Biotech Daily

Wednesday October 9, 2019

Daily news on ASX-listed biotechnology companies

VALE DR JOHN HOLADAY (1945 – 2019)

*** ASX DOWN, BIOTECH EVEN: CLINUVEL UP 60%; ANTISENSE DOWN 11%**

*** CLINUVEL UP 63% ON FDA SCENESSE EPP APPROVAL**

*** ORTHOCELL: 'CELGRO WITH MICROSURGERY REPAIRS NERVE DAMAGE'**

*** PHYLOGICA: 'CPP TAKES ANTISENSE DRUG TO HUMAN RETINA IN-DISH'**

*** ZELDA, ILERA MARIJUANA MERGER FOR ZELIRA**

*** G MEDICAL TELLS ASX: 'REVENUE AWAITING APPROVALS'**

*** AUSTRALIAN ETHICAL TAKES PROFIT, REDUCES TO 18.5% IN ANTISENSE**

*** CEO KATE QUIRKE TAKES 6% OF ALCIDION**

*** KENNEDY, CALEDONIA INCREASE, DILUTED TO 8% OF ALCIDION**

*** MACKINNON, ISLE OF WIGHT INCREASE, DILUTED TO 8% OF ALCIDION**

*** IMUGENE UNMARKETABLE PARCEL FACILITY**

*** ADALTA APPOINTS DR TIM OLDHAM CEO; STARTS ON $300k**

*** RESPIRI LOSES CEO MARIO GATTINO**

*** PAINCHEK CEO PHILIP DAFFAS 11% PAY RISE**

MARKET REPORT

The Australian stock market fell 0.71 percent on Wednesday October 9, 2019, with the ASX200 down 46.7 points to 6,546.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and two were untraded. All three Big Caps fell.

Clinuvel was the best, up $16.91 or 60.2 percent to $45.00 with 1.4 million shares traded. Orthocell climbed 20.25 percent; Dimerix improved 9.5 percent; Cyclopharm was up 6.25 percent; Pharmaxis and Pro Medicus were up five percent or more; Immutep was up 4.2 percent; Compumedics and Impedimed improved more than three percent; Ellex, Kazia, Polynovo and Proteomics rose two percent or more; with Prescient up 1.8 percent.

Antisense led the falls, down 1.2 cents or 10.9 percent to 9.8 cents, with 16.5 million shares traded. Amplia lost 7.8 percent; Imugene, LBT, Oncosil, Optiscan and Uscom fell more than four percent; Neuren and Resonance were down more than three percent; Actinogen, Mesoblast, Telix and Volpara shed more than two percent; with Cynata, Next Science and Resmed down more than one percent.

VALE DR JOHN HOLADAY (1945 - 2019)

It is with great regret Biotech Daily reports that founder and chief executive officer of QRX Pharma Dr John Holaday was shot and killed in Charlotte, North Carolina.

According to close friend and former QRX chief operating officer Dr Ed Rudnic, Dr Holaday was on his way to a business meeting in the Charlotte central business district when shots were fired from a nearby alley, striking Dr Holaday in the head.

Dr Rudnic told Biotech Daily that Dr Holaday was taken to hospital and survived several days before succumbing to his wound on Saturday, October 5.

Dr Rudnic said the 16-year old who fired the shots appeared to have been involved in a drug deal and altercation when he fired several shots, one of which struck Dr Holaday.

QRX Pharma listed on the ASX in May 2007 to develop and commercialize a “dual opioid” combination of morphine and oxycodone, but met regulatory barriers at the US Food and Drug Administration.

Dr Holaday retired from QRX in May 2014 and was replaced by Dr Rudnic.

Dr Holaday was also a director of Neuren Pharmaceuticals from 2009 until 2013.

In 2009, Neuren said Dr Holaday had built five public and private biopharmaceutical companies over 21 years and raised more than $US450 million (BD: Nov 25, 2009).

The company said that Dr Holaday founded Entremed in 1992, serving as chairman, president and chief executive officer until his retirement in 2003, and was the co-founder, director, scientific director and senior vice president of Medicis Pharmaceutical Corp.

Neuren said Dr Holaday was the founder and chief of the Neuropharmacology Branch at the Walter Reed Army Institute of Research for 21 years.

The company said that Dr Holaday was Ernst and Young’s Entrepreneur of the Year in 2006, held more than 60 patents, had published more than 200 scientific articles and reviews and edited five books.

Dr Rudnic told Biotech Daily that Dr Holaday was the chief executive officer of Dispose Rx, a company commercializing a powder, invented by Dr Rudnic, that inactivated opioids, making them safe to dispose in the waste system.

