Biotech Daily

Wednesday August 28, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ANTISENSE UP 25%, QRX DOWN 19%**

*** WEHI TEST FOR COELIAC DISEASE SHOWS GREATER PREVALENCE**

*** MORE DATA DELAYS QRX 6 MONTHS, 2014 LAUNCH HOPES**

*** FDA APPROVES 286-PATIENT HEARTWARE DESTINATION TRIAL EXTENSION**

*** CYCLOPHARM H1 REVENUE UP 15% to $5m, LOSS DOWN 23% TO $986k**

*** CIRCADIAN REVENUE DOWN 22% TO $1m, LOSS UP 2% TO $5m**

*** IMPEDIMED REVENUE DOWN 8% TO $3m, LOSS DOWN 31% TO $8.5m**

*** BRAIN REVENUE DOWN 34% TO $4m, PROFIT TURNS TO $1.5m LOSS**

*** PROGEN REVENUE UP 24% to $3.5m, LOSS DOWN 39% TO $2m**

*** ECO QUEST 100m DIRECTOR'S OPTIONS EGM**

*** WILSON HTM REDUCES TO 5.3% OF UNIVERSAL BIOSENSORS**

*** MICHAEL KAVANAGH REPLACES NANOSONICS CEO RON WEINBERGER**

*** SUNSHINE HEART APPOINTS DR PATRICK VERTA CHIEF MEDICAL OFFICER**

MARKET REPORT

The Australian stock market fell 1.05 percent on Wednesday August 28, 2013 with the S&P ASX 200 down 54.0 points to 5,087.2 points. Fourteen of the Biotech Daily Top 40 were up, 15 fell, five traded unchanged and six were untraded.

Antisense was the best, up 25 percent to 1.5 cents with 15.6 million shares traded, followed by Allied Health up 12.05 percent to 9.3 cents with 53.0 million shares traded. Reva climbed 8.2 percent; Tissue Therapies rose 7.5 percent; Pharmaxis was up 3.7 percent; Acrux, Osprey and Patrys rose more than two percent; with Anteo, Clinuvel, Phosphagenics, Sirtex and Viralytics up more than one percent.

QRX led the falls, down 20.5 cents or 18.9 percent to 88 cents with 1.45 million shares traded, followed by Phylogica down 11.8 percent to 1.5 cents with 925,000 shares traded and Prana down 10.4 percent to 60.5 cents with 1.7 million shares traded. Optiscan lost 10 percent; Neuren fell seven percent; Genetic Technologies fell 4.4 percent; Cellmid was down 3.3 percent; Alchemia and GI Dynamics shed more than two percent; with Ellex, Medical Developments, Nanosonics, Prima and Starpharma down more than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its staff have developed a new approach to detecting coeliac disease, showing it is more common than previously recognized.

The Institute said that in a 2,500 subject study the researchers combined antibody testing measuring the immune response to gluten, with an assessment of specific genetic risk markers.

WEHI said the study more than half of the subjects had genetic risk factors for developing coeliac disease.

The research paper, entitled 'A novel sero-genetic approach determines the community prevalence of celiac disease and informs improved diagnostic pathways' has been published in the journal BMC Medicine, but at the time of publication was not available on-line.

WEHI said that Dr Jason Tye-Din and Dr Bob Anderson, worked with Barwon Health, Deakin University, Healthscope Pathology and the University of Queensland Diamantina Institute to develop and trial the new diagnostic approach.

Dr Anderson began the research at the Walter and Eliza Hall Institute and has been appointed the chief scientific officer of the Cambridge, Massachusetts-based Immusant.

Dr Tye-Din said the new approach of combining the genetic test with a panel of antibody tests would increase the accuracy of testing, decrease overall medical costs by reducing invasive diagnostic tests, and avoid medically unnecessary use of a gluten-free diet.

"Currently, bowel biopsies are recommended for anybody with positive antibody tests," Dr Tye-Din said.

"In this study the inclusion of a simple genetic test helped identify a substantial number of people whose antibody tests were falsely positive and who did not actually require a bowel biopsy to test for the possibility of coeliac disease," Dr Tye-Din said.

WEHI said that coeliac disease was caused by an inappropriate immune response to dietary gluten found in wheat, rye, barley and oats.

The Institute said that when gluten was consumed, it could cause a wide range of complaints from chronic tiredness, iron deficiency, osteoporosis, itchy rash and headaches to various digestive symptoms.

WEHI said that coeliac disease damaged the lining of the small intestine and could lead to significant medical complications such as autoimmune disease, infertility, liver failure and cancer.

The Institute said that coeliac disease usually developed in childhood and was life-long, but early diagnosis and treatment could reduce the risk of adverse health complications.

