Biotech Daily

Tuesday November 20, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 8%, GENETIC TECH DOWN 10%**

*** AVITA PREPARES FOR 2013 RECELL VENOUS LEG ULCER TRIAL**

*** SIRTEX TO ESTABLISH GERMAN MANUFACTURING FACILITY**

*** US FDA APPROVES ATCOR SPHYGMOCOR XCEL**

*** BAILLIE GIFFORD TAKES 12% OF COCHLEAR**

*** US FDA APPROVES MESOBLAST MANUFACTURING PROCESS**

*** NOVOGEN, MEI PHARMA ME-344 'A MOST LICENSABLE PRODUCT'**

*** SUNSHINE HEART REQUESTS REGULATORY TRADING HALT**

*** IDT LOSES 2nd STRIKE VOTE, WINS SPILL VOTE**

*** CIRCADIAN FACES 22% AGAINST REMUNERATION**

*** BIOXYNE SAVINGS: CEO DAVID RADFORD 0.6-TIME, DIRECTOR SHARES**

MARKET REPORT

The Australian stock market was up 0.56 percent on Tuesday November 20, 2012 with the S&P ASX 200 up 24.3 points to 4,385.7 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and five were untraded. All three Big Caps rose.

Prima was the best, up one cent or eight percent to 13.5 cents with 1.7 million shares traded. Genera and Sirtex climbed seven percent or more; Impedimed and Patrys were up five percent or more; Tissue Therapies was up 4.4 percent; Resmed rose 2.4 percent; Bionomics was up 1.6 percent; with Cochlear, CSL, Heartware and Pharmaxis up by less than one percent.

Genetic Technologies led the falls, on no news to the market, but apparently with a US broker downgrade, down one cent or 10 percent to nine cents with 1.1 million shares traded. Benitec and Compumedics lost more than six percent; Cellmid and QRX were down more than five percent; Allied Health and Reva fell more that four percent; Optiscan was down 3.3 percent; Alchemia, Neuren and Universal Biosensors shed more than two percent; Anteo, Circadian, Clinuvel and Psivida were down more than one percent; with Acrux, GI Dynamics, Mesoblast and Starpharma down by less than one percent.

AVITA MEDICAL

Avita is preparing for an 80-patient, multi-centre, randomized, controlled study of Recell spray-on-skin for the treatment of venous leg ulcers, due to begin by April 2013.

Avita said that up to five European centres would be included in the United Kingdom, Germany, France and Denmark.

The company said that in preliminary open-label studies, Recell was used at four European centres to treat about 80 patients suffering from venous leg ulcers and diabetic foot ulcers.

In 2011, Avita said that data on 10 chronic ulcer patients was presented at the International Flebology Conference in Italy, with one patient lost to follow-up due to an unrelated accident, but of the remaining nine patients, 100 percent healing was achieved in eight patients and about 90 percent re-epithelialization achieved in the remaining patient (BD: Oct 13, 2011).

The company said at that time, that it had launched Recell for the treatment of chronic leg ulcers in Europe, a market estimated at more than $1 billion and that Recell had approval as a device to harvest cells for wound treatment and could be used for the new indication of venous ulcers.

Today, Avita said that in the 80-patient data, the patients' average age was 70 years, wounds were open an average of about 13 months and averaged about 21 sq cm in size.

The company said that more than 70 percent of patients showed complete healing of the wound within seven to 12 weeks following a single treatment with Recell.

Avita said that with the current standard of care treatment it would be expected that about 43 percent of these wounds would have achieved closure during this period, showing Recell to yield a highly significant positive effect on wound healing.

The company said that pain was a critical indicator of quality of life and was reported as being significantly reduced or eliminated within 72 hours following the Recell treatment.

Avita said that given the positive results in preliminary studies, it had begun the randomized control study with protocols submitted for approval by the relevant ethics review boards at each centre.

The company said the first patient was expected to be enrolled by April 2013.

Avita chief executive officer Dr William Dolphin said that the early results in the treatment of chronic ulcers with Recell were "highly promising".

"These are hard-to-heal ulcers that pose an enormous burden on healthcare systems and seriously impact on patient's quality of life," Dr Dolphin said.

"Recell is approved for use in Europe, Australia and other markets with over 4,500 procedures conducted to date, mainly for burns," Dr Dolphin said.