Dr Holaday held a Bachelor and Master of Science from the University of Alabama, Tuscaloosa and the Doctor of Philosophy from the University of California, San Francisco.

Dr Rudnic said that Dr Holaday was married to Dori and had two sons, Sean and Jackson.

Biotech Daily met Dr Holaday many times and is shocked by the news of his untimely death. To all his family and friends, we offer our deepest condolences.

David Langsam, Marc Sinatra

CLINUVEL PHARMACEUTICALS

Clinuvel jumped 63.3 percent to $45.88 on news that the US Food and Drug Administration has approved Scenesse for erythropoietic protoporphyria (EPP).

Clinuvel said that the approval for Scenesse, or afamelanotide, was to “increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria”.

The company said that the approved labelling covered all written material about the drug, including packaging, prescribing information for physicians, and patient information leaflets, with the approved frequency and strength of 16mg once every two months.

In 2009, Clinuvel said the US Food and Drug Administration granted investigational new drug status for the photo-protective afamelanotide, allowing it to begin US trials.

The company said at that time it had posted positive interim results from a European phase III trial (BD: Jan 21, Jan 29, 2009).

Today, Clinuvel said it began trials of Scenesse, then known as CUV1647 in 2006, had FDA orphan drug designation for the erythropoietic protoporphyria in July 2008, which was followed by fast track status in May 2017 and priority review in January 2019.

Clinuvel chief executive officer Dr Philippe Wolgen said “this is one day on which all interests converge and history is written both for the US EPP patient community and investors who have actively supported our mission for the last 14 years”.

“The FDA approval of Scenesse as a new molecular entity and medical innovation is memorable for this company and for the Australian life science sector,” Dr Wolgen said.

Clinuvel said it completed a US phase III trial in 2013, subsequently published in the New England Journal of Medicine and in 2016, the FDA requested the full data sets of its erythropoietic protoporphyria trials.

The company said the FDA organized a workshop on erythropoietic protoporphyria in Silver Spring to which 150 patients and families were invited to share their experiences and the new drug application was made as a 505(b)(1) application containing integrated reports on safety and benefits, manufacturing processes and adequacy of proposed labelling, as well as Clinuvel’s post-marketing proposals to clinically follow-up erythropoietic protoporphyria patients over the long-term.

Clinuvel said that as part of the review, the real-world evidence from the European distribution of Scenesse was reviewed by the Agency.

The company said that yesterday, the FDA’s Center for Drug Evaluation and Research approved the NDA for Scenesse, following an extension of its review on May 31, 2019.

Clinuvel said that under the Orphan Drug Act of 1983, the FDA granted Scenesse seven years of market exclusivity from competitors for the designated use in erythropoietic protoporphyria, whereby a further extension of two years can be granted once a paediatric product has been approved.

The company said that Scenesse would be monitored by the US Office of Surveillance and Epidemiology which is charged with the responsibility to oversee the safe use of Scenesse during commercial distribution.

Clinuvel said that the FDA agreed with the intention to harmonize the US erythropoietic protoporphyria disease registry with one established in Europe by Clinuvel to monitor long-term use of Scenesse.

The company said that erythropoietic protoporphyria was an inherited metabolic disorder of the heme biosynthesis pathway which caused lifelong phototoxicity due to the accumulation and storage of the compound protoporphyrin IX in the blood and tissues, and when exposed to visible light and near-visible ultraviolet radiation, protoporphyrin IX was activated, causing damage to surrounding tissue.

Clinuvel closed up $16.91 or 60.2 percent to $45.00 with 1.4 million shares traded.

ORTHOCELL

Orthocell says Celgro nerve regeneration with microsurgery on 12 patients restored voluntary movement in 24 of 25 (96%) nerve repairs to previously paralysed muscles.

Orthocell said that following surgery with Celgro, patients “regained muscle function in the affected limbs and have either ceased or significantly reduced prescription pain medication, including opioid-based medications.

The company said the 12-month data from 12 of the 20 patients in the 24-month study showed that six of seven patients (85.7%) who required pain medication, including opioid-based medications, were able to significantly reduce or stop their medication completely.

Orthocell said that quadriplegic patients with damage to their fifth cervical spine were treated with Celgro, along with patients with peripheral and brachial plexus nerve damage.

“All quadriplegic patients increased movement and power of affected muscles following Celgro,” the company said.

Orthocell clinical trial lead Dr Alex O’Beirne said that the progress of the initial patients gave him “the confidence to use Celgro in more severe cases, such as quadriplegia”.

