Biotech Daily

Monday December 14, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 9.5%, LIVING CELL DOWN 10%**

*** VIRALYTICS PLACEMENT RAISES $28m, SHARE PLAN FOR $4m MORE**

*** FDA APPROVES AVITA RECELL 'EXPEDITED ACCESS PATHWAY'**

*** ONCOSIL FILES FDA PANCREATIC CANCER IDE APPLICATION**

*** FDA ORPHAN DESIGNATION FOR DIMERIX DMX-200 FOR KIDNEY DISEASE**

*** IMUGENE DELAYED HER-VAXX GASTRIC CANCER TRIAL MOVES TO ASIA**

*** MINISTER PYNE, ISRAEL PM NETANYAHU TALK INNOVATION**

*** RESAPP 400-ADULT PATIENT TRIAL APPROVED**

*** COGSTATE $2.4m PHASE III CANCER TRIAL TESTING CONTRACT**

*** UBS AG BUYS, SELLS, BORROWS, RETURNS BELOW 5% MAYNE**

*** GOODBYE PROGEN, WELCOME TBG DIAGNOSTICS**

MARKET REPORT

The Australian stock market lost 2.01 percent on Monday December 14, 2015 with the ASX200 down 100.9 points to 4,928.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Neuren was the best, up one cent or 9.5 percent to 11.5 cents, with 1.7 million shares traded.

Atcor and Polynovo climbed more than seven percent; Compumedics was up 6.2 percent; Avita, Benitec and Uscom improved more than three percent; Osprey rose 2.4 percent; Acrux, Anteo, Ellex and Psivida were up more than one percent; with Impedimed and Medical Developments up by less than one percent.

Living Cell led the falls, down 0.5 cents or 10.4 percent to 4.3 cents with 580,596 shares traded. Oncosil lost 6.1 percent; Cellmid, Genetic Technologies and Viralytics fell four percent or more; Admedus, Clinuvel and Mesoblast lost more than three percent; Antisense, Nanosonics, Pro Medicus and Universal Biosensors fell more than two percent; Bionomics, Prima, Reva and Starpharma were down more than one percent; with Cochlear, CSL, Resmed and Sirtex down by less than one percent.

VIRALYTICS

Viralytics says it has raised $28 million to accelerate its Cavatak program and will offer a share purchase plan to raise a further $4 million

Viralytics said the placement was at 61.5 cents, a 5.2 percent discount to the five-day volume weighted average price to December 9, 2015, the same price as the share plan.

The company said that the share plan record date was December 11, the plan would open on December 17, 2015 and close on January 21, 2016.

Viralytics said that the New York-based Orbimed Advisors would become a substantial shareholder and existing shareholders including the Biotechnology Value Fund and other affiliates of BVF Partners participated in the placement.

The company said that Bell Potter Securities was the lead manager with Roth Capital Partners acting as the sole US placement agent.

Viralytics said that the funds would “enable the more rapid advancement of the clinical program” including the collaborative Storm study with Merck assessing Cavatak in combination with Keytruda in late stage bladder and lung cancer patients; completion of the Canon trial in patients with non-muscle invasive bladder cancer and potential extension into a phase II study; and the completion of melanoma patient studies assessing Cavatak in combination with checkpoint inhibitors, Keytruda and Yervoy.

The company said the funds would enable further trials including intravenous Cavatak in combination with a checkpoint inhibitor in melanoma patients and other cancer types.

Viralytics said the funds would be used to manufacture Cavatak and for working capital.

Viralytics fell three cents or 4.6 percent to 62 cents.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved its Recell burns treatment under the expedited access pathway.

Avita said that the pathway aimed to give patients more timely access to life-saving medical devices, while preserving the statutory standards of safety and effectiveness for pre-market approval.

The company said that Recell met the criterion that “the device may offer significant, clinically meaningful advantages over existing legally marketed alternatives.”

Avita said that the FDA’s Center for Biologics Evaluation and Research issued the designation and further discussions would resolve a data development plan for the extent of pre-clinical and clinical data to support the pre-market approval.

The company said that a strategic data development plan, combined with priority review, was expected to reduce the timeline to approval.

Avita said it had enrolled 26 of 30 patients for its FDA approval trial and prior to expedited access pathway approval, expected regulatory approval by October 2017, pending safety and effectiveness data, under a pre-market approval route.

