Biotech Daily

Monday September 26, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: BIONOMICS UP 24%, CELLMID DOWN 6.5%**

*** FDA APPROVAL FOR OVENTUS O2VENT-T, OCTOBER LAUNCH**

*** PRESCIENT DOSES 1st FLORIDA BREAST CANCER PATIENT**

*** AIRXPANDERS: 'AEROFORM HALVES BREAST EXPANSION TIME'**

*** ASX TERMINATES BRAND TV MEDIVAC TAKEOVER**

*** ONCOSIL RECEIVES $2.3m FEDERAL R&D TAX INCENTIVE**

*** UNILIFE RUNNING OUT OF TIME FOR ASX, NASDAQ**

*** SUNSHINE HEART BELOW NASDAQ $US1 BID RULE**

*** AUSTRALIAN EXECUTOR TRUSTEES BELOW 5% IN BLUECHIIP**

*** MMJ REQUESTS 'CORPORATE TRANSACTION' TRADING HALT**

*** ADHERIUM 2.6m DIRECTORS SHARES, 43% FEES HIKE AGM**

*** ADMEDUS APPOINTS, PROMOTES SALES, MARKETING STAFF**

MARKET REPORT

The Australian stock market was flat on Monday September 26, 2016, with the ASX200 up 0.1 points to 5,431.4 points. Seventeen of the Biotech Daily Top 40 companies were up, 15 fell, seven traded unchanged and one was untraded.

Bionomics was the best on news of presenting at a New York conference, up nine cents or 23.7 percent to 47 cents with 3.1 million shares traded. Ellex climbed 7.5 percent; Anteo and Dimerix were up six percent or more; Prima was up 5.4 percent; Admedus and Oncosil were up more than four percent; Orthocell was up 3.6 percent; IDT and Impedimed rose more than two percent; Atcor, Compumedics, Living Cell, Medical Developments, Mesoblast and Reva were up more than one percent; with CSL and Pro Medicus up by less than one percent.

Cellmid led the falls, down 0.2 cents or 6.45 percent to 2.9 cents with 763,583 shares traded. Benitec lost 5.3 percent; Viralytics fell 4.9 percent; Cyclopharm, Nanosonics, Opthea and Starpharma were down more than three percent; Avita shed 2.2 percent; Acrux, Neuren, Osprey, Polynovo, Sirtex and Uscom were down one percent or more; with Airxpanders, Cochlear and Resmed down by less than one percent.

OVENTUS MEDICAL

Oventus says the US Food and Drug Administration has cleared its adjustable O2vent-T anti-snoring and sleep apnoea mouth-guard and it will be launched next month.
Oventus said that the adjustable O2vent-T device was intended to reduce or alleviate snoring, mild to moderate obstructive sleep apnoea and severe sleep apnoea where the patient was intolerant to continuous positive airway pressure devices.
The company said that the original O2vent was a three-dimensional printed titanium mandibular, or jaw, advancement device fitted in a patient's mouth, with an airway directing air to the back of the throat, bypassing nasal, soft palate obstructions and tongue obstructions and was registered with the Australian Therapeutic Goods Administration.
Oventus said that the "titratable" O2vent-T allowed the jaw position to be optimized through the adjustable mechanism.
The company said that the clearance was "an important milestone", allowing it to launch the product in the US.
Oventus said that about 12 million to18 million US adults had sleep apnoea with about 80 percent outside care or not treated effectively with other therapies.
Oventus said that the device was developed by Brisbane dentist and company founder Dr Chris Hart and was indicated for use during sleep to aid in the treatment of snoring and obstructive sleep apnoea, and TGA registration paved the way for launch into European and Asian markets.
Oventus said that a clinical study completed this year showed the company's first generation O2vent Mono was successful in treating obstructive sleep apnoea, with that snoring either eliminated or significantly reduced in 100 percent of patients.
The company said that the positive results included those people who had nasal obstructions and mainly breathed through their mouths, including when they were asleep.
"The recent clinical data strongly supports its superior performance and clearly demonstrates its effectiveness in treating a range of sleep disorders," Dr Hart said.
"It also improves oxygen levels for patients," Dr Hart said.
"It means a greater number of patients who are [continuous positive airway pressure] intolerant or mild to moderate sufferers of sleep apnoea now have an alternative treatment option available," Dr Hart said.
The company said it expected the adjustable O2vent-T to have similar or superior results as the jaw position could be optimized.
Oventus was up 3.5 cents or 4.9 percent to 75 cents.