“The microsurgery required to return arm or hand function to quadriplegic patients is complex and challenging, and can require multiple nerve repairs,” Dr O’Beirne said.

“Celgro facilitates tensionless repair and can prevent regenerating nerves being compressed or trapped by scar tissue,” Dr O’Beirne said.

Orthocell said that trial participants had traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents, resulting in impaired use of the affected limbs and, in more severe cases, quadriplegia, that is, the partial or total loss of use of all four limbs and torso), with some patients experiencing significant pain and unable to perform basic daily tasks and many unable to work.

The company said that 16 patients had been recruited to the trial with the final four expected by the end of 2019.

Orthocell said that patients received one or several nerve repairs augmented with Celgro in one or both upper limbs, with functional recovery assessed by grading the power of target muscles closest to the site of nerve repair.

The company said that at 11 of 25 nerve repairs were performed in three quadriplegic patients, with 18 of 25 (72%) nerve repairs resulting in meaningful functional recovery of affected muscles within 12 months.

Orthocell said that a quadriplegic patient with complete paralysis regained sufficient arm and hand function to perform tasks such as brushing teeth, drinking from a cup, and transferring into and out of his wheelchair.

The company said that over a 12-month period 11 nerve repairs in patients with quadriplegia improved from more than nine points of damage (80 percent) having no voluntary movement to eight showing functional recovery, or “voluntary movement with improved strength and range of motion” and the balance showing “voluntary movement restored, [with] limited strength and range of movement”.

Orthocell managing-director Paul Anderson said the results “reinforce the initial patient outcomes previously reported from our clinical study demonstrating improved predictability and consistency of return of muscle function following Celgro … treatment”.

“Seeing one of our patients progress from no strength in his arm and no movement in his fingers and thumb, to playing wheelchair rugby is extremely encouraging for our researchers and clinical partners,” Mr Anderson said.

“Our team is accelerating regulatory applications in the US, EU and Australia to make this treatment accessible to the more than 700,000 people who experience nerve damage annually,” Mr Anderson said.

Orthocell rose eight cents or 20.25 percent to 47.5 cents with 31.8 million shares traded.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says its cell penetrating peptides can deliver an anti-sense oligonucleotide more than 90 percent more effective in a “human retina in a dish” study.

In August, Phylogica said its peptide technology delivered an anti-sense oligonucleotide into human retinal pigment epithelial cells in-vitro and achieved 100 percent exon-skipping, “the desired effect of a drug cargo” (BD: Aug 6, 2019).

The company said its peptide achieved 24 percent exon-skipping at one week, 15 percent at two weeks and 19 percent at three weeks in mice (BD: Aug 22, 2019).

Today, Phylogica said it created three-dimensional models of the eye from human stem cells and conducted doses in-line with its target human dosing regime, using its cell penetrating peptide technology to deliver the drug.

The company said the first evaluation of the study showed 91 percent exon-skipping, which “refers to 91 percent of the gene’s natural RNA as converted to our intended RNA”.

Phylogica chief executive officer Dr Rohan Hockings said the result would “materially increase the probability that its flagship drug program would prove effective in human studies” as a treatment for the leading cause of childhood blindness, retinitis pigmentosa.

The company said it would seek validation of the retina in a dish results across multiple patients with different genetic mutations, enabling it to begin investigational new drug application-enabling studies before progressing to human clinical trials.

Phylogica was up half a cent or 10.6 percent to 5.2 cents with 9.5 million shares traded.

ZELDA THERAPEUTICS

Zelda says it will merge with Ilera Therapeutics to form Zelira Therapeutics, a “globally integrated company to develop clinically validated cannabis medical products”.

In March, Zelda said it had a partnership with US medical marijuana company Ilera Healthcare to licence and co-develop its products and share data (BD: Mar 12, 2019).

Today, the company said it would acquire 100 percent of the Philadelphia, Pennsylvania-based Ilera Therapeutics, which spun out of Ilera Healthcare, in an all-scrip transaction, subject to shareholder approval and sale conditions.

Zelda said the merger “brings together a leading pipeline of clinical candidates, revenue generating medicines and a combined strategy to disrupt global medicinal cannabis and pharmaceutical markets” and Zelia would generate revenue from proprietary cannabis formulations developed by Ilera launched in Pennsylvania under the Hope brand.

Zelda said that Ilera had rights to Hope in markets outside Pennsylvania and had plans to market this and other products across the US and global markets.

