Biotech Daily

Monday August 15, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 17%, ACTINOGEN DOWN 11%**

*** QBIOTICS EBC-46 FOR SOLID TUMORS 'WELL-TOLERATED, EFFICACY'**

*** MEDLAB $4.4m OF UNDERWRITTEN $5.4m FOR CANNABIS PAIN TRIAL**

*** BLUECHIIP RIGHTS OFFER FOR $1.5m**

*** MMJ PREPARES PHASE II ISRAEL CANNABIDIOL PTL101 EPILEPSY TRIAL**

*** RECCE FINDS MAXIMUM 280mg/kg RECCE-327 DOSE FOR MICE**

*** MEDADVISOR, GLAUCOMA AUSTRALIA UNITE FOR DRUG ADHERENCE**

*** CVC WITHDRAWS BIONOMICS BOARD SPILL NOTICE**

*** DIMERIX PLEADS SCHULTZ, OLD NEWS, MEETINGS TO ASX 114% QUERY**

*** BOTANIX WELCOMES US DEA CANNABIS RESTRICTIONS**

*** MMJ APPOINTS CATHERINE HARVEY COO**

*** PHYLOGICA APPOINTS DR ROHAN HOCKINGS ALTERNATE DIRECTOR**

*** RACE JOINT CO SEC DAMON SWEENY RESIGNS**

MARKET REPORT

The Australian stock market was up 0.16 percent on Monday August 15, 2016 with the ASX200 up 9.1 points to 5,540.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 were unchanged and two were untraded. All three Big Caps fell.

Benitec was the best, up two cents or 17.4 percent to 13.5 cents with 412,401 shares traded, followed by Mesoblast up 11.15 percent to $1.795 with 3.4 million shares traded. Biotron climbed 7.8 percent; Uscom improved 6.9 percent; Living Cell was up 4.1 percent; Atcor, Compumedics and Viralytics were up more than three percent; IDT rose 2.4 percent; Anteo and Psivida were up more than one percent; with Medical Developments, Pro Medicus, Sirtex and Starpharma up by less than one percent.

Actinogen led the falls, down 0.7 cents or 11.1 percent to 5.6 cents with 645,151 shares traded. Prima fell five percent; Bionomics and Oncosil were down more than three percent; Cellmid and Orthocell shed more than two percent; Acrux, Airxpanders, Avita, Osprey and Pharmaxis lost more than one percent; with Cochlear, CSL, Impedimed, Nanosonics and Resmed down by less than one percent.

QBIOTICS

Qbiotics says its eight-patient phase I/II trial of EBC-46 for solid tumors has shown that the drug is well-tolerated by all patients with evidence of efficacy.

Qbiotics said that all tumors in treated patients was “shown by the appearance of bruising and initial tumor breakdown on the section of the tumor treated”.

The company said that the human response was “very similar to what has been seen in the successful veterinary studies with EBC-46 where full tumor destruction is noted”.

Qbiotics said that tumor types treated in the human trial to date were melanoma, squamous cell carcinoma, basal cell carcinoma and breast adenocarcinoma.

In 2013, the Yungaburra, Queensland-based Qbiotics said EBC-46 came from the North Queensland’s rainforest blushwood and “demonstrated remarkable anti-tumor properties in clinical treatment of cancer in companion animals” (BD: Jun 11, 2013).

Today, the company said that it had previously reported significant efficacy of EBC-46 in the treatment of mast cell tumors and soft tissue sarcomas in dogs.

Qbiotics said that the veterinary studies had progressed to pivotal trials in the US and UK for approval in the canine oncology market.

The company said the phase I/II trial was primarily being undertaken to examine the safety of EBC-46 and the study had an extension component.

Qbiotics chief executive officer Dr Victoria Gordon said that it was “still too early to draw substantive conclusions about the potential for overall success of EBC-46 as a treatment for humans”.

“However, these initial results, that are clearly showing potential for a good safety profile for the drug combined with early signs of efficacy in a range of tumor types, are very encouraging,” Dr Gordon said.

Dr Gordon said the company had agreement from the US Food and Drug Administration Center for Veterinary Medicine to progress EBC-46 to a final study on the treatment of canine mast cell tumors, which would involve 10 investigator sites and 120 cases for the treatment of canine mast cell tumors.

Qbiotics said that the dog study was “the final clinical step to commercial use of the product in the US for canine mast cell tumors” and the company was awaiting agreement from UK regulators to undertake a final canine soft tissue sarcoma study.