PRESCIENT THERAPEUTICS

Prescient says it has dosed its first Florida patient in its 18-patient phase Ib extension trial of PTX-200 with paclitaxel for locally-advanced breast cancer.
Prescient said that the patient was the first at the Tampa, Florida-based H Lee Moffitt Cancer Centre but the trial was also being conducted at New York's Albert Einstein College of Medicine and Cancer Centre.
In February, Prescient said that the seventeenth and final patient had been dosed in the escalation stage of its phase Ib breast cancer trial at the New York Montefiore Cancer Centre (BD: Feb 17, 2016).
Last year, the company said that dose escalation of PTX-200 had proceeded to the third and final dose level of 35mg/m2 and the researchers would initiate an expansion cohort in 12 patients at the expected 35mg/m2 recommended phase II dose of PTX-200 to better characterize the safety profile of the combination (BD: Aug 26, 2015).
Prescient was unchanged at 10 cents.

AIRXPANDERS INC.

Airxpanders says that post-mastectomy women using its Aeroform tissue expander system achieved full tissue expansion in half the time of traditional saline expanders.
Airxpanders said that data from a subset of 72 patients in its 'Xpand' pivotal trial, who required tissue expansion as part of breast reconstruction, showed that the 44 women in the Aeroform group were able to achieve tissue expansion within 17 days, as compared to 35 days for the 28 women in the saline expander group and overall Aeroform reduced the reconstruction process by 10 days.
The company said that the data showed that the "significant reduction in time to expansion was achieved with equivalent safety and efficacy and resulted in increased patient satisfaction".
Airxpanders said that the data was presented at the American Society of Plastic Surgeons meeting in Los Angeles, California, September 23 to 27, 2016.
The company said that the Aeroform needle-free, patient-controlled tissue expander using a remote dosage controller was under review with the US Food and Drug Administration.
Columbia University head of plastic surgery and Xpand trial principal investigator Dr Jeffrey Ascherman said that surgeons understood the burden that tissue expansion places on women during breast reconstruction.
"As greater numbers of women have mastectomies, there is a real need to make the process shorter and more comfortable for women," Dr Ascherman said.
"This subset data is further evidence of the benefits of Aeroform in not only reducing the time to implant, but in helping women reclaim their lives faster after breast cancer," Dr Ascherman said.
Airxpanders said it had completed enrolment for its Xpand II continued access study, designed to provide existing investigators with the ability to treat patients with Aeroform while the device was under review by the FDA.
Airxpanders fell half a cent or 0.35 percent to $1.415.

MEDIVAC

Medivac says its reverse takeover by Brand TV Media has been terminated because "the ASX has refused … an extension from the October 1 2016 relisting deadline".
In August, Medivac said it had a binding term sheet with Brand TV Media Pty Ltd for a reverse takeover to become an internet video marketing and commercialization vehicle (BD: Aug 29, 2016).
Today, the company said that the ASX decision meant it was unable to satisfy the indicative timetable and relevant conditions precedent within the term sheet.
Medivac said that it and Brand TV Media had executed a letter of settlement, terminating the term sheet, releasing "one another from all liabilities thereunder".
The company said its board was "disappointed with this outcome".
In August, Medivac said the Brant TV Media takeover would require shareholder approval, with an extraordinary general meeting proposed for October 21 and December 2, 2016 the target date for completion of the acquisition.
Medivac was attempting to commercialize its Metamizer medical waste system and Sunnywipes hand hygiene products (BD: May 13, 2011; May 7, 2012).
In 2012, the company merged with Republica Capital and in 2014 sought funds to rebadge itself as Woolwich Capital (BD: Oct 29, 2012; Jan 31, 2014).
Last year, Medivac said it had a $200,000 converting loan to re-list on the ASX, changed its board and was conducting a review of its business (BD: Aug 10, 2015).
Medivac last traded at 0.3 cents.

ONCOSIL MEDICAL

Oncosil says it has received $2,297,446 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Oncosil said that the cash rebate was related to expenditure on eligible Australian and international research and development activities conducted in the year to June 30, 2016.
Oncosil was up half a cent or 4.2 percent to 12.5 cents.