"Improved leg ulcer treatment will provide tremendous relief for ulcer patients, potentially deliver significant cost savings to financially stressed healthcare systems and may open additional very large markets for Recell," Dr Dolphin said.

The company said that lower limb ulcers, which included venous leg ulcers and diabetic foot ulcers, were a major healthcare problem in developed countries due to their prevalence, high cost of treatment and significant impact on patient quality of life.

Avita said that lower limb ulcers affected about 1.5 percent of the general population in developed countries and up to three percent of people over the age of 70 years and the expense in treating them was "a major financial burden on healthcare systems".

The company said that in the US, about 6.5 million people had lower limb ulcers and associated treatment costs were more than $US25 billion a year, with similar prevalence in the UK, Germany and France.

Avita said lower limb ulcers caused pain, lack of mobility and lost work days and wages.

Avita was unchanged at 12 cents.

SIRTEX MEDICAL

Sirtex says it will establish a $4.5 million manufacturing facility in Frankfurt, Germany, to be commissioned over the next 24 months.
Sirtex said the German plant would have two 'hot cells' producing radioactive yttrium although initially only one of hot cells would be fully commissioned.
The company said that the plant would provide the flexibility to install a further hot cell when required.
Sirtex said that each hot cell would have the same capacity as similar hot cells currently installed in US and Singapore plants.
The company said that a key factor in the decision to establish a European plant was to improve logistics given the relatively short shelf life of SIR-Spheres microspheres.
Sirtex chief executive officer Gilman Wong said the decision marked "another significant milestone as Sirtex develops a global capability to meet the future demand for SIR-Spheres microspheres".
"Sirtex will continue to make appropriate investments to ensure the business is in a strong position to take advantage of this potential growth," Mr Wong said.
Mr Wong said the Sirflox clinical study was about to complete recruitment in 2013 with the results expected by early 2015 (BD: Mar 2, 2012).
"We believe that positive results from this study will drive a significant increase in demand for our treatment," Mr Wong said.
"This forms part of the plans … which we are executing to ensure we have the capability and capacity to meet increased demand for SIR-Spheres microspheres," Mr Wong said.
Sirtex climbed 77 cents or seven percent to $11.80 with 149,936 shares traded.

ATCOR MEDICAL

Atcor says the US Food and Drug Administration has cleared the Sphygmocor Xcel system for marketing in the US.
Atcor chief executive officer Duncan Ross said the approval was "an important step … as it paves the way for us to sell Xcel systems in the valuable US clinical practice market, which is also our largest potential market".
"Importantly, the Xcel system is much simpler to use and provides invaluable data for clinicians to properly manage patients with hypertension and other cardiovascular related diseases," Mr Ross said.
Atcor said that the Sphygmocor Xcel device for measuring central aortic blood pressure and arterial stiffness had been tailored for use by medical specialists in fields including cardiology, hypertension, nephrology, or kidney disease, and endocrinology.
The company said that the system was available for sale in Europe, Australia, and four Asian markets including India and it planned to file applications for regulatory approval to sell into additional markets.
Atcor was unchanged at 7.2 cents.

COCHLEAR

Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 6,041,168 shares (10.60%) to 6,652,068 shares (11.66%).
The Edinburgh-based Baillie Gifford became substantial in Cochlear in 2011 and has continued acquiring shares (BD: Aug 19, Oct 25, 2011; Feb 3, Oct 3, 31, 2012).
Cochlear was up 51 cents or 0.7 percent to $75.01 with 150,905 shares traded.

MESOBLAST

Mesoblast says it has agreement with the US Food and Drug Administration on the manufacturing process for its mesenchymal precursor cells for phase III clinical trials.
Mesoblast said that it had established with the FDA “a clear pathway for commercial manufacturing supply of its cell therapy products”.
The company said that the FDA agreed that its extensive characterization and testing of its mesenchymal precursor cells technology was acceptable and consistent with expectations for phase III clinical supplies.
Mesoblast said that the FDA agreed with its proposed assays to demonstrate potency for the product, a key requirement for entry into phase III clinical trials
The company said that the US regulator agreed with the scope of product comparability studies needed to support manufacturing optimizations and scale up as clinical and commercial supply demands increased.
Mesoblast said that the agreement was based on acceptance by the FDA of comparability data from its initial set of manufacturing runs for clinical product to be used in the phase III trial for congestive heart failure.
The company said that the FDA agreement on its manufacturing process applied to supply of mesenchymal precursor cells in phase III trials for additional indications.
Mesoblast climbed as much as 24 cents or 4.6 percent to $5.50, before closing down one cent or 0.2 percent at $5.25 with 327,792 shares traded.

