Biotech Daily

Tuesday October 20, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ATCOR UP 5%; AVITA DOWN 12.5%**

*** POLYNOVO COMPLETES 5-PATIENT NOVOSORB PROOF-OF-CONCEPT**

*** AVITA RAISES $10m**

*** AIRXPANDERS: 'AEROFORM CUTS BREAST EXPANSION TIME 50%'**

*** NOVOGEN 'RETRACTS' CANTRIXIL OVARIAN CANCER ANNOUNCEMENT**

*** WALK THE SYNCHROTRON WITH BIO-MELBOURNE**

*** ALLAN GRAY FURTHER REDUCES TO 11.4% OF ALCHEMIA**

*** GOLDMAN SACHS ABOVE 5% OF NANOSONICS, YET AGAIN**

MARKET REPORT

The Australian stock market fell 0.65 percent on Tuesday October 20, 2015, with the ASX200 down 34.1 points to 5,235.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Atcor was the best, up 1.5 cents or five percent to 31.5 cents, with 137,171 shares traded.

Admedus climbed three percent; Anteo and Pharmaxis rose more than two percent; Benitec, Circadian, CSL, Nanosonics, Neuren, Psivida and Universal Biosensors were up more than one percent; with Cochlear, Medical Developments, Resmed and Sirtex up by less than one percent.

Avita led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 1.5 million shares traded.

Oncosil lost 6.45 percent; Compumedics fell 5.7 percent; Orthocell shed 4.8 percent; Bionomics and Polynovo were down more than three percent; Acrux, Reva and Starpharma shed more than two percent; Osprey and Pro Medicus were down more than one percent; with Mesoblast down 0.9 percent.

POLYNOVO

Polynovo says the fifth and final deep burn patient has been implanted in a trial of its Novosorb biodegradable temporizing matrix (BTM) at the Royal Adelaide Hospital.
Polynovo said the proof-of-concept study was entitled 'Using a biodegradable polyurethane dermal matrix in the management of deep burn injury' and was conducted by the Hospital's Prof John Greenwood and his team.
The company said that four previous patients had "excellent results with the BTM including outstanding cosmetic and functional outcomes in the BTM-grafted areas".
Polynovo said further data analysis would be undertaken, but the matrix had "proven to be easy to apply, robust, did not spontaneously delaminate and was resistant to infection".
The company said that all the skin grafts took over the neo-dermis provided by the matrix and Prof Greenwood would present his preliminary findings of the first four patients at the Australian and New Zealand Burn Association Conference in Melbourne this week.
Polynovo said that Prof Greenwood had "indicated he intends to continue using the [matrix] within his burns management program" and approval would be sought from the TGA under the authorised prescriber program at the Royal Adelaide Hospital.
Polynovo chief executive officer Paul Brennan told Biotech Daily that the 20-patient Conformité Européenne (CE) mark trial had begun with two patients recruited at Melbourne's Alfred Hospital, with eight more patients expected to be recruited at the Alfred Hospital and 10 at France's Toulon Hospital (BD: May 8, 2015).
In a media release, Mr Brennan said the trial conclusion was "a very exciting milestone". "[Prof Greenwood] is justifiably proud of his achievements with the [matrix] as it has the potential to change the standard of care delivered to major burn victims all over the world," Mr Brennan said. "With application in both surgical wounds and burns markets, surgeons and patients are justifiably excited by the outcomes generated with our BTM."
Polynovo fell half a cent or 3.7 percent to 13 cents.

AVITA MEDICAL

Avita says it has raised $10,018,644 through the placement to sophisticated and institutional investors of 107,727,358 shares at 9.3 cents a share.
Avita said the placement was "under a broader placement approval from shareholders obtained at a meeting held on August 24, 2015".
In July, Avita said it would raise up to $20 million to list on the Nasdaq or New York Stock Exchange and support a new commercialization direction (BD: Jul 23, 2015).
The company was raising funds when it exited a trading suspension to announce the US Biomedical Advanced Research and Development Authority (BARDA) had given "a high rating to … [explore] the possible use of Recell under a disaster preparedness program" and in September it was awarded a BARDA contract worth up to $77 million to provide up to 25,000 Recell wound treatment units (BD: Aug 26, 28, 31; Sep 30, 2015).
Today, Avita said that most of the funds were from current institutional shareholders including Hunter Hall and One Funds Management as Trustee for Asia Pacific Healthcare Fund II, which is managed by Bioscience Managers, whose directors Jeremy Curnock Cook and Matt McNamara were also Avita directors, with Oceania Capital and DMP Asset Management new shareholders participating in the placement.
Avita said that the funds would cover on-going operational expenses for at least the next 12 months and support the BARDA contract program.
The company said that Lake Street Capital Markets acted as lead agent and Griffin Securities acted as co-placement agent.
Avita fell 1.5 cents or 12.5 percent to 10.5 cents with 1.5 million shares traded.

AIRXPANDERS

Airxpanders says it has presented the final data from its 150-patient trial of Aeroform for breast reconstruction at the American Society of Plastic Surgery meeting in Boston.

In August, Airxpanders said the pivotal trial showed that subjects in the study arm achieved successful exchange to a permanent implant with the same safety profile as saline tissue expanders (BD: Aug 25, 2015).

Today, the company said that the post-mastectomy trial showed that the Aeroform tissue expander was a safe and effective alternative to saline tissue expanders, reducing the time to expansion from 46 days for the saline group to 21 days for the Aeroform group with 98 percent of patients saying the device was easy to use and convenient

Airxpanders said the positive outcome was “a major milestone” and the basis on which it was seeking US Food and Drug Administration clearance for the device.

The company said that 150 women aged 18 to 70 years were treated at 17 US sites, randomized to the investigational or saline control groups, and underwent immediate or delayed placement of the tissue expanders.

