Biotech Daily

Thursday November 7, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PATRYS UP 24%, GENETIC TECHNO DOWN 8%**

*** PRIMA TRIAL CHANGES, DROPS LICENCE, ISRAEL-PALESTINE DEAL**

*** NOVOGEN, YALE JOINT VENTURE CANTX FOR OVARIAN CANCER**

*** CENTENARY INSTITUTE, MIRRX COLLABORATE ON miRNA BLOCKMIR**

*** J&J'S LIFESCAN ENDS UNIVERSAL BIOSENSORS TEST STRIPS**

*** BIOTECH DAILY IS EIGHT, TODAY**

*** UNILIFE CEO ALAN SHORTALL REBUTTS US LEGAL ACTION**

*** UNILIFE PLEADS SCHULTZ, US LAW SUIT TO ASX 16% FALL QUERY**

*** ANTEO'S CEO DR GEOFF CUMMING STARTS ON $400k**

*** PHYLOGICA REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.22 percent on Thursday November 7, 2013 with the S&P ASX 200 down 11.8 points to 5,422.0 points. Nineteen of the Biotech Daily Top 40 stocks were up, six fell, 10 traded unchanged and five were untraded. All Big Caps rose.

Patrys was the best, up 0.9 cents or 23.7 percent to 4.7 cents, with 34.4 million shares traded, followed by Antisense up 13.3 percent to a post-10-to-one-consolidation 17 cents with 20,000 shares traded.

Nanosonics climbed 5.4 percent; Anteo, Avita, Benitec, Mesoblast and Universal Biosensors were up more than four percent; Atcor, Ellex and IDT were up more than three percent; Cellmid, QRX and Starpharma rose more than two percent; GI Dynamics, Impedimed, Osprey and Sirtex were up more than one percent; with Cochlear, CSL, Resmed and Tissue Therapies up by less than one percent.

Genetic Technologies led the falls, down 0.5 cents or 7.7 percent to six cents with 1.1 million shares traded.

Allied Health lost 6.25 percent; Prana fell 4.3 percent; Pharmaxis was down 3.85 percent; Circadian shed two percent; with Bionomics down 1.4 percent.

PRIMA BIOMED

Prima hopes to re-start its phase II/III second remission ovarian cancer trial by July 2014, begin a resected pancreatic cancer trial and drop breast and colorectal cancer indications.

In a teleconference, Prima chief technical officer Dr Sharron Gargosky said that the company had reviewed the phase II CAN-003 trial results, which showed no significant difference in progression free survival for the combined first and second line remission patients, but said that there was “a favorable progression-free survival signal in second line remissions”.

Dr Gargosky said that changes to the CAN-004 or Canvas trial included no further recruiting of first remission patients, while continuing to treat those enrolled and a new cohort of 210 second remission patients randomized one-to-one for CVac and control with a primary endpoint of overall survival.

Prima chief executive officer Matt Lehman told the teleconference that the company was in the process of submitting the changed protocols to regulators to the end of 2013 and expected to restart the trial by July 2014, with a 12 to 15 month recruitment period.

Mr Lehman said the trial would have annual efficacy reviews, concluding “probably towards the end of 2016”.

“Without a doubt we have experienced a significant setback with first remission patients, but we have gained experience, have a good team and a good cash balance,” he said.

He said the CAN-003 trial overall survival data was expected by the end of 2014.

Mr Lehman said that the company had shelved plans for trials in breast and colorectal cancer “for the time being”.

“We do believe they will benefit [from CVac treatment] but the timelines for overall survival data is too long and not the best use of resources,” Mr Lehman said.

Mr Lehman said Prima would proceed with the single-arm, 40-patient, pilot CAN-301 resected, post surgery, pancreatic cancer trial also expected to begin by July 2014.

Mr Lehman said that CAN-301 trial was expected to provide information on whether to proceed with a further trial, with endpoints of safety, overall survival and immune response.

He said that the subset of pancreatic cancer patients with a good surgical outcome had better overall survival than the total group, with different response profiles dependent of surgical outcomes.

Mr Lehman said that the licence agreement to mucin-1 patents held by the Seattle, Washington-based Oncothyreon (formerly Biomira) had been terminated and the patents had expired in all jurisdictions except Canada where they were due to expire in 2014 and the US where they would expire in 2014.

He said that terminating the agreement removed potential $8.5 million milestone payments but a new licence might need to be negotiated with Oncothyreon if CVac was to be commercialized in the US before 2018.

Mr Lehman announced a profit-sharing agreement with the Tel-Aviv, Israel-based Neopharm for CVac in both Israel and the Palestinian Territories.

