



Biotech Daily

Friday November 7, 2014

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market climbed 0.78 percent on Friday November 7, 2014 with the S&P ASX 200 up 43.0 points to 5,549.1 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and three were untraded.

Benitec was the best, up four cents or 6.56 percent to 65 cents with 418,697 shares traded, followed by Osprey up 6.54 percent to 57 cents with 108,954 shares traded.

Bionomics climbed 5.9 percent; Impedimed was up 4.55 percent; Pharmaxis and Viralytics were up more than three percent; Sirtex rose 2.55 percent; Avita and Mesoblast were up more than one percent; with CSL, Resmed and Starpharma up by less than one percent.

PatrYS led the falls, down 0.4 cents or 19.05 percent to 1.7 cents with 15.8 million shares traded, followed by Genetic Technologies down 18.2 percent to 1.8 cents with 229,142 shares traded.

Cellmid lost 7.4 percent; Atcor fell 6.7 percent; IDT was down 5.3 percent; Admedus, Biotron and Clinuvel fell more than four percent; Antisense. Circadian, Nanosonics, Prana and Prima shed more than two percent; Neuren and Tissue Therapies were down more than one percent; with Acrux and Medical Developments down by less than one percent.

BIOTECH DAILY NINTH BIRTHDAY EDITORIAL

Not the best day, on not the best week, of not the best year, to be trumpeting Biotech Daily's ninth birthday.

The conviction of Genetic Technologies founder Dr Mervyn Jacobson by a unanimous Supreme Court of Victoria jury on Wednesday morning was the harbinger for the tragedy that entered its final act in the County Court this morning, with former Phosphagenics chief executive officer Dr Esra Ogru, scientist Dr Robert Gianello and former Progen director Dr Woei-Jia Jiang sent to gaol for stealing more than \$6 million (see below).

Biotech Daily reports on these matters for the same reason all newspapers report criminal activity and the subsequent convictions and sentences – so that everyone knows the law and no one can say that they didn't know the penalties for breaking the law.

As Justice Felicity Hampel said in her sentencing of the Phosphagenics Three, it is hard to understand how someone with a Doctorate of Philosophy from a prestigious university, awarded the degree for providing a thesis of integrity, could not understand what was wrong with issuing false invoices.

And although there are very few direct acts of criminality detected in Australian biotechnology, there have been previous convictions, including Martin Soust at Select Vaccines, who tried to pump the share price for a bonus. Former Acuvax chief executive officer Dr William Ardrey is currently before the courts.

There are other matters that concern Biotech Daily, including extravagant claims for unproven technologies and some companies' inability to report to the ASX transparently.

This year has seen some significant technology and commercialization failures, with Prana's PBT2 not meeting its endpoint for Alzheimer's, QRX failing to win US registration for its Moxduo dual opioid, Alchemia's HA-irinotecan failing to meet its phase III endpoint, Bionomics BNC105 failing a phase II trial for kidney cancer and Phosphagenics acne treatment also failing to meet its primary endpoint.

But there has been good news. Persistence at Clinuvel had paid off, with a takeover bid preceding long-awaited European approval for Scenesse and a significant share price jump reflecting the news. Psivida also showed that tenacity is all and finally won US approval, as well as European approval, for its licenced Iluvien drug.

The sector has had a large number of significant capital raisings, Bionomics won a remarkable licencing deal from Merck for BNC375 for Alzheimer's disease, including \$20 million upfront, Shire acquired the privately run Fibrotech for about \$600 million and on the eve of a State election, the Victoria Government has been a cornerstone for a potential \$200 million Medical Translation Fund

Biotech Daily has pumped out about 250 editions a year for nine years and we believe we have not missed a single major announcement.

None of this would be possible without you, our subscribers. Thank you, kindly.

David Langsam, Editor

PHOSPHAGENICS

Former Phosphagenics chief executive officer Dr Esra Orgu, scientist Dr Robert Gianello and Dr Woei-Jia Jiang have been gaoled for stealing \$6,146,732.70 from the company.

In the Melbourne County Court, Justice Felicity Hampel sentenced Dr Orgu to six years in gaol, with a two year minimum before being eligible for parole, with co-accused Dr Robert Gianello sentenced to four years, with a minimum of two years and Dr Woei-Jia Jiang sentenced to two years and six months, with a minimum of 12 months.

The sentencing took nearly two hours as Justice Hampel explained the fraudulent invoicing conceived by Dr Orgu and initially assisted by Dr Gianello and later with the complicity of Dr Jiang and the use of companies they controlled to obtain a financial advantage by deception from Phosphagenics and its subsidiary Vital Health Sciences.

