Biotech Daily

Wednesday March 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: USCOM UP 18%, ANTISENSE DOWN 22%**

*** STRONGBRIDGE 'CASH POSITION' RETURNS ANTISENSE ATL1103**

*** AVITA CLAIMS REGENERCELL EFFICACY FOR VENOUS LEG ULCERS**

*** FEDERAL GOVERNMENT TO TRANSFER SYNCHROTRON TO ANSTO**

*** IDT EXTENDS THIOTEPA CONTRACT $13m, 4 YEARS**

*** SIEMENS PAYS UNIVERSAL BIO MILESTONES FOR LOWER STRIP PRICES**

*** US PATENT FOR ATCOR SPHYGMOCOR BLOOD PRESSURE TEST**

*** TISSUE THERAPIES CREATES US SUBSIDIARY FACTOR THERAPEUTICS**

*** HAAKMANS, DUSSMAN INCREASE, DILUTED TO 37% OF SIMAVITA**

*** REGENEUS PLEADS SCHULTZ, 'MEDIA' TO ASX 70% QUERY**

*** TOM BLOOMFIELD REPLACES PRIMA CO SEC DEANNE MILLER ON LEAVE**

MARKET REPORT

The Australian stock market climbed 0.96 percent on Wednesday March 9, 2016 with the ASX200 up 49.2 points to 5,157.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded.

Uscom was the best, up 2.5 cents or 17.9 percent to 16.5 cents with 6,320 shares traded, followed by Osprey up 10.2 percent to 27 cents with 107,133 shares traded. Admedus climbed 8.3 percent; Biotron and Mesoblast were up more than six percent; IDT rose 5.3 percent; Neuren and Sirtex improved more than four percent; Actinogen, Anteo and Bionomics were up more than three percent; Acrux, CSL and Prima rose more than two percent; with Cochlear, Impedimed, Pro Medicus and Psivida up by less than one percent.

Antisense led the falls, down 1.2 cents or 21.8 percent to 4.3 cents with 648,451 shares traded. Benitec and Clinuvel fell more than seven percent; Compumedics was down 5.3 percent; Universal Biosensors fell four percent; Ellex, Living Cell, Orthocell and Polynovo were down more than three percent; Avita and Medical Developments shed two percent or more; Nanosonics fell 1.4 percent; with Resmed, Reva, Starpharma and Viralytics down by less than one percent.

ANTISENSE

Antisense says that Strongbridge has handed back COR-004 or ATL1103 for endocrinology applications, including acromegaly, citing its “cash position”.

Last year, the Trevose, Pennsylvania-based Strongbridge, formerly known as Cortendo, paid Antisense a non-refundable upfront fee of $6.2 million in a licence deal worth up to $131 million (BD: May 15, 2015).

Antisense managing director Mark Diamond told Biotech Daily at that time that Cortendo would pay for all further development of ATL1103 for endocrine applications, while Antisense would retain the rights for all other indications as well as the commercialization rights of ATL1103 for endocrine applications in Australia and New Zealand.

In 2014, Antisense said that a 26-patient, phase II trial of ATL1103 for acromegaly met is primary efficacy endpoint (BD: Sep 3, 2014).

Antisense has previously investigated ATL1103 for diabetic retinopathy, nephropathy and some forms of cancer (BD: Oct 12, 2009; Apr 11, 2011).

Also last year, Strongbridge attempted to raise $US87,632,875 in a US initial public offer to list on the Nasdaq and fund its programs, but in October said it had raised $US25 million.

Today, Antisense said that Strongbridge wanted “to prioritize its resources and development work on other areas of its endocrine portfolio”.

Antisense quoted Strongbridge saying that “a consequence of this project prioritization enables it to fund operations into the fourth quarter of 2017”, which would be after the expected receipt of data from its lead drug candidate COR-003 phase III ‘Sonics’ trial for Cushing’s syndrome.

Mr Diamond told Biotech Daily today that Strongbridge had manufactured a batch of clinical grade ATL1103 and had filed for orphan drug designation for ATL1103 in both Europe and the US.

Mr Diamond said that Strongbridge was conducting toxicology studies and the status of those studies was yet to be defined.

In a media release, Antisense said that Strongbridge had passed on feedback from the US Food and Drug Administration in relation to its development plans for ATL1103, which Antisense was reviewing with its own scientific and regulatory experts.