Avita research and technology vice-president Andrew Quick said that the FDA’s decision “tallies with our view that Recell is a unique offering for helping burns victims, and as such, approval would be preferable sooner than later”.

Avita said that the FDA’s ‘Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions’ program was introduced in April and it was one of the first to achieve a designation of meeting the criteria and the program included involvement of FDA management and the use of a case manager.

Avita said the FDA had approved Recell for up to 24 compassionate use patients.

Avita was up 0.3 cents or 3.2 percent to 9.8 cents with 1.6 million shares traded.

ONCOSIL MEDICAL

Oncosil says that it has filed an investigational device exemption with the US Food and Drug Administration for its localized radiation treatment for pancreatic cancer.
Oncosil said that following the granting of the exemption it would begin a clinical trial to support its pre-market approval application.
The company said that the pre-investigational device exemption process involved an FDA review of the proposed clinical investigational plan including the endorsement of clinical endpoints and outcomes measures.
Oncosil said that the investigational device exemption (IDE) submission was prepared by its medical and regulatory team over six months, in parallel with its Conformité Européenne (CE) mark application process and on-going review with the European regulatory body.
The company said that it expected the CE mark decision in 2016.
Oncosil chief executive officer Daniel Kenny said that he was “delighted to report that we have filed our investigational device exemption submission with the US FDA”.
“This represents a key milestone in the development timeline for Oncosil in the US,” Mr Kenny said.
“In conjunction with our on-going CE mark process with the European regulator, the company now has an active global regulatory licensing pathway,” Mr Kenny said.
Oncosil fell one cent or 6.1 percent to 15.5 cents with 1.2 million shares traded.

RESAPP HEALTH

Resapp says it has approval to enrol the first of 400 adults in a trial of its respiratory diagnostic at the Perth, Western Australia-based Joondalup Health Campus.
Resapp said that the Joondalup emergency department provided services to about 100,000 patients a year of which 80,000 were adults and 20,000 were children.
The company said that the study would gather data from adults presenting to the emergency department with respiratory conditions, such as upper respiratory tract infections, bronchitis, pneumonia, asthma and chronic obstructive pulmonary disease.
Resapp said that the aim of the study was to demonstrate that the technology, which had been shown “to be highly accurate for diagnosis of childhood respiratory conditions, can be extended to adults”.
In November, Resapp said the diagnostic had accuracy ranging from 87 percent to 99 percent in differentiating respiratory illnesses in children (BD: Nov 10, 2015).
Resapp chief executive officer Dr Tony Keating said that with more than 450 children enrolled in the paediatric study in eight months “we have demonstrated the robustness of our machine learning algorithms to accurately diagnose the majority of childhood respiratory diseases”.
“Including adults in the [Joondalup Health Campus] study not only provides access to one of Australia’s busiest [emergency departments], it utilises much of the same clinical team and logistics allowing us to achieve fast adult patient enrolment,” Dr Keating said.
Dr Keating told Biotech Daily he hoped the first adult diagnosis would be this week.
Resapp said that it would work with the University of Queensland to analyze the clinical data, with preliminary results expected by July 2016.
The company said that it planned to extend the adult study to a second site, a large private emergency department on the East coast of Australia.
Resapp was unchanged at 8.8 cents with 5.7 million shares traded.

DIMERIX (FORMERLY SUN BIOMEDICAL)

Dimerix says that the US Food and Drug Administration has granted orphan drug designation for DMX-200 for focal segmental glomerulo-sclerosis.

Dimerix said the designation applied to propagermanium and irbesartan the constituent parts of DMX-200 and focal segmental glomerulo-sclerosis was a leading cause of chronic kidney disease, for which there were no currently approved therapies.

The company said that patients with focal segmental glomerulo-sclerosis who progressed to kidney failure and received a kidney transplant, had a 30 to 40 percent chance of the condition reoccurring.

Dimerix said that the orphan drug designation program provided the status to drugs for disorders that affected fewer than 200,000 people in the US, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug and qualified the sponsor for seven-year market exclusivity on approval and qualified the sponsor for regulatory and financial support measures as the treatment progresses through pre-clinical and clinical development in the US.

Dimerix executive chairman Dr James Williams said the designation was “an important step in our strategy for the rapid commercial development of DMX-200 for the treatment of chronic kidney disease”.