Zelda said Ilera chairman Osagie Imasogie and directors Lisa Gray and Dr Oludare Odumosu would join the Zelira board, with Zelda chairman Harry Karvelis as deputy chairman along with directors Jason Peterson and Dr Richard Hopkins continuing and directors Mara Gordon and Dr Stewart Washer stepping down following approval.

The company said Dr Hopkins would be the chief executive officer except for the US, where Dr Odumosu would be the chief executive officer with Tom Borger US chief business officer, Dr Deborah Cooper director of clinical operations except for the US and Dr Meghan Thomas the manager of operations except for the US.

Zelda said it would acquire Ilera through 113,601,290 consideration shares and 362,620,322 class A and 362,620,322 class B performance rights, which would convert into shares on US sales of $US1,000,000 for class A and $US2,500,000 for class B.

The company said that it expected to complete the acquisition by mid-December 2019.

Zelda was up 0.3 cents or 3.85 percent to 8.1 cents with 5.1 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical has told the ASX it is awaiting regulatory approvals for its Prizma medical sensor agreements with Silverlake, Boletong, FCL, Zingmobile and Hygea.

Last week, G Medical said it was “in the process of preparing a response to an ASX query” in response to recent shareholder enquiries and a suspension from trading due to a failure to respond to an ASX query (BD: Sep 6, Sep 10, Oct 2, 2019).

Today, the ASX published G Medical’s replies to its September 2, 2019 query, which asked about the current status of its 2017 Silverlake agreement, Boletong agreement, MEDTL Medical Technologies agreement, First Channel (FCL) agreement, Zingmobile agreement, Guangzhou facility agreement and Hygea agreement in regard to regulatory approvals and purchase orders of its Prizma device and GMP Patch.

G Medical said that it was seeking approval from the National Medical Products Administration (NMPA, formerly China Food and Drug Administration) for its Prizma device and GMP Patch, US Food and Drug Administration (FDA) approval of its GMP Patch and over-the-counter FDA approval of its Prizma device.

The company told the ASX that it had not received revenues from most of the contracts as the mobile telephone-based sensors had not been approved and it could not provide timeframes for regulatory approvals because they were “outside the control of the company and may be subject to extended and unknown delays by the associated governing and regulatory bodies”.

G Medical said its Silverlake distribution agreement was in effect while it awaited NMPA approval for its Prizma device, which it expected in mid-2020 and it expected Silverlake to perform its purchase and distribution obligations, which had “not changed in any capacity since the execution of the Silverlake agreement”.

The company said its Boletong agreement remained in effect while it awaited NMPA approval for its Prizma device and it was satisfied that Boletong would satisfy agreement terms, despite the purchase timeframes passing without any purchases, due to communications with Boletong who “personally confirmed that the Boletong agreement remains unchanged”.

G Medical said its MEDTL agreement was cancelled “due to non-performance”.

The company said it received $US3,332 ($A4,942) from FCL for 21 units for sampling and testing purposes in 2018 as part of its FCL agreement but had not received Taiwanese and Indian regulatory approval “to allow for the marketing and sale and distribution of the Prizma device in Taiwan and India”.

The company said it was satisfied that FCL would satisfy agreement obligations due to communications with the company and because it “continued to pursue its regulatory approval processes”.

G Medical said it had not formalized its arrangements with its tier one partners and “is unable to confirm the timing of FCL formalising its arrangements with its tier one partners”.

The company said its Zingmobile agreement had expired “on the basis that the relevant regulatory certification condition to the Zingmobile agreement (being in-country Singapore regulatory approval for the Prizma) was not met within the requisite expiry deadline”.

G Medical said it continued to seek mandatory regulatory clearances with Zingmobile and awaited NMPA approvals for its medical devices in order to begin production and distribution from its Guangzhou, China facility.

The company said it could not anticipate when monthly payments as part of the Hygea agreement would resume because of an internal restructure at Hygea, but it was satisfied that agreement obligations for an anticipated revenue of $US21.85 million would be performed, due to a review of financial data and communications with Hygea.

G Medical was in an extended suspension and last traded at 8.1 cents.

ANTISENSE THERAPEUTICS

Australian Ethical Investment says it has reduced its substantial shareholding in Antisense from 83,833,333 shares (19.96%) to 77,735,287 shares (18.5%).

The Sydney-based Australian Ethical said that between October 4 and October 8, 2019, it sold 6,098,046 shares for $682,235 or 11.2 cents a share.

In March, Australian Ethical said it bought 16,000,000 shares in a placement at 3.3 cents a share (BD: Mar 13,18, 2019).