Antisense said it was assessing its contractual position on the intended termination of the licence.

The company said it would regain control of, and have all rights to develop and commercialize, ATL1103 with the orphan drug designations from the FDA and European regulators, expected by June 2016.

Antisense said that Strongbridge had manufactured a non-clinical batch of ATL1103 for animal safety studies.

The company said that it was currently conducting an open-label, higher dose study of ATL1103 in four acromegaly patients, dosed with ATL1103 up to 300mg twice weekly for 13 weeks, with the dosing of two patients completed and no reports of any serious adverse events related to dosing.

Antisense said that a third patient began dosing on February 2, 2016 and the screening of a potential fourth patient was in progress.

The company said that it was not aware of any clinical of non-clinical findings in the development of ATL1103 that prevented its further commercialization.

In 2010, Israel’s Teva Pharmaceuticals handed-back ATL1102 for multiple sclerosis after working on the compound for two years (BD: Feb 11, 2008; Mar 24, 2010).

Antisense fell 1.2 cents or 21.8 percent to 4.3 cents.

AVITA MEDICAL

Avita says a 52-patient clinical trial of Regenercell for chronic venous leg ulcers showed statistically significant improvements in wound healing, pain and quality of life.

Avita said that the randomized, multi-centre trial showed significant decreases in wound size from the time of treatment to the end of the 14-week study, with wounds in the Regenercell group closing an average of 9.1cm^2 compared to 1.2 cm^2 for the control group of conventional medical therapy (p = 0.014).

The company said that In addition to significant decreases in wound size, patients in the Regenercell group reported significant drops of nearly 2 points on a 10-point pain rating scale two weeks after treatment (p = 0.017) compared to the control group, which showed no decrease in pain after two weeks.

Avita said that the Charing Cross venous leg ulcer questionnaire quality of life measure showed consistent improvements for social interaction, domestic activity, emotional status and cosmetic appearance.

The company said that despite the small sample size, statistical significance was shown on the emotional status portion of the questionnaire (p = 0.044).

Avita said that there was no difference in the adverse event rate observed in the Regenercell and control groups, with all adverse events consistent with those seen in similar patient populations, supporting the low-risk profile associated with the skin cell harvesting approach.

The company said that non-significant trends included complete wound closure of 26.9 percent in the Regenercell group compared to 15.4 percent in the control group, with larger ulcers of 10cm^2 to 80cm^2 showing a closure incidence of 23.1 percent in the Regenercell group, compared to 7.1 percent in the control group.

Avita said that larger ulcers “appeared to heal in nearly half the time, with first closure of large ulcers happening in a mean time of 43 days with Regenercell, versus 84 days in the control group”.

The company said that “treatment using Regenercell definitively places the wounds on a healing trajectory”.

Avita said that the positive results indicated that the cellular suspension delivered by Regenercell showed “great promise” as a treatment for healing chronic wounds that had resisted other approaches in a sizable area of unmet medical need and a statistically-powered pivotal trial was justified.

The company said that the results bolstered its strategy of extending its regenerative medicine device beyond its traditional market of burns, into larger medical indications.

Avita said that in the UK, 1.65 percent of the population aged more than 65 years had venous leg ulcers, costing the National Health Service more than GBP1billion ($A1.92 billion) a year, mainly from on-going home visits for dressing changes of treatment-resistant ulcers.

The company said that the condition was increasing as the population aged, with a potential market of more than 12 million people in the main markets, including 3.2 million patients in the US.

Avita research and technology vice-president Andrew Quick said that venous leg ulcers “tend to be a hidden epidemic, because patients are largely immobile and unseen in their homes”

“We believe this positive data demonstrates that our treatment approach could become a frontline therapy, if we find in a wider population that we can reduce patient pain, improve their life quality, and of course, heal them,” Mr Quick said.

Avita fell 0.2 cents or two percent to 9.8 cents with 1.6 million shares traded.

FEDERAL GOVERNMENT, AUSTRALIAN SYNCHROTRON

The Federal Government says that it supports transferring ownership of the Australian Synchrotron to the Australian Nuclear Science and Technology Organisation.

In a media release, the Minister for Industry, Innovation and Science Christopher Pyne said that the Government had committed $520 million to the Synchrotron under the National Innovation and Science Agenda.

