Biotech Daily

Monday July 25, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 22%; ONCOSIL DOWN 7%**

*** MTP CONNECT 10-YEAR COMPETITIVENESS, PRODUCTIVITY PLAN**

*** CORRECTION: FACTOR THERAPEUTICS**

*** POLYNOVO TO TRIAL MATRIX INSULIN FOR TYPE 1 DIABETES**

*** TBG, PROGEN COMPLETE PG545 DOSE ESCALATION TRIAL**

*** OPTISCAN $1.4m RIGHTS OFFER**

*** WPP'S IKON SUES CELLMID'S ADVANGEN FOR $939k**

*** RACE HIRES CRYSTAL PHARMATECH FOR BISANTRENE FORMULATION**

*** SIMAVITA TO DELIST FROM TORONTO STOCK EXCHANGE**

*** RESPIRI AIRSONEA 85% ACCURACY 'IMPRESSIVE, A MAJOR MILESTONE'**

*** SRV BELOW 5% OF DIMERIX**

*** BOTANIX OFFERS UNMARKETABLE PARCELS FACILITY**

*** AVEXA REQUESTS 'ENTITLEMENT OFFER' TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.64 percent on Monday July 25, 2016 with the ASX200 up 35.4 points to 5,533.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and three were untraded.

Benitec was best, up 2.5 cents or 21.7 percent to 14 cents with 862,633 shares traded. Both Antisense and Orthocell climbed 20.6 percent; Neuren rose 8.9 percent; Biotron improved 7.8 percent; Atcor, Clinuvel, Pharmaxis and Reva were up more than three percent; Acrux, Actinogen, Factor, Mesoblast and Prima rose more than two percent; Airxpanders, Avita, CSL, Nanosonics, Sirtex, Universal Biosensors and Viralytics were up more than one percent; with Cochlear up 0.35 percent.

Oncosil led the falls, down one cent or 7.4 percent to 12.5 cents, with 1.2 million shares traded. Admedus lost six percent; Cellmid fell 5.9 percent; Bionomics and Starpharma were down more than three percent; IDT shed two percent; Ellex, Living Cell, Medical Developments, Osprey, Prana and Uscom were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

MEDICAL TECHNOLOGIES & PHARMACEUTICALS GROWTH CENTRE

MTP Connect chief executive officer Sue MacLeman says her Federal Government-funded initiative aim is “to drive competitiveness and productivity of the sector”.

Ms MacLeman told Biotech Daily that the launch of a 10-year plan at Melbourne’s Monash University tonight would explain the role of the Medical Technologies & Pharmaceuticals Industry Innovation Growth Centre, or MTP Connect.

Ms MacLeman said that the Growth Centre was one of six created by the federal Government and provided with $248 million over four years and that of the $10 million a year available to MTP Connect $3 million was for operations and programs, while the rest would provide for matched-funding projects for specific sector programs.

Ms MacLeman said that the Growth Centre’s aim was to remove roadblocks and bureaucratic barriers as well as duplication of programs and to build “a skills and knowledge base for commercialization”.

She said that rather than scientists inventing something and looking for a need, it would be better to find the need and look for a technology to respond to it.

Ms MacLeman said that MTP Connect was “a strategic independent voice for the sector” and was also charged with promoting the sector to the world.

“It all about getting the sector to work more effectively together and remove roadblocks,” Ms MacLeman said.

She said that Australian needed to have the capability to manufacture its inventions from biologics through to devices, in turn creating a demand for a highly skilled workforce.

Ms MacLeman said that the 10-year sector competitiveness plan asks “what are the key priorities and what can we do to achieve them?”

“We can take specific action on each priority,” Ms MacLeman said.

Ms MacLeman said that as MTP Connect chief executive officer she had been involved in meetings with Federal Government Ministers, chief scientist Dr Alan Finkel and other sector leaders.

Ms MacLeman said that the key-note speaker for the Melbourne meeting would be Monash Institute of Pharmaceutical Studies director Prof Bill Charman.

In a media release, MTP Connect said that Ms MacLeman and chairperson Dr Bronwyn Evans would take the draft 10-year sector competitiveness plan on an Australia-wide tour in July and August.

MTP Connect said the draft plan identified seven growth priorities addressing specific elements of the value chain, including the need to identify and promote “knowledge priorities focused on current and future market needs”, create a highly productive commercialization environment from research to early clinical trials and proof-of-concept; transform the small and medium sized enterprize sub-sector to support the growth of smaller companies into larger, more stable and successful companies; support the development of digitally enabled devices and data analytics; strengthen Australia as an attractive clinical trial research destination; position Australia as the preferred partner for emerging Asian markets; and support advanced manufacturing.