Justice Hampel said that Dr Orgu had used her position as the head of research and development and later as chief executive officer of Phosphagenics to defraud the company of more than \$6 million between November 2004 and July 2013.

Justice Hampel said that Dr Orgu determined the amounts to be claimed and the purported reasons to be given for the claims.

Justice Hampel said that Dr Orgu was charged with seven counts of obtaining a financial benefit by deception and that Dr Gianello and Dr Jiang were each charged with three counts of obtaining a financial benefit by deception.

"It's hard to understand how three people with Ph Ds in biochemistry could be pleading guilty to these charges," Justice Hampel said.

Justice Hampel said that initially the first invoices from Bynex Pty Ltd were for work done by Dr Gianello at Monash University for Vital Health Sciences outside normal hours "but this quickly changed" and all invoices were marked for the attention of Dr Orgu and she approved them for payment.

Her Honor said that there was an email correspondence between Dr Orgu and Dr Gianello.

"They were at times shocking in the gloating for the use of the funds," Justice Hampel said. "This was straight-out collusion."

Justice Hampel said that the fraud continued unchecked and undetected until 2008 when the then chief financial officer Dr Hodges was concerned about Dr Gianello's involvement in Bynex and Dr Orgu sought to distance Dr Gianello from Bynex. Dr Orgu allayed Dr Hodges fears but the Bynex scam came to an end.

Justice Hampel said that Dr Orgu had a chance meeting with Dr Jiang and they had discussions about running a legitimate business for locating offshore contract research organizations for Phosphagenics, including ways of making this a profitable venture.

Her Honor said that on May 1, 2008, Dr Ogru's first child was born with the fatal genetic disease, molybdenum cofactor deficiency type A, and immediately began a search for a cure, eventually discovering the drug cPMP in development in Cologne, Germany.

Justice Hampel said that Dr Ogru emailed Dr Gianello to get Dr Jiang to send invoices, saying: "We need to get the cash flowing quickly".

Justice Hampel said the mechanism for Dr Jiang sending invoices from TABridge Pty Ltd was established along with "the division of the spoils" which took considerable time to prepare "with no pause to consider the legality and morality".

Justice Hampel said that in 2013 Phosphagenics appointed a new chief financial officer, Anna Legg, who raised concerns about the TABridge invoices. Dr Ogru took steps to conceal the fraud and after Ms Legg reported the matter to Phosphagenics audit committee, Dr Ogru attempted to have Ms Legg dismissed from the company and Ms Legg went to co-chief executive officer Harry Rosen.

Justice Hampel said that the seventh charge related to the commercialization of cPMP, in which Dr Ogru created a joint venture with Dr Gianello and inventor Dr Guenter Schwarz and charged Phosphagenics for its activities. In 2011, the US based Alexion Pharmaceuticals bought the joint venture paying \$US680,000 to Dr Ogru and Dr Gianello.

"This is bare-faced fraudulent activity ... and the ill-gotten gains went to lifestyle spending," Justice Hampel said.

Her Honor said that after the birth of Dr Ogru's first child the method of fraud changed but a relatively small amount went on caring for her child, while much of the spending was on lifestyle and the credit card spending claimed from Phosphagenics was the same before and after the birth of her child.

Justice Hampel said that a Doctorate of Philosophy implied a rigor in research and companies should be able to believe that a Ph D graduate had integrity. Her Honor said that Dr Ogru had committed "a profound breach of trust" and had she needed money "Mr Rosen would have provided funds if you asked", which Justice Hampel said was also the case for Dr Jiang.

Justice Hampel said that as Dr Gianello had been Dr Ogru's doctoral supervisor at Monash University "you should have been modelling integrity both before and after."

Justice Hampel told the three that their reputations were in tatters, that Dr Ogru had lost her family home, albeit acquired by her father and rented back to her family, while Dr Gianello and Dr Jiang had both lost their family homes.

Justice Hampel said that apart from these charges, all three had been of good character and had no prior convictions, all three had pleaded guilty and had cooperated with the Australian Securities and Investments Commission investigation.

Justice Hampel said that about \$5.2 million of the more than \$6 million was likely to be recouped and all three had signed deeds with Phosphagenics to repay the funds including future earnings and any revenue from the cPMP acquisition.

“Each of you are shamed, your families have already suffered hardship and will continue to suffer hardship,” Justice Hampel said.

“You epitomized the success story of the intelligent, hard-working child of immigrant parents and excelled at school,” Justice Hampel told Dr Ogru. “You wanted everything in a hurry and had a sense of entitlement.”