Dr Tye-Din said the new testing strategy showed coeliac disease potentially affected at least one in 60 Australian women and one in 80 men, while previous estimates had the number of Australians with coeliac disease as no more than one in 100.

WEHI said Dr Tye-Din was also a gastroenterologist at the Royal Melbourne Hospital and said the findings were surprising and shed light on the medical burden of coeliac disease.

"It is concerning that a significant number of people in the community with coeliac disease have not been diagnosed," Dr Tye-Din said.

"Making a diagnosis based on a blood test alone or commencing a gluten-free diet without a confirmatory bowel biopsy is inappropriate and can impose an unnecessary and lifelong treatment," Dr Tye-Din said.

"Although small bowel biopsy is needed to confirm coeliac disease it is costly and invasive," Dr Tye-Din said," Reducing unnecessary procedures is better for patients, eliminating an invasive test, and better for the economy by reducing healthcare costs."

"This study provides a strategy to improve the diagnosis of coeliac disease in the community by combining the benefits of antibody and genetic testing."

QRX PHARMA

QRX says that despite a 'complete response letter' from the US Food and Drug Administration it expects to launch its dual opioid Moxduo in 2014.

QRX said that the FDA would “allow time to submit and evaluate further information required for the FDA to fully consider the respiratory safety advantages of Moxduo from Study 022”.

FDA complete response letters can be final rejection notices, but QRX chief executive officer Dr John Holaday told Biotech Daily this morning that more data would be filed and discussions about the approval of the dual opioid Moxduo were continuing with the FDA.

QRX chief operating officer Dr Edward Rudnic told a teleconference that, previously, the FDA had approval, approvable and non-approvable letters but the latter two had been merged into complete response letters and the current letter was equivalent to an approvable letter, requiring more information.

Dr Holaday told the teleconference that QRX needed to file data from the Study 022 which had been brought into question, following the discovery that oxygen saturation time data was incorrect due to incorrect settings for time zones and daylight savings times at one centre (BD: Jun 26, 2013).

Dr Holaday said that the data had been corrected and checked for more than 30 million oxygen saturation data values from all of the 375 patients who received Moxduo, morphine or oxycodone, but it had not been filed in time for the August 26, 2013 Prescription Drug User Fee Act (PDUFA) date.

Dr Holaday said that the remaining data, rather than the entire new drug application, would be filed “in the next few weeks” and the FDA would have six months from filing to respond.

“We believe we are on-track for a launch in 2014,” Dr Holaday said.

In a media release QRX said it submitted amendments to its new drug application on August 9 and 14, 2013, but the FDA said that additional time was required to complete and evaluate supporting documentation.

The company said the FDA previously confirmed that the combination rule trial (Study 008) satisfied efficacy requirements and that there were no safety issues in any of the studies submitted as part of the original application.

Last year, QRX fell 71 percent on the FDA complete response letter rejecting its application for Moxduo IR and requiring further data (BD: Jun 27, 2012).

In June 2013, QRX said that data for 64 of the 375 subjects at a single trial site in Study 022 comparing Moxduo to equi-analgesic doses of morphine or oxycodone had incorrect time codings that needed to be corrected (BD: Jun 27, 2013).

QRX chief executive officer Dr John Holaday said at that time the adjusted data would be filed “in the next several weeks” and the Prescription Drug User Fee Act date would be delayed from August 26 to November 2013.

The equi-analgesic dose study Study 022 provided mixed results when Moxduo (12mg morphine and 8mg oxycodone) was compared to either 24mg morphine or 16mg oxycodone alone (BD: Jun 14, 2012).

“We remain confident in MOXDUO as a potential therapeutic option for the millions of patients suffering from moderate to severe acute pain and will continue our efforts and work with the FDA and our partners to bring this therapy to market,” Dr Holaday said.

QRX said that Moxduo was being developed for moderate to severe acute pain, a $US2.5 billion segment of the $US8 billion spent annually on prescription opioids in the US.

QRX fell as much as 28.5 cents or 26.3 cents to 80 cents, before closing down 20.5 cents or 18.9 percent to 88 cents with 1.45 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has approved an additional patient cohort for its 'Endurance' pivotal, destination therapy study.

Heartware said the FDA approved an investigational device exemption supplement for up to 286 patients receiving the Heartware Ventricular Assist System, as well as up to an additional 143 control patients using a randomization scheme consistent with the Endurance protocol.

The company said that patients would be followed for 12 months after implant and that data would be incorporated with the existing Endurance data into a pre-market approval application for the Heartware system for destination therapy.

Heartware said that the protocol for the additional cohort was designed to confirm clinical observations that sites adhering to more regular monitoring and management of patient blood pressure witnessed a notably lower incidence of neurological events.

