahan and Prof Lars Lidgren unopposed.
The company's most recent Appendix 3B new issue announcement said that Orthocell had 78,980,000 shares on issue at the time of the meeting, meaning that the votes against Mr Callahan's options amounted to 6.8 percent of the company, sufficient to requisition extraordinary general meetings.
Orthocell fell half a cent or 1.2 percent to 42 cents.

AVEXA

Avexa's annual general meeting passed all resolutions, but with up to 12.2 percent opposition to the remuneration report.
Avexa said that 26,712,603 votes (12.2%) opposed the adoption of the remuneration report, with 191,969,172 votes (87.8%) in favor.
The company's most recent Appendix 3B said that Avexa had 925,650,566 shares on issue meaning that the opposition to the remuneration report amounted to 2.9 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.
The re-election of chairman Iain Kirkwood, an amendment to the constitution and approval of the 10 percent placement facility passed by a slightly wider margin.
Avexa was unchanged at 1.5 cents.

CYNATA THERAPEUTICS

Cynata says that sophisticated investors will underwrite the conversion of its outstanding CYPO listed options expiring on December 31, 2014.
Cynata said that including options already exercised, the transaction meant the company would receive proceeds of $2.9 million.
The company said that the underwriters were Ardroy Securities, Nesoi Investment Management and Jackie Au Yeung and would be paid a fee of two percent, for a total aggregate consideration of $42,488.
Cynata was up 6.5 cents or 17.6 percent to 43.5 cents.

BIOPROSPECT

Bioprospect says it has formally changed its name to Medibio and expects its ASX code to change to MBB in due course.
Separately, Bioprospect requested a trading halt for "a material agreement".
Trading will resume on November 27, 2014 or on an earlier announcement.
In recent months, Bioprospect's major shareholder Leo 'The Gun' Khoury has reduced his holding below substantial and the company has dropped its previous technologies including Termilone anti-termite treatment, the Solargran pine needle extract for horses and the Frontier oil and gas development, for a circadian rhythm heart-rate diagnostic for depression and other mental illnesses (BD: Nov 19, 2012; Jan 22, Sep 16, Nov 5, 2014).
Bioprospect was untraded at 0.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that chief executive officer Alison Mew will resign effective from December 31, 2014 for personal, health-related reasons.

Genetic Technologies chairman Dr Mal Brandon said the board was “extremely disappointed to have to announce Ms Mew’s resignation and though regretful, the board fully understands and supports her decision to step down”.

Dr Brandon said that the board “wishes to express its thanks and gratitude to Ms Mew for her dedication, commitment and contribution during her time with the company”.

“Ms Mew has played a key role in the establishment of the company’s US operations along with securing the Australian laboratory’s US compliance and most recently the successful launch of the second generation breast cancer risk assessment test, Brevagenplus,” Dr Brandon said.

Genetic Technologies said that, effective immediately, chief financial officer Eutillio Buccilli had been appointed chief operating officer and chief financial officer, with Phenogen Sciences senior vice-president of sales and marketing Mark Ostrowski assuming the role of president of Phenogen.

The company said it would begin a search for a new chief executive officer.

Genetic Technologies was unchanged at 1.4 cents.

PROBIOTEC

Probiotec says that founding chief executive officer and major shareholder Wayne Stringer will retire as chief executive officer in 2015.

Probiotec said it was founded in 1997 and was a manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, complementary medicines and specialty ingredients.

Probiotec chairman Max Johnston said that Mr Stringer’s “dynamic and tireless leadership has seen the company transform from a small dairy trading company into a leading and innovative pharmaceutical and healthcare supplier servicing many of the leading global healthcare players and bringing innovative research projects to market”.

The company said that it would “undertake a full review of [its] organizational needs”.

In his most recent appendix 3Y Change of Director’s Interest Notice, Mr Stringer said he held 8,950,786 shares, about 16.9 percent of the company.

Probiotec was up 1.5 cents or 5.6 percent to 28.5 cents.