MTP Connect was established under the Federal Government’s National Innovation and Science Agenda “to promote and accelerate innovation and entrepreneurship, to identify and remove barriers to success and to deliver sectoral competitiveness, collaboration and productivity” (BD: Dec 7, 8, 2015; Feb 26, 2016).

MTP Connect said the events would be a “networking opportunity” bringing businesses, industry and the science and research sector together to build links, unlock commercial opportunities and drive innovation”, with meetings in Melbourne on July 25, Adelaide July 26, Sydney August 3, Brisbane August 22, and events planned for Perth and Canberra.

To register, go to: http://www.mtpconnect.org.au/content/sector-competitiveness-plan.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Friday's edition reported that Factor Therapeutics expected to report results from its 168-patient, phase II, US trial of VF-001 for venous leg ulcers by June 2017.
Factor Therapeutics executive director Dr Christian Behrenbruch told the investor conference that results were expected by October 2017.
The mistake was made by the reporter and Biotech Daily apologizes unreservedly.
The edition also reported that the European Medicines Agency defined VF-001 as "a class II device with a medical component".
In fact the EMA classifies VF-001 as "a class III device with a medical component".
This error was made by the Friday sub-editor after a rather good lunch, courtesy of Factor Therapeutics.
The Friday sub-editor has been seconded to Detox Mansion Monthly and has been replaced in that demeaning role by the Friday reporter.
Factor Therapeutics was up 0.1 cents or 2.3 percent to 4.4 cents.

POLYNOVO

Polynovo says it will partner with Beta Cell Technologies' Prof Toby Coates and Prof John Greenwood to develop alternatives for islet cell transplantation for diabetes.
Polynovo said that beta islet cells made the hormone insulin and in type 1 diabetes, or juvenile onset diabetes, these cells were damaged and insulin production was impaired or absent.
The pancreas produces the islets of Langerhans which make the hormones glucagon through the alpha cells and insulin from the beta cells.
Polynovo said that the current treatment and management for type 1 diabetes patients included lifelong insulin injections, or in selected cases human islet cell transplantation.
The company said that islet cell transplantation involved transplanting islet cells from an organ donor into the liver of the recipient.
Polynovo said that a 30-pig study of its biodegradable temporizing matrix (BTM) as an alternative method for islet transplantation into the skin rather than the liver would begin in September 2016.
The company said that the matrix showed promise due to the safety profile and the high vascularity achieved when integrated into the skin.
Polynovo said that if successful, insulin injection might no longer be required.
The company said that type 1 diabetes affected more that 120,000 Australians and was a major cause of death and disability in young Australians.
Polynovo said that the research was supported by a grant from the US Juvenile Diabetes Research Foundation.
The company said that Prof Coates was a clinician-scientist and renal transplant nephrologist at the Royal Adelaide Hospital and a professor in Medicine at the University of Adelaide and was the director of South Australia's Centre for Islet Transplantation and the head of kidney and pancreas islet transplantation at the Royal Adelaide Hospital.
Polynovo said that in June 2016 Prof Coates received Juvenile Diabetes Research Foundation funding of $US742,000 over two years for development of alternative sites for islet transplantation.
The company said that Prof Greenwood was the Royal Adelaide Hospital Adult Burns Service director and the co-developer of the biodegradable temporizing matrix.
Polynovo was unchanged at 27 cents with one million shares traded.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG says it has “successfully completed the primary objective of a phase I clinical trial of PG545 in patients with advanced solid tumors” (BD: Aug 22, 2013; Dec 19, 2014).
TBG said that the 23-patient trial was conducted by its wholly-owned subsidiary Progen PG500 Series Pty Ltd, Progen’s former research and development team.
The company said that the dose-escalation study assessed the safety and tolerability of PG545 in patients with advanced solid tumors at sites across Australia, in four dose cohorts, as a once-weekly intravenous infusion.
TBG said that Progen PG500 Series Pty Ltd held an end-of-cohort meeting with the study investigators and the medical monitor after the completion of an expansion cohort evaluating a dose of 100mg, which was declared the maximum tolerated dose.
Progen PG500 drug development director Dr Keith Dredge said the company had established “a safe and well-tolerated dose for PG545 which is considered to be a therapeutic dose”.
“We are currently analyzing biomarker samples, the results of which will be reported in due course,” Dr Dredge said.
“One patient remains on-study and full results of the phase I study will be presented at a major international cancer conference in due course,” Dr Dredge said.
TBG was unchanged at 20 cents.