Qbiotics is a public unlisted company.

MEDLAB CLINICAL

Medlab says its fully underwritten rights issue at 30 cents a share has raised $4,396,947 of the hoped-for $5,361,150 and the underwriters will place the shortfall.

In July, Medlab said the principal use of funds would be to accelerate its research and development program and begin human trials using its cannabis-based pain management therapy (BD: Jul 18, 2016).

The company said at that time that its leading non-management shareholder Farjoy Pty Ltd had underwritten the issue of about 17,870,500 new fully paid ordinary shares, with Farjoy requesting that chief executive officer Sean Hall and chairman Michael Hall agreeing to limit their participation to $900,000 in shares to increase the company’s liquidity and the balance to be handled by lead manager Shaw and Partners.

Medlab said that the 3,214,010 shares shortfall would be taken up by the underwriter.

Medlab fell 1.5 cents or 3.5 percent to 41.5 cents.

BLUECHIIP

Bluechiip says it hopes to raise $1.51 million through a one-for-three non-renounceable rights offer at 2.25 cents a share.
Bluechiip said the funds would be used for the development and launch of technology with partner Genea Biomedx for assisted reproductive technologies, complete and convert current evaluation and development trials with pipeline partners in the US, EU and Asia and for corporate overheads.
The company said that the record date would be August 22, the offer would open August 25 and close of September 9, 2016.
Bluechiip fell 0.1 cents or 3.85 percent to 2.5 cents.

MMJ PHYTOTECH

MMJ says it expects to start an Israel-based, phase II trial of its cannabidiol PTL101 capsules for treating intractable epilepsy in children by the end of 2016.
MMJ said that PTL101 capsules contained organically derived, highly purified cannabidiol using its Gelpell technology.
The company said that its phase I study trial demonstrated the safety and performance of its Gelpell cannabidiol capsules (BD: Feb 11, 2016).
MMJ said that about 100,000 children in North America had treatment-resistant epilepsy, causing uncontrollable seizures and drug therapy was ineffective in the treatment of epileptic seizures for about 30 percent of intractable epilepsy patients.
The company said that “a number of currently available epilepsy drugs … [had] significant side effects including the impairment of a patient’s motor skills and cognitive abilities”.
MMJ said it was in the final stages of preparing for a phase II trial of PTL201 capsules for spasticity-related symptoms associated with multiple sclerosis.
MMJ was unchanged at 25.5 cents.

RECCE

Recce says two studies by its US independent contract research organization have shown 280mg/kg to be the maximum tolerated dose of its Recce-327 antibiotic in mice.
Recce said that a previous study showed that a 70mg/kg dose was efficacious against infections by Methicillin-resistant Staphylococcus aureus in mice (BD: May 25, 2016).
Today, the company said that the aim of each of the two recent tests was to determine the upper limit of dosing by injection, without stress from toxicity and a four-fold window was “twice that which we believe the [US] Food and Drug Administration typically considers safe”.
Recce said that the test was conducted on six groups of 10 mice each, with non-survival being due to death, which was not observed, or culling on the basis of greater than 25 percent weight loss, which occurred minimally or visual assessment of a mouse’s health deteriorating.
The company said that the second study showed that no mouse in a group of five showed any distress or significant weight loss with a daily dosing regime of 140mg/kg on each of five consecutive days and observation for a further 11 days.
Recce said it had reported “very good data for Recce-327 from the three tests which are the most common reasons for test drugs’ failure in early testing required by the FDA” with the drug candidate highly water soluble, not causing genetic toxicity, mutagenicity or cancer, a sufficiently wide window between efficacy and toxicity.
Recce fell half a cent or 1.85 percent to 26.5 cents.

MEDADVISOR

Medadvisor says it has an agreement with Glaucoma Australia to help improve medication adherence in patients with glaucoma.

Medadvisor said that Glaucoma Australia was “the peak not-for-profit patient support organisation for people living with glaucoma in Australia” and would promote its drug compliance platform to more than 300,000 Australians believed to have glaucoma.

The company said that glaucoma was the leading cause of irreversible blindness worldwide and could occur at any age, with risk increasing with age and expected to cost Australia $4.3 billion by 2025.

Medadvisor said that Glaucoma Australia would encourage glaucoma patients to use the Medadvisor platform which sends drug reminders to the patient’s pharmacist.