He said that following reimbursement for manufacturing costs, Prima would receive 50 percent of all net profits as well as “minor development milestone payments”.

Prima chief financial officer Marc Voigt said that the company had $31.37 million in cash at September 30, 2013 and a projected loss for the year to June 30, 2014 of $14 million.

Mr Voigt said there had been a significant take up in American depository receipts, each equivalent to 30 Australian shares, from two hundred in July 2013 to nearly 2.5 million in October 2013.

Prima climbed as much as 0.5 cents or 12.8 percent to 4.4 cents but closed unchanged at 3.9 cents with 15.8 million shares traded.

NOVOGEN

Novogen says it has created a joint venture Cantx with Yale University to develop chemotherapy strategies for ovarian cancer.

Novogen said it would own 85 percent of Cantx which would bring together its drug technology platform which was capable of killing ovarian cancer cells as well as ovarian cancer stem cells with Yale's in-vitro and in-vivo tests for evaluating the clinical potential of the drugs.

The company said Cantx would based in New Haven, Connecticut-based with research and development at the New Haven laboratories of Yale Medical School's Prof Gil.

Novogen said that Prof Mor was the first researcher to isolate ovarian cancer stem cells: responsible for initial ovarian tumor growth and tumor recurrence following chemotherapy.

Novogen said it would retain ownership of its drug technology intellectual property and grant Cantx access for drug development purposes only.

The company said that it would continue to exploit the same intellectual property for a range of other clinical indications including glioblastoma, along with its newly-acquired anti-tropomyosin drug technology.

Professor Mor said there had been "no new therapies for ovarian cancer for the past 30 years and a fresh approach is urgently needed".

"Current chemotherapy unfortunately only does half the job," Prof Mor said.

"It is reasonably effective at killing the predominant somatic cancer cells, but by not killing the cancer stem cells," Prof Mor said.

"Around 70 percent of patients who respond to first round chemotherapy will eventually experience tumor recurrence," Prof Mor said.

"Our experience with the Novogen super-benzopyran family of drugs leads us to believe that this is the future," Prof Mor said.

"These drugs show a high degree of activity against ovarian cancer stem cells where no other drug in our experience has worked," Prof Mor said.

"This program will be the first in the world dedicated to finding an effective treatment for ovarian cancer, with the advantage that promising treatments are capable of being moved quickly into clinical studies in months instead of years," Prof Mor said.

Novogen chief executive officer Dr Graham Kelly said the joint venture with Yale "brings a level of expertise, resources and firepower that is unique in the field of ovarian cancer".

Dr Kelly said the fight against ovarian cancer would occur on two fronts with a variant of lead drug candidate Trilexium "identified as a powerful killer of ovarian cancer stem cells and is being packed into a delivery system specially designed by Prof Mor's laboratory that is to be given intra-peritoneally, the abdominal cavity, where it seeks out ovarian cancer cells."

"When anti-cancer drugs are injected intravenously, usually only three percent or so of the drug actually reaches the tumor," Dr Kelly said. "With this delivery system, virtually all injected drug reaches the tumor, thereby ensuring maximum anti-cancer effect."

Dr Kelly said the second front was longer-term through personalizing chemotherapy.

"As we make small structural changes to these drugs, we find that they change their target," Dr Kelly said.

"Each super-benzopyran drug is highly efficient at killing cancer stem cells from the one individual, but no single drug is able to kill cancer stem cells across all individuals," Dr Kelly said. "This leads us to conclude that we have identified for the first time a family of drugs capable of identifying different mutations within a cancer."

Dr Kelly said Cantx would create a panel of drugs able to kill cancer stem cells across a range of patients so that appropriate drugs could be matched to individual tumors.

Novogen fell two cents or eight percent to 23 cents with 1.2 million shares traded.

CENTENARY INSTITUTE OF CANCER MEDICINE AND CELL BIOLOGY

Sydney's Centenary Institute says it will work with Mirrx Therapeutics to develop oligonucleotide drug candidates targeting vascular endothelial cadherin (VE-cadherin).

The Vejle, Denmark-based Mirrx said that it was developing novel, micro-RNA (miRNA) blocking technology, Blockmirs, which were antisense oligonucleotides that selectively bound to a micro-RNA binding site on a target messenger RNA (mRNA).

Mirxx said the approach blocked single miRNA-to-mRNA interactions, resulting in targeted regulation of specific mRNAs, potentially reducing unintended effects on gene activity observed using more conventional miRNA antagonists.

