Biotech Daily

Monday June 27, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRANA UP 7%; ATCOR DOWN 8%**

*** BOTANIX $3.5m TAKES BONE TO CANNABINOID DERMATOLOGY**

*** BARDA AWARDS AVITA FURTHER $11m FOR RECELL**

*** CLARITY, QUEENSLAND UNI, PHEBRA SHARE $2.5m CRCP GRANT**

*** PHARMAUST PREPARES FOR MONEPANTEL (PPL-1) DOG CANCER TRIAL**

*** CYCLOPHARM $336k FOR CANADA ASSOCIATION SUPPORT**

*** MGC RECEIVES $45k FOR CANNABIS COSMETICS**

*** REGAL FUNDS TAKES 10% OF PRESCIENT**

*** DIMERIX TO RELEASE 247m ESCROW SHARES**

*** ANATARA LOSES CEO PAUL SCHOBER, GAINS MIKE WEST, KYLIE DAVIS**

*** SOMNOMED APPOINTS JIM EVANGER US SUBSIDIARY CEO**

*** MGC LOSES DIRECTOR NICK CASTLEDEN**

MARKET REPORT

The Australian stock market recovered 0.47 percent on Monday June 27, 2016, with the ASX200 up 24.0 points to 5,137.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and one was untraded.

Prana was the best, up 0.7 cents or 7.1 percent to 10.5 cents with 252,564 shares traded. Compumedics was up 6.7 percent; Admedus and Genetic Technologies climbed more than five percent; Medical Developments, Neuren, Starpharma and Universal Biosensors were up more than three percent; Avita, CSL, Nanosonics and Orthocell were up more than one percent; with Acrux, Cochlear and Pro Medicus up by less than one percent.

Atcor led the falls, down one cent or 7.7 percent to 12 cents with 290,448 shares traded. Biotron lost 6.9 percent; Airxpanders was down 5.3 percent; Viralytics fell 4.7 percent; Antisense was down 3.2 percent; Actinogen, Benitec, Ellex, Prima and Uscom shed more than two percent; Impedimed, Living Cell, Mesoblast and Opthea were down more than one percent; with Resmed and Sirtex down by less than one percent.

BONE MEDICAL, BOTANIX PHARMACEUTICALS

Botanix chief executive officer Matt Callahan says the company has raised $3.5 million for its backdoor listing through Bone to develop its cannabinoid dermatology products.

Mr Callahan told Biotech Daily that the capital raising at two cents a share was over-subscribed and, subject to regulatory approvals, he expected the company to re-list on the ASX under the new code of BOT.

Mr Callahan said that with chairman Graham Griffiths and chief scientific advisor Dr Bill Bosch, the group company was on an investor road show to increase awareness of the company and it program.

Mr Callahan said that the entirely synthesized cannabinoid would be delivered through the Permetrex technology which he said helped push the active ingredient through the skin, with initial target indications named as acne, psoriasis and atopic dermatitis, also known as severe eczema.

He said that the technology employed “super-saturation” to drive the active ingredient through the skin.

Mr Callahan said the company hoped to begin an 18 patient, phase I, dose-escalation safety trial in Australia or the US by April 2017, with data by September 2017.

He said the safety trial would be followed by an 18-patient, phase Ib acne pilot trial by the end of 2017.

Mr Callahan said that the capital raised was expected to provide a runway that would take the company to the completion of the phase Ib trial.

Mr Callahan said that the company planned a phase II trial comparing BTX1503 for acne against a placebo, under an investigational new drug application to the US Food and Drug Administration, to begin by July 2018.

He said that Botanix planned a phase IIb trial comparing BTX1503 to an existing active drug for acne and finally a large phase III trial for US approval.

Mr Callahan said that BTX1503 for acne switched-off excess oil production, reducing sebum and inflammation, blocking cell proliferation and reducing infection.

Mr Callahan said that the company’s pipeline included BTX1308 for plaque psoriasis and BTX1204 for atopic dermatitis.