NOVOGEN

Novogen says 67 subsidiary, MEI Pharma’s lead drug ME-344 has been named “one of the top 10 most licensable oncology products”.
Novogen said that the nomination for the mitochondrial inhibitor drug candidate ME-344 was made by Elsevier Business Intelligence and Campbell Alliance.
MEI Pharma said that projects were selected on criteria including unmet medical need, market potential, diversity of indications, strong science, multi-level partnering opportunities, potential for new opportunities beyond initial indications and corporate stability.
MEI Pharma chief executive officer Dr Daniel Gold said it was an honor to have ME-344 “considered among the most attractive oncology opportunities in the industry”.
“We believe ME-344 is a novel compound with a unique mechanism of action that has the potential to complement standards-of-care and significantly improve treatment outcomes for patients with cancer,” Dr Gold said.
“Our phase I clinical trial of ME-344 in patients with solid refractory tumors is nearing completion of enrolment and we look forward to reporting its results, along with our plans for its next phase of clinical development, during the second quarter of 2013,” DR Gold said.
Novogen fell half a cent or five percent to 9.5 cents.

SUNSHINE HEART

Sunshine Heart has requested a trading halt pending an announcement “regarding a regulatory development”.
Trading will resume on November 22, 2012 or on an earlier announcement.
Sunshine Heart last traded at three cents.

IDT

IDT lost its 'second strike' remuneration vote with 27.46 percent opposed but easily won the consequent spill resolution with 73.56 percent of the vote.
Under the 2011 Corporations Act Amendment any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
IDT had more than 25 percent vote against the remuneration report last year and today's vote triggered an automatic spill resolution (BD: Oct 12, 2012).
IDT said there were 4,320,515 proxy votes (72.54%) in favor of the remuneration report with 1,635,650 proxy votes (27.46%) against, but the spill resolution failed with 2,671,557 proxy votes against the spill (73.56%) and 960,346 proxy votes (26.44%) in favor.
Resolutions on the election of directors Dr Roger Aston, Robert Burnet and chairman Dr Graeme Blackman were passed overwhelmingly.
IDT has about 43.2 million shares on issue, so the strongest opposition came from 3.7 percent of all shares on issue, insufficient to requisition extraordinary general meetings.
IDT was unchanged at 20 cents.

CIRCADIAN TECHNOLOGIES

Circadian came within 500,000 votes of a first strike on its remuneration report with 21.52 percent opposition, despite the resolution being carried "on a show of hands".
Circadian said that all resolutions to the annual general meeting were passed on "a show of hands" with 2,640,434 proxy votes (21.52%) opposing the company's remuneration plan and 9,624,645 proxy votes (78.48%) in favor.
There was similar dissent against the re-election of director Dominique Fisher and the issue of 88,226 'performance shares' to chief executive officer Robert Klupacs.
The greatest dissent was against a subsequent approval of the issue of shares with 3,250,014 proxy votes (27.5%) against and 8,564,922 proxy votes (72.5%) in favor.
Circadian's most recent Appendix 3B share issue announcement said there were 48,544,794 shares on issue, meaning that the strongest opposition came from 6.7 percent of all shares on issue, sufficient to requisition extraordinary general meetings.
Circadian fell half a cent or 1.3 percent to 37 cents.

BIOXYNE

Bioxyne says that to save money, chief executive officer David Radford will work part-time and directors will receive half their fees in shares.
Bioxyne said Mr Radford would work reduce his hours and salary by 40 percent reducing his salary from $400,000 a year to $240,000 a year.
The company said it was focused on the development of HI-064OV for chronic obstructive pulmonary disease, with Vaxine with a further study planned for 2013 (BD: Sep 24, 2012).
Earlier this year Bioxyne's 320-patient phase IIb trial of HI-164OV did not met its exacerbations of chronic obstructive pulmonary disease endpoints (BD: June 28, 2012).
Bioxyne said the director shares would be issued at a five-day volume weighted average price prior to the end of each quarter.
Bioxyne fell 0.3 cents or 9.4 percent to 2.9 cents.