Mirxx said the Mirrx Centenary Institute lead drug candidate CD5-2 exemplified this selectivity by preventing miR-27a regulation of VE-cadherin, while allowing miR-27a to regulate its other messenger RNA targets

The Institute's media release said that pharmacological modulation of VE-cadherin expression had the potential to treat a broad range of diseases for which regulation of vascular permeability and angiogenesis were important, including ischemic conditions, inflammation, oedema and solid tumors.

The Institute said that the agreement included cross-licensing of patents, collaborative research and joint commercialization activities.

The Institute said that VE-cadherin was a key cell-cell junctional protein in the endothelial lining of the blood vessels that regulated junctional structure and downstream signalling events, including regulation of vascular permeability and promotion of normal angiogenesis.

Mirrx and Centenary said they discovered that VE-cadherin expression was regulated in-part by the micro-RNA miR-27a.

The media release said that this negative regulator was itself down-regulated during angiogenic processes, for example after an ischemia event, leading to increased expression of VE-cadherin and reduced vascular permeability and stimulation of angiogenesis.

The Institute said in-vivo CD5-2 studies in a variety of animal models demonstrated that the drug potently inhibited vascular permeability and promotes angiogenesis, leading to increased blood flow, decreased oedema and faster recovery, for example, in the industry standard hind limb ischemia mouse model.

Mirrx and the Centenary Institute said they had published the discovery and characterization of CD5-2 in the journal Blood, in a paper entitled 'Regulation of vascular leak and recovery from ischemic injury by general and VE-cadherin-restricted miRNA antagonists of miR-27a'.

Mirrx chief executive officer Dr Thorleif Møller said the Centenary Institute had "to the best of our knowledge … provided the first therapeutic in-vivo proof of concept for blocking micro-RNA binding sites in messenger RNA".

"Moreover, the partnership has validated our second generation Blockmir design with improved specificity and potency," Dr Møller said.

Centenary Institute executive director Prof Mathew Vadas said that "leaky blood vessels, as manifest by tissue swelling that can ultimately obstruct blood supply, is a very important clinical problem from the emergency room all the way to rehabilitation".

"The potential of a useful drug preventing vascular leak is very exciting and we look forward to its clinical development in collaboration with Mirrx," Prof Vadas said.

The Sydney-based biotechnology commercialization company Bio-Link Australia said it facilitated the Mirrx and Centenary Institute discovery of CD5-2 and the collaboration and commercialization agreement and it was engaged to facilitate licencing of CD5-2 to a biopharmaceutical company for further development and commercialization.

UNIVERSAL BIOSENSORS

Universal Biosensors says Johnson & Johnson's Lifescan will manufacture its own Onetouch Verio blood glucose test strips effective from December 31, 2013.

Universal Biosensors had been paid one US cent per strip under the quarterly service fee agreement with Lifescan, which continues irrespective of the manufacturer of the strips.

For the year to December 31, 2012, Universal Biosensors received service fees of $2.2 million implying as the sole manufacturer it made about 220 million strips and received product revenue of $19.4 million implying that the strips sold for about 8.8 cents each (BD: Feb 14, 2013).

Today, the company said that the quarterly service fees were a key driver for its business.

Universal Biosensors chief executive officer Paul Wright told Biotech Daily that despite the revenue from the manufacture of the strips, the profit margins were tight.

Mr Wright said that 30 of the about 100 staff worked in manufacturing with some of those continuing on the Siemens blood clot tests project, but there would be staff reductions following the end of the manufacturing contract.

Universal Biosensors said that the change would enable it "to focus its manufacturing capabilities and resources on its exclusive long term supply arrangements with Siemens and other opportunities that are expected to generate higher margins".

The company said it would "free-up significant cash resources that would otherwise have been committed to working capital for blood glucose test strip manufacturing".

Universal Biosensors said that due to the reduction in revenues associated with test strip manufacturing it would qualify for a 45 percent refundable tax offset on its eligible research and development costs in 2013, expected to be a cash inflow of about $5 million to $6 million and increase the likelihood of being eligible for the Federal Government tax credit in 2014.

The company said that it would restructure its organization to reduce direct and indirect operating costs associated with Verio production wherever possible.

Universal Biosensors was up 2.5 cents or 4.7 percent to 56 cents.

BIOTECH DAILY

Biotech Daily is eight years old today.

We have published about 2,000 editions in that time and to the best of our knowledge not missed a single important news announcement.

Every mistake (to which we have been alerted) has been corrected and the 'Backcopies' page of the website has every article back to May 2008.