UNILIFE CORP

Unilife says it is non-compliant with Nasdaq rules for not filing its annual report for the year to June 30, 2016 in a timely manner to the Securities and Exchange Commission.
Unilife said it was also required to file audited financial statements to the ASX no later than September 30, 2016, and had been denied a waiver of the rule by the ASX.
The company said that if it did not file its audited statements by the ASX deadline, trading in its Chess depositary interests (CDIs) on the ASX would be suspended immediately prior to the open of trading on October 3, 2016 and if trading of its CDIs was suspended on the ASX, the Nasdaq would halt trading of its common stock.
Unilife said it had submitted a plan for Nasdaq compliance and the Nasdaq had granted an exception until November 7, 2016 to regain compliance.
The company said that the Nasdaq required an update to the compliance plan no later than October 4, 2016, including plans to file the annual report and indicate the progress towards the original compliance plan.
Unilife said that the Nasdaq letter had “no immediate effect on the listing of the company’s common stock on the Nasdaq Global Market”.
Unilife fell 0.6 cents or 9.7 percent to 5.6 cents with 1.3 million shares traded.

SUNSHINE HEART

Sunshine Heart says it has received a letter from the Nasdaq that it has not demonstrated compliance with the $US1.00 bid price requirement for listing.
Sunshine Heart said that it would request a hearing to demonstrate compliance with all requirements for listing on the Nasdaq Capital Market and request an extension of time.
On Friday night on the Nasdaq, Sunshine Heart closed down two US cents or 2.7 percent to 72 US cents (94.55 Australian cents, equivalent to 0.47 cents prior to its departure from the ASX, when it was trading at 2.5 cents) with 20,581 shares traded (BD: Apr 29, 2013).

BLUECHIIP

The Adelaide-based Australian Executor Trustees says it has increased its holding in Bluechiip from 10,313,200 shares to 11,921,273 but has been diluted below five percent.
Last week, Bluechiip said it had raised $1,488,294 in a rights issue and shortfall facility at 2.2 cents a share (BD: Sep 22, 2016).
Bluechiip was unchanged at 2.6 cents.

MMJ PHYTOTECH

MMJ has requested a trading halt “pending an announcement regarding a material corporate transaction”.
Trading will resume on September 28, 2016 or on an earlier announcement.
MMJ last traded at 23 cents.

ADHERIUM

Adherium will vote to lend directors funds to acquire 2,621,367 shares and increase the aggregate fee pool for non-executive directors by 42.9 percent to $500,000 a year.
The Adherium notice of meeting said that loans would be provided to chairman Thomas Lynch to acquires 600,000 shares at 50 cents each, with a further 300,000 shares each to directors Prof John Mills, Dr William Hunter, Jeremy Curnock Cook, Bruce McHarrie and Bryan Mogridge, along with $260,684 to chief executive officer Garth Sutherland to acquire 521,367 shares.
The company said that the board had been expanded from six to seven directors and to increase the chairman's salary from $80,000 a year to $100,000 a year, along with an increase in non-executive directors fees from $40,000 a year to $50,000 a year it proposed to increase the director's fee pool from $350,000 to $500,000 a year.
Adherium said that it would seek shareholder approval to issue 16,046,097 shares to FIL Limited and re-elect directors Dr Hunter and Mr Lynch.
The meeting will be held at K&L Gtaes, Level 25, 525 Collins Street, Melbourne on October 27, 2016 at 11am (AEDT).
Adherium was up half a cent or 1.4 percent to 36.5 cents.

ADMEDUS

Admedus says it has appointed Michael Walker as its Europe vice-president and Eileen Petersen as "field force optimization manager".
Admedus said that Mr Walker was based in Zurich and was an experienced executive with marketing and sales experience and formerly worked for Roche, Novo Nordisk and CSL.
The company said that Ms Peterson had worked in product and brand management with Baxter and Synovis in the US, driving sales and delivering clinical education programs.
Admedus said that Su Lawton had been promoted to marketing director and previously worked in the cardiovascular medical device industry for 15 years including with St Jude, Sorin, Vascutek and Edwards Life Sciences.
The company said that Chris Olig had been appointed business development and portfolio planning director and would be based in Minneapolis, Minnesota.
Admedus said that Mr Olig had more than 25 years' experience in medical devices including at Medtronic.
Admedus executive chairman Wayne Paterson said the company had "turned the ship and we are now heading in the right direction in terms of sales growth and reducing expenses".
"The new appointments strengthen our global marketing capabilities, which will benefit our Adapt technology portfolio," Mr Paterson said.
Admedus was up 1.5 cents or 4.8 percent to 33 cents with 1.7 million shares traded.