He said that all three contained the same cannabinoid active ingredient in different Permetrex formulations aimed at each specific indication.

Mr Callahan said that the Permetrex technology was developed by Dr Gene Cooper, who was formerly with Proctor and Gamble and Elan Corporation in Dublin, Ireland and in Philadelphia, Pennsylvania.

He said that the company was based in Philadelphia with trials conducted in Australia.

Mr Callahan said that during the next 12 months, the company would undertake further pre-clinical studies including toxicology and completion of manufacturing and testing.

Mr Callahan said that the synthetic cannabinoid in the Permetrex delivery system had multiple applications including melanoma and other skin diseases.

Mr Callahan said that Bone Medical’s executive chairman Robert Towner would continue as a director of Botanix.

In presentation materials, Botanix said that the US acne market was worth $3 billion a year with 50 million people with acne and no new drugs approved since 2005.

Bone was created by Proxima investors, licencing oral peptides for osteoporosis and from Proxima subsidiaries, with Proxima co-founder Dr Roger New formerly Bone’s chairman (BD: Jul 11, Sep 22, 2011; Jan 29, Apr 4, May 12, Jun 20, 2014).

In 2014, Bone terminated the agreements with Proxima as it was “not in the commercial interests of the company to continue with Proxima” (BD: Nov 19, Dec 9, 2014).

Bone was in a suspension.

AVITA MEDICAL

Avita says that the US Biomedical Advanced Research and Development Authority has provided a further $US7.96 million ($A10.73 million) for Recell operations.
Avita said that funds would provide operational support to develop its treatment of burn injuries “secondary to detonation of a nuclear device”.
The company said that the funds would support work towards filing a pre-market application with the US Food and Drug Administration, along with initiatives to gain familiarity and acceptance of Recell within US burn centres, including health economic modelling of the benefits associated with Recell, continuing engagement with burn centres under its open investigational device exemptions for treating burn injuries including extensive burns associated with compassionate use.
Avita said the funds would assist in the recruitment of personnel at its Northridge, California office, for regulatory, supply chain, quality systems, clinical support and reimbursement roles.
Avita said the funds would supplement the Biomedical Advanced Research and Development Authority (BARDA) contract worth up to $US53.9 million, announced last year (BD: Sep 30, 2015).
Avita chief executive officer Adam Kelliher said the “non-dilutive capital to fund our activities in the US, which we would otherwise have had to fund ourselves, greatly supports Avita Medical on its commercial journey”.
Avita said the initial BARDA contract funded its FDA approval trial, in which all treatments had been completed, with patients to be observed for a 52-week safety period.
The company said that as well as an initial procurement of 5,000 devices, the contract also funded an education programme, so that burns surgeons across the US would be trained as well as supplied with the medical devices, should there be a mass casualty event involving numerous burn injuries.
Avita said that the procurement order could be placed prior to FDA approval based on the possibility for deployment of Recell devices under an emergency use authorization.
The company said it expected FDA approval by October 2017.
Avita was up 0.1 cents or 1.1 percent to 9.2 cents.

CLARITY PHARMACEUTICALS, UNIVERSITY OF QUEENSLAND, PHEBRA PTY LTD

Clarity says it has won a $2,513,000 Federal cooperative research centres projects grant, in partnership with the University of Queensland and Phebra Pty Ltd.
Clarity said the funds would build a competitive site for clinical trials in nuclear medicine and would focus on a phase I/IIa trial in childhood cancer using Sartate.
The company said the grant would help develop Sartate in a second indication, following its successful work in adults with neuroendocrine tumors and a second pipeline product, a radiopharmaceutical for prostate cancer.
Clarity said the funds would be used to develop products and train scientists in product development at the University of Queensland’s Centre for Advanced Imaging.
The company said that the Sydney-based Phebra was a specialty pharmaceutical company, which would contribute its experience in drug formulation, manufacture, regulatory compliance and product sales.
Clarity chief executive officer Dr Matt Harris said the grant would help increase the company’s focus “on other fields of unmet need such as paediatric cancer, an area of medicine where we believe imaging, precision medicine and tailored therapy can play a significant role in improving outcomes for these kids”.
Clarity is a private company.