Without counting the number of articles published, this year certainly feels like it has been our busiest, with an increasing number of backdoor listings and one initial public offer, Regeneus, vying for space with greater interest from research facilities and private and unlisted companies.

Biotech Daily has continued to enjoy a net increase in subscribers and has noted a particular interest in the sector from Western Australia-based companies and investors, as well as from overseas.

Our subscribers have allowed Biotech Daily to be the journal-of-record for the industry, eschew all paid advertising and report without fear or favor.

It is a great privilege to publish real journalism about the most exciting sector in Australia.

To our subscribers and readers, we thank you all very much.

David Langsam
Editor

UNILIFE

Unilife chief executive officer Alan Shortall says a US law suit naming him, the company and other officers of the company “is entirely meritless”.

“This law suit has been brought under US securities law by a shareholder holding a very small parcel of shares and mostly repeats the allegations of a lawsuit filed by a former employee, which we are in the process of defending and which we believe to be groundless,” Mr Shortall said.

“The former employee claims that he was terminated in retaliation for reporting alleged regulatory violations by Unilife,” Mr Shortall said.

“However, the former employee was in fact terminated due to poor performance and we believe filed the lawsuit in retaliation after Unilife refused to comply with his demand for severance payments, which he was not entitled to due to the reasons for his termination,” Mr Shortall said.

“We are being advised by lawyers in the US with respect to both of these claims and they have informed us that, in the US, securities law claims of this nature are not uncommon as a means of opportunistic lawyers trying to attract clients,” Mr Shortall said.

“I am confident that Unilife will prevail with regards to both of these claims and can assure you that Unilife will vigorously defend itself against these actions,” Mr Shortall said.

“With respect to the allegations made in these claims, I can assure all of you that Unilife is in full compliance with all applicable regulatory requirements,” Mr Shortall said.

Mr Shortall said that two regulatory compliance audits of the company’s quality system were performed this year with “no deviations from applicable quality standards … noted”.

Mr Shortall said the audits were carried out performed by National Standards Authority of Ireland and the US Food and Drug Administration.

The Wayne, Pennsylvania-based law firm Ryan & Maniskas said that it had filed a class action lawsuit in the US District Court for the Middle District of Pennsylvania on behalf of all persons or entities that purchased the common stock of Unilife between July 13, 2011 and September 9, 2013.

Ryan & Maniskas said that the complaint alleged that the defendants “made materially false and misleading statements and omitted materially adverse facts about the company’s business, operations and prospects”.

Ryan & Maniskas said the complaint alleged the defendants concealed from the investing public that the Unifill syringes failed to comply with the FDA validation process;) the company’s quality management system failed to comply with FDA regulations; the company purposefully increased its purchases of Unifill component parts to make suppliers believe Unilife was producing at increased volumes despite the fact that there was no customer demand or manufacturing capacity to support such purchases; and as a result the company’s statements were materially false and misleading at all relevant times.

Ryan & Maniskas alleged that “as a result of defendants’ false and misleading statements, the company’s stock traded at artificially inflated prices during the class period”.

Ryan & Maniskas said the complaint alleged that on August 30, 2013, a former Unilife employee filed a complaint alleging that Unilife terminated his employment for reporting various regulatory violations to the appropriate authorities, including that Unilife “ran fake production at its facility in order to lead visiting investors to believe that demand for the company’s products were high”.

Ryan & Maniskas alleged that the company purposefully suppressed internal reports demonstrating that the cost of developing the company’s syringes was higher than the price the company was able to sell to customers and Unilife failed to comply with the FDA’s required validation process.

Unilife was up 4.5 cents or 10.5 percent to 47.5 cents with 1.7 million shares traded.

UNILIFE

Unilife 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 fell 16 percent from 50 cents on November 5, to 42 cents on November 6, 2013 a 10.5 percent fall and noted an increase in trading volume.
Unilife said there was no information it had not published other than the US lawsuit (above).

ANTEO DIAGNOSTICS

Anteo says that chief executive officer Dr Geoff Cumming's updated three year remuneration package includes a base salary of $400,000 a year, plus superannuation.
Anteo said the contract would be reviewed annually and included a short-term incentive cash bonus pending revenue targets and a long term incentive of 6,000,000 unlisted options with an exercise price of 12 cents within four years from the date of issue.
Anteo was up 0.3 cents or 4.35 percent to 7.2 cents with 11.7 million shares traded.

PHYLOGICA

Phylogica has requested a trading halt "pending the release of an announcement in relation to a capital raising".
Trading will resume on November 11, 2013 or on an earlier announcement.
Phylogica last traded at 2.1 cents.