CELLMID

Cellmid says that Ikon Communications Pty Ltd has filed legal action for $939,056 against its wholly-owned consumer health subsidiary Advangen International Pty Ltd.
WPP company secretary Chris Rollinson told Biotech Daily that Ikon was a wholly-owned subsidiary of WPP AUNZ, which in turn was 60 percent-owned by the London-based WPP communications agency.
Last year, Cellmid raised $4.0 million to accelerate sales of Advangen’s FGF5 inhibitor hair growth products, marketed as Évolis (BD: Jul 30, 2015).
In February, Cellmid said that most of its revenue for the six months to December 31, 2015 was from its Évolis business with sales of $1,216,254 (BD: Feb 25, 2016)
Today, Cellmid said that Ikon’s claim for $939,056 was under a services agreement entered into by the parties on June 15, 2015, with Ikon alleging that Advangen failed to pay certain invoices for services rendered in relation to an advertising campaign.
Cellmid said that Advangen “strongly disputes that Ikon is entitled to be paid for the work the subject of the invoices”.
“It is Advangen’s position that Ikon has breached the services agreement, failed to provide certain services at all or adequately and engaged in misleading and dishonest conduct that has caused Advangen loss and damage,” Cellmid said.
Cellmid said it intended to defend its position and cross claim for payments made for services not provided or properly provided by Ikon, as well as for any further damages.
Cellmid said that it would ensure there was adequate security for its costs and if necessary, apply for an order that security for costs be provided by Ikon.
Cellmid said that, with its operating entities including Advangen, it took its responsibility to prudently deploy shareholders’ capital seriously.
The company said that Advangen had sought a commercial resolution of the dispute to avoid legal proceedings but this was unsuccessful.
Cellmid said that “additional information, to the extent legally permissible, will be shared during the investor call” on July 27, 2016.
Cellmid fell 0.2 cents or 5.9 percent to 3.2 cents with 5.4 million shares traded.

OPTISCAN IMAGING

Optiscan says it expects to raise $1,415,000 in an underwritten two-for-nine rights issue at 2.5 cents a share.
Optiscan said that the non-renounceable rights issue was underwritten by Life Sciences Pty Ltd and would fund working capital, general administrative costs and proposed expenditure on its confocal microscope technologies.
The company said that the offer was open to shareholders at the record date of July 28, the issue would open on August 3 and close on August 12, 2016.
Optiscan was suspended at two cents.

RACE ONCOLOGY

Race Oncology says it has signed a development agreement with the New Jersey-based Crystal Pharmatech contract research organization for Bisantrene for cancer.
Race said that the agreement covered a development program for up to three months.
The company said that manufacturing and formulation techniques had improved since the 1990s, when Bisantrene development was stopped.
Last year, Race chief executive officer Peter Molloy told Biotech Daily that Bisantrene was a phase II/III drug previously trialled in 44 clinical studies and on more than 2,000 patients, which showed it did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer, had been approved in France for acute myeloid leukaemia but never launched, because it was effectively “lost” in a string of pharmaceutical company mergers (BD: Aug 27, 2015).
Today, Race said that the Crystal Pharmatech program was “aimed at developing improved salt forms of Bisantrene, purification of the drug and a process for developing an optimum formulation.
“This project is one of first development steps in our progress towards a filed investigational new drug application,” Mr Molloy said.
“We expect it will result in an optimised Bisantrene drug product and formulation that will become the basis for our submission to the [US Food and Drug Administration] and the final manufactured Bisantrene product that we bring to market in Europe under our named patient program,” Mr Molloy said.
Race said that when the product optimisation was completed it intended to transfer the process to a third party manufacturer for production to meet clinical requirements and expected sales demand under the named patient program.
Race fell 1.5 cents or 5.45 percent to 26 cents.