Mr Pyne said that ANSTO was “best placed to own the Synchrotron given its long-standing record of operating large-scale landmark research infrastructure”.

“The Government committed $520 million to the Synchrotron as part of the NISA, to operate the Australian Synchrotron for the next decade, should the facility transfer to ANSTO,” Mr Pyne said.

In announcing the $520 million for the Synchrotron in the Agenda last December there was no mention of a change of ownership (BD: Dec 7, 2015).

An ANSTO spokesman told Biotech Daily that ANSTO had been managing the Synchrotron since 2012.

Mr Pyne said that change of ownership would “ensure continual access to the unique properties of the Synchrotron’s light beams, as researchers will be able to reveal in exquisite detail the innermost structures of a range of materials”.

“This has applications for many industries, including mining, manufacturing, food security, the environment, energy, bio-security and health,” Mr Pyne said.

The media release said that the transfer of ownership was expected to happen in July 2016, subject to successful negotiations with shareholders, including the Victorian Government.

“While they may not know it, the Synchrotron affects many Australians every day,” Mr Pyne said. “It has allowed medical researchers to make critical breakthroughs in health care, supporting the development of life-saving treatments.”

“Given the importance of the Synchrotron, it is not surprising that many champions and supporters of science, research and innovation have worked behind the scenes to position the Government to make this decision,” Mr Pyne said.

IDT AUSTRALIA

IDT says it has secured an additional four years of contracted earnings, worth up to $13.4 million, for its oncology drug active pharmaceutical ingredient Thiotepa.

IDT said it was one of a small number of manufacturers of Thiotepa, a drug used in relapsing hormone-dependent cancers, which was seeing market growth through its use in preparing patients for bone marrow transplants.

The company said that the current agreement, with an unnamed German pharmaceutical customer, was scheduled to expire at the end of 2016, but the exclusivity and minimums covered by the extension applied for a further two years in one major jurisdiction and four years for the rest of the world, and both parties would be free to develop products using the active ingredient material.

The company said that the volumes contracted to be sold were 67 percent above 2015 levels in the first two years of the extension and during the period of exclusivity the price increased by 57 percent over the previous contractual price.

IDT said that the aggregate impact of the changes would result in income over the next five years of $12.2 million to $13.4 million, at today’s exchange rate.

The company said that the agreement extension can be re-negotiated and further extended with the consent of both parties at its conclusion.

IDT was up 1.5 cents or 5.3 percent to 30 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says Siemens has agreed to advance $US3.75 million ($A5.05 million) in milestones in return for reduced initial test strip prices.

Universal Biosensors said that Siemens Healthcare Diagnostics would prepay all outstanding milestone payments by July 2016.

Universal Biosensors chief financial officer Salesh Balak told Biotech Daily that the changes were a benefit for the company.

"Although we are taking a smaller fee on lower tiers of sales volumes, we will receive $US3.75 million at least a year ahead of schedule and we help make Siemens more competitive through those early sales," Mr Balak said.

Mr Balak said that there were three programs the company agreed to undertake for Siemens, with the first program the the Xprecia Stride blood coagulation analyzer, completed in 2014 and granted Conformité Européenne (CE) mark (BD: Dec 9, 2014).

Mr Balak said that Universal Biosensors was entitled to $US1 million milestone payments relating to each of the next two programs but one of those had been dropped and replaced.

Mr Balak said that the $US1 million milestone for the dropped program had been transferred to a new, fourth program, along with Siemens agreeing to an additional $US1.25 million milestone for that program.

Mr Balak said that Universal Biosensors had agreed to a reduction in the price of the test strips manufactured and supplied to Siemens for the Xprecia Stride blood coagulation test, applicable only to the sale of product at the lower volume tiers.

In a media release Universal Biosensors said that the reduction in strip price would "provide Siemens with greater flexibility during the early stages of product introduction".

The company said that, to date, it had been paid a total of $US8 million for five of the seven milestones under the collaboration agreement.

Universal Biosensors said that with Siemens it had agree "to focus resources on an alternative product that offers the potential for greater return on investment to both companies".

Universal Biosensors chief executive officer Paul Wright said that the prepayment would provide the company "with additional cash resources in the short term, while the realignment of our development program with Siemens ensures we are working on projects that offer the greatest return on our collective investment in the longer term".