Justice Hampel said that the needs of Dr Ogru’s first child were considerable and that tempered the sentence, but the motive was greed, before and after the birth of the child.

Justice Hampel said that Dr Ogru’s work on cPMP had led to the saving of 12 other babies lives, “but defrauding Phosphagenics cannot be justified as an altruistic advancement of science” and said the amounts defrauded and personal benefit were \$6 million and \$4 million, respectively, over nine years in “a sophisticated fraud with many layers of concealment”.

For the seven charges, Justice Hampel sentenced Dr Ogru to a term of six years imprisonment with a minimum of two years to be served before she would be eligible for parole, and noted that if not for the guilty plea, the penalty would have been eight years with a minimum of three years.

Justice Hampel said that although Dr Gianello was a dedicated scientist and a devoted father with “an impressive array of supporting character references” and was 60 years of age and unlikely to find work, creating hardship for his wife and young son, the funds he received “went to lifestyle, not saving lives” and he received significant personal benefit in a sophisticated and sustained fraud.

Justice Hampel sentenced Dr Gianello to four years imprisonment with a two year minimum before being eligible for parole.

Justice Hampel said that Dr Jiang had not sought to blame anyone else and had fully cooperated once the fraud had been uncovered.

Her Honor said that Dr Jiang had joined the other two in an established fraud and perhaps because they were trusted friends and Dr Ogru and Dr Gianello had no compunction about their actions that might have “clouded your judgment”.

As Dr Ogru took steps to cover-up the fraud Dr Jiang accepted his wrong-doing and resigned from the board of Progen and told Progen and Phosphagenics director Stuart James of the involvement, Justice Hampel told the court.

“You have paid about \$100,000 more than your personal benefit and signed a deed for continued payments,” He Honor said.

Justice Hampel sentenced Dr Jiang to two years and six months imprisonment with a 12 months minimum before being eligible for parole.

Phosphagenics was unchanged at 7.2 cents.

See also Biotech Daily: July 1, 22, 24, 2013; Jun 11, Aug 20, 21, 22, Oct 9, 2014.

[NOVOGEN](#)

Novogen says that through its Cantx joint venture with Yale University, drug candidate Cantrixil has shown efficacy for late-stage ovarian cancer in mice.

Novogen said that Cantrixil was a construct of the cytotoxic anti-cancer drug candidate, TRXE- 002-1, in a cyclodextrin, or sugar, ball.

The company said that Cantrixil was designed to be injected into body cavities such as the peritoneal and pleural cavities, to seek and destroy cancer stem cells, primarily responsible for the initiation of cancer, its spread, and its continued growth in the face of chemotherapy.

Novogen said that Cantrixil was being developed as a first-line, second-line and salvage therapy for ovarian cancer, and for the treatment of the late-stage conditions, malignant ascites and malignant pleural effusion, with a phase I study to be conducted in women with late-stage ovarian cancer unresponsive to standard therapy.

The company said that Cantrixil passed an animal model of first-line therapy in ovarian cancer and a follow-up study was conducted to test efficacy in an animal model of refractory ovarian cancer.

Novogen said that to date, no drug had produced any lasting or meaningful inhibition of the growth of the cancer in this model, which involved the injection of human ovarian cancer stem cells into the peritoneal cavity of mice where they attached and grew on the abdominal organs, as they do in women.

The company said that the tumors displayed the same appearance and range of cell types as found in their human counterparts.

Novogen said that the mice were treated with paclitaxel, the standard first-line chemotherapy used in ovarian cancer, producing a temporary anti-cancer effect, followed by rapid tumor growth despite ongoing paclitaxel treatment, again mimicking what happens in late-stage ovarian cancer in women.

Novogen chief executive officer Dr Graham Kelly said that when Cantrixil was injected into the peritoneal cavity of the mice with paclitaxel-resistant cancers, "tumor development in the great majority of mice was completely eradicated".

"In fact, microscopic examination of the abdominal tissues could detect no evidence of micro-metastases of cancer stem cells, suggesting that Cantrixil had been effective in wiping out the cancer via its ability to kill the cancer stem cells," Dr Kelly said.

"The great majority of experimental drugs fail in the clinic after showing encouraging anti-cancer activity in animals," Dr Kelly said.

"One of the main reasons for this is that the animal model is completely unrepresentative of the human situation," Dr Kelly said.

"Cantx has gone to extraordinary lengths to produce an animal model that is as close to the human situation as it is possible to get, certainly a far more stringent test than has ever been used for any other drug targeting ovarian cancer," Dr Kelly said.