SIMAVITA

Simavita says it will voluntarily delist from the Toronto Stock Exchange Venture Exchange, or TSX-V, on August 3, 2016.
The company said it applied to delist from the TSX-V following a restructure of its operations to decrease costs, as well as minimal transaction volume associated with share movements on the TSX-V and the majority of investors being Australia-based.
Simavita said that a single listing would better serve investors and investment in the company, but due to the potential cost associated with changing the company’s domicile, it would continue to maintain a Canadian holding company.
The company said its shares would be traded as CHESS depositary Interests for the time being.
Simavita fell 0.3 cents or 3.6 percent to 8.1 cents.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says that achieving 79.2 percent sensitivity for its Airsonea asthma wheeze diagnostic is “a major milestone”.

Respiri said that the independent research study conducted by the University of Chicago confirmed that the Airsonea device could “reliably detect wheezing in subjects” and had a specificity rate of 91.0 percent.

Sensitivity measures the “true positives” meaning that that the Airsonea missed 20.8 percent of asthma patients, whereas specificity measures “true negatives” meaning that the test wrongly assessed 9.0 percent of patients without a wheeze as having an asthma wheeze.

Respiri said that “the overall percentage agreement between a panel of certified pulmonary physicians and our Airsonea technology for the presence or absence of wheeze was an impressive 85 percent”.

Karmelsonix listed on the ASX in 2006 to develop the respiratory diagnostics originally invented by the Haifa, Israel-based Dr Noam Gavriely (BD: Nov 24, 2006).

In 2011, Karmelsonix changed its name to Isonea and by January 2015 had appointed its fourth chief executive officer in 12 months, changing its name to Respiri and starting the 90-patient Chicago trial (BD: Aug 30, 2011; Jan 23, Oct 27, Nov 25, 2015).

In June, Respiri raised $4.3 million in a rights issue at three cents (BD: Jun 17, 2016).

With investment from poker machines operator Bruce Mathieson, Isonea’s market capitalization peaked at $194 million at September 30, 2013, with a share price above 80 cents, but fell to $11 million at December 31, 2014.

Today, the company said the research study was led by University of Chicago medicine professor and principal investigator Prof Edward Naureckas.

Respiri said that breathing sound files recorded by Airsonea were collected from diagnosed asthmatics and diagnosed chronic obstructive pulmonary disease wheezing subjects, as well as non-wheezing subjects.

The company said that 150 breath-sound recordings were assessed by Prof Naureckas and four pulmonary physicians.

Respiri said that the results indicated that the device could not only detect wheezing in long periods of recording, but also in short periods of recording, as reflected by a single breath cycle of inspiration and expiration.

Respiri chairman Leon L'Huillier said the results were “a significant achievement for the business”.

“The results of the independent research study confirm the ability of our smartphone enabled technology to detect and measure wheeze,” Mr L'Huillier said. This will help families living with asthma and is an important step in our commercialisation strategy.”

Respiri was unchanged at 7.4 cents.

DIMERIX

SRV Custodians says it has ceased its substantial shareholder in Dimerix reducing from 89,732,256 shares (6.42%) to 49,732,256 shares (3.37%).

The Perth Western Australia SRV Custodians ceasing substantial shareholder notice, signed by company secretary Sofie De Wolf, said that SRV sold 40,000,000 shares for $280,000 or 0.7 cents a share on June 27, 2016.

In 2015, SRV Custodians said in a substantial shareholder notice, signed by director Matthew Callahan, that SRV was the trustee for the SRV Tech Trust and acquired the shares in consideration for 7,390,267 Dimerix shares (BD: Jul 6, 2015).

Dimerix was unchanged at 0.7 cents.

BOTANIX PHARMACEUTICALS (FORMERLY BONE MEDICAL)

Botanix says it will offer an unmarketable parcel facility for shareholders holding parcels of shares worth less than $500.

Botanix said that the record date closing price on July 20 2016 was 4.9 cents making an unmarketable parcel 10,204 shares or fewer.

The company said that 1,269 shareholders holding 1,055,112 shares held unmarketable parcels and the sale facility would allow them to sell their shares without using a broker or paying brokerage.

Botanix said it would pay all costs of the sale for shareholders who use this facility, excluding tax consequences from the sale which remains the shareholder's responsibility.

The company said it valued all shareholders, but it incurred considerable administrative costs associated with maintaining a large number of unmarketable parcel holdings and the sale would reduce administrative costs.

Botanix fell 0.3 cents or 5.7 percent to five cents with four million shares traded.

AVEXA

Avexa has requested a trading halt pending an announcement "in connection with a proposed pro-rata, non-renounceable entitlement offer and associated underwriting".

Trading will resume on July 27, 2016 or on an earlier announcement.

Avexa last traded at 3.3 cents.