The company said it would collaborate with Glaucoma Australia to produce a series of patient education messages to be delivered through the Medadvisor platform to help improve medication adherence and understanding of the condition.

Medadvisor chief executive officer Robert Read said that improved medication adherence could lead to better health outcomes, such as delaying the onset of vision loss.

Glaucoma Australia national executive officer Geoff Pollard said glaucoma medication persistence was 56 percent by six months, reducing to 48 percent at one year and “any tool which can assist patients to better manage and understand their medication is welcome, and we believe Medadvisor is a great solution for patients living with glaucoma”.

Medadvisor was unchanged at 3.5 cents.

BIONOMICS

Bionomics says that the Sydney-based CVC has withdrawn its notice of intention to call a general meeting.

In March, CVC called for the removal of Bionomics chairman Graeme Kaufman and director Trevor Tappenden and Bionomics announced “a consultation process to consider the views of shareholders as to the governance arrangements and future direction of the company” (BD: Mar 16, 2016).

CVC said at that time that “under the stewardship of the incumbent board there has been a series of fundamentally flawed decisions which have led to a significant erosion in shareholder value, have been materially prejudicial to the company's current and in many instances longstanding and supportive shareholders and have displayed a lack of financial and strategic competence to the material detriment of all the company's stakeholders”.

In June, Bionomics appointed David Wilson and Peter Turner as directors and last week announced that chairman Graeme Kaufman would retire from the company at the end of this month (BD: Jun 16, Aug 8, 2016).

Mr Tappenden remains as a director.

Bionomics fell one cent or 3.5 percent to 27.5 cents.

DIMERIX

Dimerix has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 114.3 percent from 0.7 cents on July 27 to 1.5 cents today, August 15, 2016, and noted an increase in trading volume.

Dimerix said that it made four announcements between July 28 and August 1, and held investor meetings in Sydney, Melbourne and Perth between August 9 and 11, 2016.

Dimerix closed unchanged at 1.2 cents with 34.5 million shares traded.

BOTANIX PHARMACEUTICALS (FORMERLY BONE MEDICAL)

Botanix says that the US Drug Enforcement Agency has published a decision to keep cannabis and its constituent chemicals, including cannabidiol, as schedule 1 drugs.
Botanix said it was developing a synthetic cannabidiol for skin diseases and was preparing for its first human studies in acne with its lead product BTX1503.
The company said the DEA decision was a response to petitions requesting it reschedule cannabis from schedule 1, to be subject to less regulation and provide easier access.
Botanix said the DEA response followed a US Food and Drug Administration evaluation in consultation with the National Institute on Drug Abuse and said that scientifically valid and well-controlled clinical trials were the most appropriate way to conduct research on the medicinal uses of cannabinoids and the FDA approval process was the appropriate way to assess whether a cannabis product was safe, effective and had an accepted medical use.
Botanix executive director Matt Callahan said that the DEA decision "validates the development approach we are pursuing".
"The only way to secure marketing approval for a product that contains a chemical found in cannabis plant is to conduct well-controlled human trials and follow the well-established drug approval pathway and that is exactly what Botanix is doing," Mr Callahan said.
Botanix said it was undertaking manufacturing and testing activities of BTX1503 for acne product in the US and planned to conduct its first human trial by July 2017.
Botanix fell 0.4 cents or 9.1 percent to four cents.

MMJ PHYTOTECH

MMJ says it has appointed Catherine Harvey as chief operations officer, effective from September 1, 2016.
MMJ said that Ms Harvey would be based in Sydney and would work to design and deliver its commercial and regulatory strategy.
The company said Ms Harvey was an experienced pharmaceutical industry executive, most recently as Mundipharma Sydney's business development and corporate affairs director and as the Zurich Switzerland-based Nycomed's business development manager
MMJ said that Ms Harvey would receive 3,000,000 unlisted options, vesting in three tranches and exercisable at the 5-day volume-weighted average price prior to September 1, 2016 and within four years of issue.

PHYLOGICA

Phylogica says that Dr Rohan Hockings has been appointed as an alternate non-executive director for Dr Bernard Hockings.
Phylogica said that Dr Rohan Hockings managed "a special purpose acquisition fund within the health care sector".
Phylogica was up 0.1 cents or 7.1 percent to 1.5 cents with 2.5 million shares traded.

RACE ONCOLOGY

Race says that joint company secretary Damon Sweeny has resigned and Peter Webse will continue as the sole company secretary.
Race fell half a cent or 2.3 percent to 21 cents.