Dimerix was unchanged at 0.7 cents.

IMUGENE

Imugene says it has hired the Sydney-based contract research organization Novotech for its 83-patient phase Ib/II trial of HER-Vaxx in gastric cancer, to begin by July 2016.

Last year, Imugene said that it had “substantially finalized” the clinical protocol for the trial which was expected to begin in 2015 (BD: Jan 18, 2015).

Imugene chief operating officer Leslie Chong told Biotech Daily that the company reformulated Her-Vaxx to increase and potentiate improved immunogenicity [and] along with this reformulation, we wanted to conduct thorough toxicology and pre-clinical studies”.

Imugene said an investigational new drug application was expected to be filed with the US Food and Drug Administration in “early 2016” and investigators would recruit patients with human epidermal growth factor receptor 2 (HER-2)-positive gastric cancer at cancer centres in Asia.

The company said the two part study would begin with a phase Ib open-label, dose-escalation study to evaluate the safety as well as the pharmacokinetics of HER-Vaxx and select the optimal dose for the phase II trial.

Ms Chong told Biotech Daily that the phase Ib trial would involve up to 15 patients and the phase II trial would enrol up to 68 patients.

Imugene said the phase II study would be a randomized, controlled study of HER-Vaxx plus standard-of-care against standard-of-care alone.

The company said that the phase Ib/II study in gastric cancer followed the phase I trial in breast cancer, which “indicated the potency of the HER-Vaxx approach in the induction of an anti-cancer antibody response”.

Imugene said that pre-clinical immunology studies of the new formulation by chief scientific officer Prof Ursula Wiedermann showed stronger antibody responses.

The company said that it had previously indicated that it intended to take HER-Vaxx into the clinic in Australia and Eastern Europe but had “come to the view that Asia is the ideal place to study HER-Vaxx in gastric cancer given the incidence of the disease and the availability issues around existing anti-HER2 drugs in the region”.

Imugene fell 0.1 cents or 9.1 percent to one cent with 9.5 million shares traded.

FEDERAL GOVERNMENT

Bolstering Australia's innovation sector was one of the key topics on the table when The Minister for Industry, Innovation and Science Christopher Pyne has discussed innovation with Israel Prime Minister Benjamin Netanyahu in Jerusalem.

A media release from Mr Pyne's office said the meeting "was timely, given the very recent release of the Government's National Innovation and Science Agenda, which included a $36 million global innovation fund [including] … five 'landing pads' for start-up entrepreneurs, one of which will be located in Tel Aviv".

"Israel has one of the highest concentrations of innovation and entrepreneurship in the world," Mr Pyne said. "Australia has a lot of similarities with Israel, including its educated workforce and small population, but when it comes to start-ups and commercializing research, we are failing to keep up."

"We value the people-to-people links and the commercial and diplomatic ties we share but we also value our educational and research ties, which have never been more important, given Australia's new emphasis on innovation," Mr Pyne said.

"Israel has a remarkable rate of success in commercializing innovation and turning bright ideas into viable commercial outcomes," Mr Pyne said.

COGSTATE

Cogstate says it has a three to four year $US1.7 million ($A2.4 million) contract with an unnamed pharmaceutical company for phase III trial cognitive testing.

Cogstate said it would provide computerised cognitive testing technology and associated services to be used in the phase III oncology clinical trial, "to provide a more complete understanding of the impact of treatment".

The company said that symptom management and maintaining quality of life were key metrics for assessing treatment benefit.

Cogstate was up four cents or 9.8 percent to 45 cents.

MAYNE PHARMA

The Singapore-based UBS AG and related bodies corporate say they have ceased their substantial holding in Mayne Pharma.

Earlier this month, UBS AG said it had become substantial in Mayne Pharma with 40,366,577 shares or 5.02 percent (BD: Dec 7, 2015).

UBS AG said that between December 3 and December 9, 2015 in more than 60 trades it bought, sold, borrowed and returned Mayne Pharma shares.

Mayne was unchanged at $1.32 with 2.2 million shares traded.

PROGEN PHARMACEUTICALS, TBG DIAGNOSTICS

Progen says it has officially changed its name to TBG Diagnostics and will begin trading under the code TDL following reinstated to quotation by the ASX.

Progen said it was "continuing to work through the next stages of finalising re-compliance".

Progen, or TBG, last traded at 22.5 cents