Universal Biosensors fell 1.5 cents or four percent to 36 cents.

ATCOR MEDICAL

Atcor says the US Patent and Trademark office has allowed a patent entitled 'Brachial Cuff' providing coverage until May 2031.

Atcor said the patent was closely similar to the patent awarded in Japan in February "and further confirms Atcor's position as the leader in this field".

In February, Atcor said that Japan has granted a patent entitled 'Brachial Cuff' for measuring central aortic pressure waveforms using a standard brachial cuff with a transfer function (BD: Feb 17, 2016).

Today, Atcor chief executive officer Duncan Ross said the patent strengthened the company's market position "as we continue rollout of Sphygmocor to doctors in the $US800 million clinical practice market".

Atcor was unchanged at 17.5 cents.

TISSUE THERAPIES

Tissue Therapies says that it has established a wholly-owned US subsidiary company Factor Therapeutics USA LLC for its US operations.

Tissue Therapies, which said it was trading as Factor Therapeutics, said that Factor USA was a Delaware-domiciled company, with the same governance structure as the Australian parent, and would establish a contracting platform in the US, as well as manage human capital in relation to US-based clinical activities planned for later this year.

Tissue Therapies executive director Dr Christian Behrenbruch said the company had "previously articulated our intention to become more US-centric in our development activities and this subsidiary formation is part of executing the administrative changes necessary to enable this".

"The formation of a US company is also relevant to being flexible with our near-term executive search goals," Dr Behrenbruch said.

Tissue Therapies said that it had begun the search for several regulatory and quality assurance staff in Australia and the US, to support planning clinical activities.

The company said that its regulatory and intellectual property director Dr Hedie Meka had resigned.

Tissue Therapies was unchanged at four cents.

SIMAVITA

Simavita says Dussman and directors Damien and Justin Haakman have increased their holdings from 31,493,464 shares to 38,160,131 shares, but were diluted to 36.64 percent.

In a second complicated and confusing Canadian regulatory filing, the Narre Warren South, Melbourne-based Dussman said it was acting as the trustee for Devonia Investment Trust, the Charolais Super Fund No 2 and the Charolais Super Fund No 3 (BD: Aug 7, 2014).

Today, Dussman, Damien Haakman and Justin Haakman said that Dussman acquired 6,666,667 Chess depositary interests at 15 cents each and 1,333,333 unlisted options exercisable at 15 cents by March 2, 2017 (BD: Jan 25, 2016).

In 2014, in a similar filing, Dussman said that it acquired 6,168,880 Chess depositary interests at 45 cents a share in a then recent placement (BD: Jun 19, 23, 2014).

The 2014 regulatory filing did not say that Damien Haakman was a non-executive director of Simavita, which was disclosed in a separate, previous ASX Appendix 3Y Change of Director's Interest Notice.

In an announcement entitled 'Important Announcements and Strategy Update' Simavita said Mr Haakman would retire as a director on February 29, 2016 (BD: Feb 16, 2016).

Simavita was up 0.2 cents or four percent to 5.2 cents.

REGENEUS

Regeneus has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price climbed from 9.1 cents on March 2 to 15.5 cents, a 70.3 percent increase, today, March 9, 2016 and noted an increase in trading volumes.

Regeneus said that it was the subject of media coverage on February 28 and 29, 2016 following its January 12, 2016 announcement of positive safety data from its stem cell trial for knee osteoarthritis, as well as its February 29, 2016 half-yearly reports (BD: Jan 25, 2016).

Regeneus fell one cent or 7.4 percent to 12.5 cents.

PRIMA BIOMED

Prima says that Tom Bloomfield has been appointed as company secretary while general counsel and company secretary Deanne Miller is on maternity leave.

Prima said that Mr Bloomfield's appointment is effective from March 8 and Ms Miller will take leave from March 16, 2016.

The company said that Mr Bloomfield was the general manager of share registry Boardroom's corporate secretarial services and was the company secretary to ASX-listed, unlisted and private companies.

Prima said that Mr Bloomfield held a law degree and a graduate diploma in applied corporate governance.

Biotech Daily wishes Deanne all the best for her maternity leave.

Prima was up 0.1 cents or 2.6 percent to four cents with 4.1 million shares traded.