The company said that patient enrollment could begin at the 50 centers participating in the Endurance clinical trial, following institutional review board approvals at each of the centers.

Heartware said that last November the FDA approved its left ventricular assist system for the bridge-to-transplant indication (BD: Nov 21, 2012).

The company said it then began a post-approval study to assess device performance "in a real-world setting".

Heartware said that its post-approval study was a registry of 600 patients who received a Heartware ventricular assist device and an additional 600 control patients derived from a contemporaneous group of continuous flow, intra-corporeal left ventricular assist device patients entered into the Intermacs database.

The company said it expected enrollment for both arms of the study to be completed by the end of 2013.

Heartware fell two cents or 0.8 percent to $2.53.

CYCLOPHARM

Cyclopharm says that revenue for the six months to June 30, 2013, was up 15.4 percent to $4,779,759 reducing net loss after tax 22.6 percent to $986,314.

Cyclopharm said that the improvement "was due to the recognition of a tax benefit totaling $304,034 primarily from [a research and development] tax incentive refund", partly offset by increased administration expense driven by costs with prosecuting our litigation against the Australian Nuclear Science and Technology Organisation.

The company said that molecular imaging revenue was up 5.3 percent to $686,346 with Technegas "the financial foundation of the group" with earnings before interest taxation depreciation and amortization of $217,345 compared to the previous corresponding period's $257,442 loss, with volume sales of the division's key product, patient administration sets 13 percent higher than the prior year.

Cyclopharm said that diluted loss per share increased 167.2 percent from 0.64 cents in the previous year to 1.71 cents for the six months to June 30, 2013.

The company said it had cash and cash equivalents of $7,582,040 at June 30, 2013, compared to $9,032,983 at December 31, 2012.

Cyclopharm said that net tangible assets per share fell 9.1 percent to 20 cents at June 30, 2013.

Cyclopharm was unchanged at 20 cents.

CIRCADIAN

Circadian says its net loss after tax for the 12 months to June 30, 2013 was up 1.7 percent to $4,754,793 on revenue down 22.3 percent to $1,153,687.
Circadian said that royalty income, comprising 54.0 percent of all revenue, was up 22.0 percent to $622,701 for the 12 months to June 30, 2103.
The company earns royalties and licencing income for vascular endothelial growth factor (VEGF) receptor antibodies, as well as from the sale of research reagents.
Circadian said that net tangible asset backing per share fell 19.5 percent to 33 cents at June 30, 2103 compared to 41 cents in the previous period.
The company said diluted loss per share was 9.79 cents compared with 10.39 cents in the previous corresponding period.
Circadian said it had cash and equivalents of $11,003,941 at June 30, 2013 compared to $16,439,225 at June 30, 2012.
Circadian was unchanged at 27 cents.

IMPEDIMED

Impedimed says its net loss after tax for the 12 months to June 30, 2013 was reduced 31 percent to $8,464,000 on revenue down eight percent to $2,925,000.
Impedimed said that global lymphoedema revenue for the 12 months to June 30, 2103 increased by 35 percent, including a 51 percent increase in the US, while the test and measurement division fell $300,000 to $800,000 and body composition revenue fell $200,000 to $700,000.
Impedimed said that net tangible asset per share fell 44.4 percent from nine cents at June 30, 2012 to five cents at June 30, 2013.
The company said diluted loss per share was five cents compared with eight cents in the previous corresponding period.
Impedimed said it had cash and equivalents of $7.3 million at June 30, 2013 compared to $14.5 million at June 30, 2012.
Impedimed was untraded at 16 cents.

BRAIN RESOURCE

Brain says revenue for the 12 months to June 30, 2013 fell 34 percent to $3,916,000 taking last year's $388,000 net profit after tax turning to a $1,460,000 net loss after tax.
Brain said that the change in revenue "was primarily from the gain on initial recognition of the joint venture which positively impacted in 2012 and the negative impact of the US elections in 2013".
The company said that net assets per share fell six percent from 19.6 cents to 18.4 cents, while net tangible assets per share fell 55 percent from -5.6 cents to -8.7 cents.
Brain said its assets were "primarily intellectual property [which were] excluded from the NTA calculation, with the effect that the greater the value our intellectual property becomes, the lower the NTA value".
The company said that diluted loss per share was 1.57 cents compared to the previous year's earnings of 0.42 cents.
Brain said it had $3,784,665 in cash and equivalents at June 30, 2013 compared to $9,205,987 for the previous corresponding period.
Brain fell one cent or 2.8 percent to 35 cents.