In 2018, Australian Ethical said it bought 46,599,422 shares at the time of an Antisense placement at 2.4 cents a share (BD: Apr 11, May 3, 8, 2018).

Antisense fell 1.2 cents or 10.9 percent to 9.8 cents with 16.5 million shares traded.

ALCIDION GROUP

Alcidion chief executive officer Katrina Doyle, known as Kate Quirke, says she has become a substantial shareholder in Alcidion with 55,542,557 shares or 6.17 percent.

The Melbourne-based Ms Quirke said that on October 4, 2019 she received 14,400,747 shares as non-cash consideration worth $727,238 for the sale of her shares in MKM Health and Patientrack (BD: Apr 24, 2018).

Alcidion fell 1.5 cents or 5.8 percent to 24.5 cents with 5.4 million shares traded.

ALCIDION GROUP

Donald Kennedy and Caledonia Nominees say they have increased and been diluted in Alcidion from 51,781,713 shares (6.43%) to 71,702,358 shares (7.96%).

In a substantial shareholder notice the Sydney-based Caledonia's director Mr Kennedy said they received non-cash considerations as repayment for loans to MKMS and was diluted following the exercise of 5,000,000 options by former director Brian Leedman.

ALCIDION GROUP

Colin Mackinnon and Isle of Wight say they have increased and been diluted in Alcidion from 51,911,713 shares (6.44%) to 70,563,015 shares (7.83%).

In a substantial shareholder notice the Sydney-based Isle of Wight director Mr Mackinnon said they received non-cash considerations as repayment for loans to MKMS and was diluted following the exercise of 5,000,000 options by former director Brian Leedman.

IMUGENE

Imugene says it has a share sale facility for holders of unmarketable parcels of its shares, worth less than $500, at 2.2 cents a share, on the record date of October 1, 2019.

Imugene said the closing date was November 27, 2019.

Imugene fell 0.1 cents or 4.8 percent to two cents with 6.6 million shares traded.

ADALTA

Adalta says it has appointed Dr Tim Oldham as chief executive officer replacing Samantha Cobb effective from October 14, 2019, starting on $300,000 a year.
Adalta said Dr Oldham had more than 20 years' experience in executive roles in Europe, Asia and Australia, was currently a director of Acrux, Immunexus and the Bio-Melbourne Network.
The company said Dr Oldham was previously "executive leader" at Tijan Ventures, the chief executive officer of Cell Therapies, Hospira's head of Asia Pacific, an executive with Mayne Pharma Europe, an executive at McKinsey & Co and a director of Respiri.
The company said that along with his base salary of $300,000, not including superannuation, Dr Oldham would be eligible for performance-based short-term incentives up to 40 percent of his base salary and 4,929,060 long-term incentive options over shares, equal to three percent of the company, exercisable at 25 cents each within six years.
Adalta was up one cent or 6.7 percent to 16 cents.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says Mario Gattino will resign as chief executive officer and it will commence its search for a new chief executive officer.
Respiri said it would provide further updates in due course.
In 2017, Respiri said that Mr Gattino had replaced executive chairman Leon L'Huillier who resumed his role as a non-executive chairman (BD: Dec 22, 2017).
In 2018, the company said that Mr L'Huillier and director John Ribot-de-Bresac were replaced by Mark Ziirsen and Brendan Mason, with Dr Tom Duthy later appointed a director (BD: May 31, Oct 24, 2018).
In November 2018, Respiri said that Mr Ziirsen, Mr Mason and Dr Duthy had been replaced by Ross Blair-Holt and Prof Bruce Thompson (BD: Nov 27, 2018).
In 2015, the then Isonea lost its fourth chief executive officer in 12 months with Greg Tunny following Stephen Tunnell, who replaced Jerry Korten who in turn replaced Michael Thomas (BD: Nov 13, 2013; Jan 19, Feb 4, Sep 24, 2014; Jan 23, 2015.
Gambling machine operator Bruce Mathieson is Isonea's major shareholder through his Investment Holdings with his last known holding 71,999,999 shares or 15.21 percent.
Respiri fell 1.25 cents or 16.3 percent to 6.4 cents with two million shares traded.

PAINCHEK

Painchek says chief executive officer Philip Daffas will have a pay rise, with his fixed salary increasing 11.1 percent from $225,000 to $250,000.
Painchek said Mr Daffas' short-term incentives would go up 25 percent from $112,500 to $150,000 and he would receive long-term incentives of $200,000.
Painchek was up half a cent or 1.5 percent to 33 cents with 2.5 million shares traded.