PHARMAUST

Pharmaust says the University of Cambridge's Dr Jane Dobson will oversee and evaluate the role of monepantel, formerly PPL-1, for canine cancers.

Pharmaust said that the appointment of Dr Dobson from the University of Cambridge's Department of Veterinary Sciences followed the signing of a materials transfer agreement.

The company said that the phase II trial would enrol dogs who failed standard of care and followed the Sydney phase I trial by Dr Angela Frimberger (BD: Jun 17, 2015).

Last year, Pharmaust said PPL-1 had "significantly suppressed a key cancer marker in two dogs evaluated" and was safe and well tolerated by all 11 dogs treated in its trial.

The company trialled PPL-1 in combination with carboplatin in two dogs with cancer and said that neither dog suffered any adverse events despite both having progressive, advanced cancers and few treatment options, with one dog, treated with 5mg/kg PPL-1 in addition to carboplatin, having stable disease for a short period (BD: Jul 16, 2016).

Today, the company said it had a research and option agreement with Novartis Animal Health and the study was important for the potential of monepantel in veterinary cancer.

Pharmaust said that to overcome poor palatability of the drug it had arranged for the manufacture of 20,000 capsules of reformulated monepantel by the Nottingham, England-based Juniper Pharma Services for trial in humans and dogs.

Pharmaust was up 0.2 cents or 2.5 percent to 8.3 cents.

CYCLOPHARM

Cyclopharm says a $C325,000 ($A336,224) five-year partnership with Canada's Association of Nuclear Medicine will promote Technegas and its use in lung imaging.

Cyclopharm said it would provide the Association with $C35,000 ($A36,192) a year during the next five years and in-kind support over the next three years' worth $C150,000.

The company said that the partnership was consistent with its objectives of developing the US market for Technegas for functional lung ventilation imaging agent, following expected regulatory approval and expanding the use of Technegas across the company's existing 55 established markets as well as other new markets and clinical applications to include chronic obstructive pulmonary disease, asthma, pulmonary hypertension and lung cancer.

Cyclopharm said it would assist the Association to promote appropriate and safe nuclear medicine services across Canada and to position the Association as a major educator and contributor to the development of nuclear medicine in the rest of the world.

The company said that the Association would advocate the use of nuclear medicine in the diagnosis and follow-up of pulmonary embolism based on clinical best practices, particularly those endorsed by the European Association of Nuclear Medicine, which endorsed Technegas for functional lung ventilation imaging.

Cyclopharm said that the Association would advocate peer reviewed, validated clinical trials and evidence-based guidelines on the use and benefits of nuclear medicine imaging in applications beyond pulmonary embolism, such as chronic obstructive pulmonary disease, asthma, pulmonary hypertension and lung cancer and would develop educational programs promoting clinical nuclear medicine best practice for lung ventilation and perfusion imaging across Canada and the US following Technegas approval.

Cyclopharm chief executive officer James McBrayer said the Association's "leadership and clinical advocacy demonstrated through education and activism in support of the practice of nuclear medicine is an example for the rest of world to follow".

"Given the level of passion and expertise demonstrated by its members, it is no coincidence that Canada is our largest single market for Technegas," Mr McBrayer said.

Cyclopharm climbed 6.5 cents or 7.8 percent to 89.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has received its “first material revenues” from its distribution deal with California’s C&M CBD Holding LLC.

MGC said it had received a 10 percent deposit of EUR30,000 ($A45,000) from its first order of EUR300,000 ($A450,000) of MGC Derma Anti-Aging line of cannabidiol-based cosmetics products in California and the first year order was for more than 60,000 units of the cannabinoid anti-aging cosmetics with a contract value of about EUR1.2 million.