"The fact that Cantrixil has produced such a dramatic and durable anti-cancer effect in this model gives us every confidence that we can deliver a comparable effect in the clinic," Dr Kelly said.

"I consider this a major step forward for both Novogen and for patients with ovarian cancer," Dr Kelly said.

"And to people who would point out that this effect is still only pre-clinical, I would respond that to the best of my knowledge, this effect is beyond anything that any other drug has achieved, whether it is in the clinic or not," Dr Kelly said.

Novogen was in a suspension for a capital raising and last traded at 12 cents.

VIRALYTICS

Viralytics says that Cavatak in combination with checkpoint inhibitors produces superior efficacy in a mouse melanoma study, compared to either agent alone.

Viralytics said that it presented the data on the activity of Cavatak (Coxsackievirus A21) in combination with mouse homologues of either the anti-CTLA-4 monoclonal antibody, Ipilimumab or the anti-PD-1 monoclonal antibody, Pembrolizumab, two checkpoint inhibitors at the Society for Immunotherapy of Cancer meeting in National Harbor, Maryland.

The company said that in both cases, the combination of Cavatak with the checkpoint inhibitor produced superior efficacy outcomes in a mouse melanoma study, compared to the efficacy of either agent alone.

Viralytics chief executive officer Dr Malcolm McColl said the updated results of Cavatak used in combination with the checkpoint inhibitor agents was “a major opportunity for Viralytics to contribute to an exciting new field of cancer treatment”.

The company said that the poster was presented by chief scientific officer Dr Darren Shafren and was entitled ‘Combination of a novel oncolytic immunotherapeutic agent, Coxsackievirus A21 and PD-1 or CTLA-4 blockade significantly reduces tumor growth in an immune competent mouse melanoma model’ and is available on the company’s website.

Viralytics was up one cent or 3.6 percent to 29 cents.

PATRYS

Patrys says that “due to complications in the manufacturing process there will be a delay in the availability of the finished product for the planned trial” of PAT-SM6 for cancer.

Patrys said the problems that occurred with the process “were unforeseen but have now been solved”.

In March, Patrys reported that four of 12 patients in its phase I/IIa trial of PAT-SM6 for refractory or relapsed multiple myeloma had stable disease with two patients stable for more than 130 days, with then chief executive officer Dr Marie Roskrow saying the results “strongly support further evaluation of PAT-SM6 in combination with carfilzomib which is the basis of our planned Amgen-sponsored clinical trial.” (BD: Mar 27, 2014)

In May the company said it expected to begin the combination trial by the end of 2014 (BD: May 28, 2014).

Today, Patrys said that the delay would impact the timing in obtaining approval for the trial from the Paul Ehrlich Institut and the trial was expected to begin by July 2015.

Patrys fell 0.4 cents or 19.05 percent to 1.7 cents with 15.8 million shares traded.

NANOSONICS

Nanosonics annual general meeting cast 24,646,228 votes (17.0%) against the re-election of director Dr David Fisher, with 120,187,812 votes (83.0%) in favor.

The company’s most recent Appendix 3B new issue announcement said that Nanosonics had 264,332,826 shares on issue, meaning that the votes against Dr Fisher amounted to 9.3 percent of the company, sufficient to requisition extraordinary general meetings.

The remuneration report was passed overwhelmingly.

Last year, chairman Maurice Stang faced opposition from 23.6 percent of votes cast at the annual general meeting (BD: Nov 8, 2014).

Nanosonics fell 2.5 cents or 2.5 percent to 98.5 cents with 944,830 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it is on a 45-day Nasdaq notice to comply with maintaining a minimum of \$US2.5 million (\$A2.9 million) in stockholder equity.

Genetic Technologies said that the Nasdaq letter said that the company reported that for the year ended June 30, 2014 it reported stockholders' equity of about \$US1.7 million and it did not meet the alternatives of market value of listed securities or net income from continuing operations, it longer complied with the Nasdaq Marketplace Listing Rules.

The company said that the Nasdaq letter said it had 45 days, until December 22, 2014, to submit a plan to regain compliance and if the plan was accepted, it could be granted an extension of up to 180 days from November 5, 2014 to evidence compliance.

Genetic Technologies said the deficiency notice did not immediately affect its Nasdaq listing.

The company said the Nasdaq rules only applied to trading on the Nasdaq Capital Market and not ASX trading.

Genetic Technologies fell 0.4 cents or 18.2 percent to 1.8 cents.