Airxpanders said that in the 98 women receiving the Aeroform expander, expansion was performed with incremental dosing up to 30cc/day, and the 52 women in the saline control group received the standard course of percutaneous injections of saline, and following complete expansion, both groups went to the final stage of reconstruction, exchange of the expander and placement of a permanent breast implant, the trial endpoint.

Airxpanders said the non-inferiority trial found that treatment success rates, excluding non-device related failures, were statistically similar as were the safety profiles, and the time to complete the expansion and reconstruction process was statistically significantly shorter in the Aeroform group, due to the gradual, patient-controlled method of expansion.

The New York-based Columbia University head of plastic surgery and trial principal investigator Dr Jeffrey Ascherman said the Aeroform device “provided the patients in this trial with a faster and more convenient form of tissue expansion versus saline devices”.

“A hidden benefit of this device is the fact that the patient can play an active role in recovering her body after breast cancer,” Dr Ascherman said. “My patients have thoroughly enjoyed this role and I am confident that this will appeal to many women across the US and around the world when widely available.”

Airxpanders chief executive officer Scott Dodson said that “the excellent results from the Xpand pivotal trial validate that the Aeroform expander is a safe and effective alternative treatment option for the many women undergoing mastectomy and breast reconstruction”.

“We believe women will be pleased to have the choice to control their expansion in a more convenient and faster way, during their difficult road to breast reconstruction,” Mr Dodson said.

“We have already submitted the pivotal study results to the FDA under the 510(k) clearance process so as to make this device available to all women who are considering breast reconstruction following their mastectomy,” Mr Dodson said.

Airxpanders said that the Aeroform device had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approved.

The company said that the goal of reconstructive breast surgery was to recreate symmetrical natural-shaped breasts after mastectomy, but about 60 percent of women do not complete breast reconstruction after mastectomy “due to fear of a lengthy and painful process, with multiple procedures and trips to their doctors’ office”.

Airxpanders said that Aeroform was a carbon-dioxide filled, injection free remote-controlled tissue expander, enabling women to control the rate of expansion which can make the process easier, more comfortable and shortened the time to reconstruction.

Airxpanders fell 3.5 cents or 3.9 percent to 85.5 cents.

NOVOGEN

Novogen says it wants to “retract” yesterday’s announcement of Cantrixil utility with platinum for ovarian cancer.

Yesterday, Novogen said that data was presented at the American Association for Cancer Research meeting in Orlando, Florida on October 18, 2015 (BD: Oct 19, 2015).

“Novogen retracts this announcement following a mistaken understanding of which data … was to be presented,” the company said.

“Despite this clarification, the scientific data announced remains accurate and relevant, the details of which will be disclosed on a separate occasion,” Novogen said.

Novogen was unchanged at 15.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its October 26 Bio-Briefing will tour an Australian Synchrotron beam line and visit three Australian Research Council centres of excellence.

The Bio-Melbourne Network said that the facility tour, including a beam line tunnel walk-through, would show “how advances in imaging technology could be harnessed to drive significant new industry collaborations, through cutting-edge preclinical imaging techniques that underpin the biotechnology and medical technology industries”.

The Network said that the Bio-Briefing, entitled ‘Seeing is Believing’, would showcase the Synchrotron and three ARC Centres of Excellence exploring next-generation technologies in cellular and whole imaging, creating new intellectual property and technology.

The Network said that imaging technology was advancing rapidly and global markets for medical imaging devices and applications continued to grow, driven by increasing healthcare demand.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that “new imaging techniques provide powerful tools for preclinical development and enhance early-stage research and development decision-making and new molecular imaging techniques can give early reads on the effectiveness of therapeutics and diagnostics increasing the speed and decreasing the cost of product development”.

The Network said that the speakers at the briefing would include the Australian Synchrotron’s senior imaging and medical therapy scientist Dr Chris Hall, ARC Centre for Bio-Nano Science’s chief investigator and director Prof Tom Davis, ARC Centre for Integrative Brain Function’s director Prof Gary Egan and the ARC Centre for Advance Molecular Imaging’s Business Development Manager Dr Mike Bettess.

The October 26, 2015 Bio-Briefing will be held at the Australian Synchrotron, 800 Blackburn Road, Clayton with registration from 3.45pm for the Bio-Briefing and tunnel walk-through from 4pm to 5.30pm followed by a networking session.

To register go to: http://www.biomelbourne.org/events/view/387.

ALCHEMIA

Allan Gray Australia says it has reduced its holding in Alchemia from 43,124,804 shares (13.28%) to 36,920,695 shares (11.37%).

In September Allan Gray said that between June 24 and September 25, 2015 it sold 13,630,363 shares for $856,142 or 6.3 cents a share (BD: Sep 30, 2015).

Today, Allan Gray said that between September 25 and it sold 6,204,109 shares for $507,722 or 8.2 cents a share.

Alchemia was up 0.1 cents or 1.2 percent to 8.7 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says that, yet again, it has become substantial in Nanosonics with 14,750,081 shares or 5.20 percent.

Goldman Sachs said that between June 22 and October 15, 2015 it acquired between one single share and 1,344,230 shares for no cost, with the single largest purchase 194,961 shares for $258,323 or $1.325 a share.

Throughout October, Goldman Sachs has repeatedly increased above or reduced below the five percent substantial threshold in Nanosonics, primarily borrowing or returning shares “to the counterparty under a repurchase agreement” for no applicable consideration (BD: Oct 2, 5, 15, 16, 2015).

Previously, under a counterparty agreement, Goldman Sachs returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australian, HSBC Custody Nominees Australia and the Bank of New York Mellon (BD: Apr 13, 2015).

Nanosonics was up 1.5 cents or 1.1 percent to $1.43.