PROGEN

Progen says that revenue for the year to June 30, 2013, was up 23.8 percent to $3,510,103 reducing net loss after tax 39.2 percent to $2,092,134.
Progen said that most of the revenue came from the Pharmasynth drug manufacturing business which was up 40.2 percent to $2,816,281 for the year to June 30, 2013.
The company said the decrease in loss was “mainly attributed to the decrease in research and development expenditure of $515,572 resulting from significant reduction in clinical trial costs”.
Progen said that diluted loss per share fell 46.0 percent from 13.9 cents in the previous year to 7.5 cents for the year to June 30, 2013.
The company said it had cash and cash equivalents of $1,447,774 at June 30, 2013, compared to $1,834,442 at June 30, 2012.
Progen said that net tangible assets per share fell 21.7 percent to 18 cents at June 30, 2013.
Progen fell half a cent or 2.7 percent to 18 cents.

ECO QUEST

Eco Quest will vote to issue 50,000,000 options each to chairman Dr Stewart Washer and Dr Ross Macdonald.
The company said that the free options would be exercisable at two cents a share and would expire five years after the date of issue.
Eco Quest said that 25,000,000 options each for Dr Washer and Dr Macdonald would vest on issue, with a further 15,000,000 options each when the 10-day volume weighted average price reached four cents a share and the final vesting of 10,000,000 options each when the 10-day volume weighted average price reached six cents a share.
The company said that shareholders would also vote to ratify the issue of 30,000,000 placement shares at one cent each and 45,750,000 share plan shares at one cents each.
The meeting will be held at Level 2, 1 Walker Avenue, West Perth, Western Australia on September 27, 2013 at 11.30am (AWST).
Eco Quest fell 0.2 cents or 8.7 percent to 2.1 cents with 3.3 million shares traded.

UNIVERSAL BIOSENSORS

Wilson HTM Investment Group has reduced its substantial holding in Universal Biosensors from 11,314,750 shares (6.5%) to 9,284,910 shares (5.31%).
Wilson HTM said that between May 1 and August 23, 2013, “individually managed accounts” along with Wilson HTM funds bought and sold shares with 10,500,000 shares sold for $7,143,778 or an average price of 68.0 cents a share, and 578,151 shares sold for $395,338 or 68.4 cents a shares.
Biotech Daily understands that Wilson HTM has collectively reported large numbers of transactions within its funds under the individual purchase and sale statements.
Universal Biosensors was untraded at 69 cents.

NANOSONICS

Nanosonics says it has appointed non-executive director Michael Kavanagh as chief executive officer replacing Dr Ron Weinberger, effective from October 21, 2013
Nanosonics said that Dr Ron Weinberger who is a key inventor of the technology had been appointed head of technology development and commercialization.
The company said that both positions would be directors.
Nanosonics chairman Maurie Stang said the appointments would lead the company "through its next phase of growth and reflect the strategic importance of our expansion initiative to establish Nanosonics as a global leader in advanced microbial control technologies".
Mr Stang said that Mr Kavanagh joined the board in July 2012 and had made "a significant contribution to the overall strategic growth agenda for the organization".
Nanosonics said that Mr Kavanagh had more than 20 years experience in the healthcare market and was currently Cochlear's head of marketing, an executive position he has held for 10 years
The company said that Mr Kavanagh held a Bachelor of Science from University College Dublin and a Master of Business Administration from the University of Queensland.
Mr Stang said that "central to the growth strategy is the development and commercialization of a highly innovative portfolio of technologies based on our core [intellectual property] and disinfection platform".
"To lead this effort Dr Ron Weinberger will take the newly created office of president technology development [and] commercialization," Mr Stang said.
Mr Stand said that Dr Weinberger had "extensive experience and knowledge of the infection control marketplace".
Nanosonics fell 1.5 cents or 1.7 percent to 88.5 cents.

SUNSHINE HEART

Sunshine Heart says it has appointed Dr Patrick Verta as chief medical officer.
Sunshine Heart said that Dr Verta had more than 20 years medical experience, with the majority in cardiovascular.
The company said that previously Dr Verta was Neomed's chief medical officer and vice-president of clinical affairs and before that was Abbott Vascular's medical director of clinical research and business development.
Sunshine Heart said that along with experience in clinical trials, Dr Verta had co-authored 17 manuscripts on novel medical device therapies in peer-review journals and was credited with two patents on data management and electronic data capture.
The company said that Dr Verta held a Doctorate of Medicine from the Faculté de Médecine in Paris, France as well as a Doctorate of Veterinary Medicine from the Ecole Nationale Vétérinaire d'Alfort, France and a Masters Degree in Biostatistics from the University of Paris.
On the Nasdaq last night Sunshine Heart fell 43 US cents or 3.5 percent to $US11.83 ($A13.18, equivalent to 6.6 cents prior to leaving the ASX) with 514,495 shares traded.