MGC was up 0.2 cents or 4.8 percent to 4.4 cents with 10.6 million shares traded.

PRESCIENT THERAPEUTICS

Regal Funds Management has become a substantial shareholder in Prescient with 16,976,352 shares or 9.90 percent of the company.

The Sydney-based Regal Funds said that it acquired the shares between May 23 and June 23, 2016 at nine cents a share and the registered holder was UBS Nominees.

In May, Prescient said it had raised $7.0 million in a two-tranche placement at 9.0 cents a share, with a further $3.4 million to be raised through a rights issue at the same price, which is currently underway (BD: May 18, 2016).

This year, Regal became substantial in Oncosil, Adherium and Airxpanders and in 2014 underwrote $1.4 million of Suda options (BD: Jul 1, 2014; Feb 10, Mar 31, Jun 14, 2016).

Prescient fell 0.2 cents or 2.35 percent to 8.3 cents.

DIMERIX

Dimerix says it will release 246,917,395 vendor consideration shares from voluntary escrow on July 3, 2016.

According to Dimerix most recent Appendix 3B, following the release of the escrow shares there would be 1,437,640,129 shares available for trading, with no more shares in escrow.

Dimerix was up 0.1 cents 14.3 percent to 0.8 cents with 43.8 million shares traded.

ANATARA LIFESCIENCES

Anatara says Dr Mel Bridges will replace chief executive officer Dr Paul Schober, with Dr Mike West appointed chief operating officer and Kylie Davis clinical trials manager.

Anatara said that Dr Bridges would take on the role of executive chairman and chief executive officer, replacing Dr Schober who was appointed chief executive officer in 2015 and promoted to managing-director in February (BD: Feb 24, 2015; Feb 8, 2016).

“We have a very close relationship with Paul and expect this to be a smooth transition, aided strategically by a number of new appointments and a generous notice period,” Dr Bridges said.

Anatara said Dr West would be appointed chief operating officer from July 1, 2016 and he had expertise in manufacturing, regulatory and drug launch scale-up with Smithkline Beecham, Alchemia and the University of Queensland Centre for Drug Design and Development and had been a member of the pharmaceutical subcommittee to the Australian Therapeutic Goods Administration drug evaluation committee.

The company said that Ms Davis was formerly a senior veterinary clinical research associate with animal health company Zoetis and had more than nine years experience coordinating and monitoring veterinary clinical studies, including trials in pigs, cattle, poultry and companion animals.

Anatara fell 10 cents or 7.4 percent to $1.25.

SOMNOMED

Somnomed says it has appointed Jim Evanger as the chief executive officer of its recently formed subsidiary Sleep Centres America Inc.

Somnomed said that Mr Evanger was previously American Sleep Medicine LLC chief executive officer which was “one of the largest chains of sleep centres in the US” treating more than 30,000 patients a year.

The company said that Mr Evanger’s mission would be to develop its direct-to-patient obstructive sleep apnoea treatment business, “in line with the business model successfully developed over the last three years by Simple Sleep Services in Texas and over which Somnomed obtained an exclusive licence in April 2016”.

Somnomed said that Mr Evanger would plan the roll-out and operation of its direct-to-patient sleep treatment centres in the US, recruit the team to implement the plan, with the aim to open the first five outlets by July 2017 and increase the outlets over the next three years to a minimum of 25 centres.

The company said that as a long term incentive, Mr Evanger would be entitled to 2.5 percent of the shares in Sleep Centres America vesting over four years.

Somnomed was up 11 cents or 3.4 percent to $3.33.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says that non-executive director Nick Castleden has resigned, effective from June 24, 2016, “to focus on other business interests”.

MGC said that Mr Castleden was appointed a director in May 2014.

The company said the board comprised executive chairman Brett Mitchell, managing-director Nativ Segev, executive director Roby Zomer and non-executive director Dr Ross Walker.