



# Biotech Daily

Friday May 29, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: GENETIC TECHNOLOGIES UP 16%, OPTISCAN DOWN 9%**
- \* **EX-AVANTOGEN, ACUVAX DR WILLIAM ARDREY 4-YEARS GAOL**
- \* **ALCHEMIA TUMBLES 58% ON FONDAPARINUX 47% SALES FALL**
- \* **GORDAGEN PHASE I SUB-LINGUAL VITAMIN E TOCOTRIENOLS TRIAL**
- \* **NOVOGEN APPLIES FOR US ANTI-TROPOMYOSIN PATENT**
- \* **SIRTEX REQUESTS 'MORE MAJOR STUDY RESULTS' TRADING HALT**
- \* **REVA AGM 18% DISSENT ON ONE RESOLUTION**
- \* **WAYNE HOLMAN, RIDGEBACK TAKE 6% OF PRIMA**
- \* **ROD GIBSON, ROSHERVILLE TAKE 5.5% OF REPRODUCTIVE HEALTH**
- \* **RAY RIDGE REPLACES REPRODUCTIVE CFO, CO SEC DONALD STEPHENS**
- \* **IMPEDIMED INVENTOR PROF LEIGH WARD WINS CLUNIES ROSS AWARD**
- \* **VICTORIA, STC MEDTECH'S GOT TALENT SELECTS FIVE FINALISTS**

## MARKET REPORT

The Australian stock market climbed 1.12 percent on Friday May 29, 2015 with the S&P ASX 200 up 64.1 points to 5,777.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, 14 traded unchanged and two were untraded. All three Big Caps were up.

Genetic Technologies was the best, prior to news after the market closed that a journal article supported its Brevagen test, up 0.6 cents or 16.2 percent to 4.3 cents with 6.1 million shares traded. Prana climbed 12.5 percent; Ellex was up 6.1 percent; Biotron rose 4.35 percent; Universal Biosensors was up 3.3 percent; Medical Developments rose 2.1 percent; Bionomics, Cochlear, CSL, Impedimed, Nanosonics, Neuren, Psivida, Resmed, Reva and Starpharma were up one percent or more; with Mesoblast up 0.3 percent.

Optiscan led the falls, down 0.6 cents or 9.4 percent to 5.8 cents with 181,455 shares traded. Antisense lost eight percent; Atcor and GI Dynamics were down more than six percent; Clinuvel, Pharmaxis and Prima fell more than four percent; Benitec was down 3.7 percent; with Avita and IDT shedding more than two percent.

## AVANTOGEN, ACUVAX, ACTIVISTIC

Former Acuvax chief executive officer Dr William Ardrey has been gaoled for four years and ordered to repay Phoenix Eagle Company \$394,759.38.

In the Perth District Court today, Justice Laurence Levy told Dr Ardrey he had been convicted after a five-week trial on 18 counts of fraud and that between February 1 and October 4 in Perth “you caused a detriment to Phoenix Eagle Pty Ltd in varying amounts.[and] the total amount in the frauds is \$394,759.38”.

Dr Ardrey was appointed chief executive officer of the then Avantogen, later Acuvax and now Activistic, on August 29, 2006 and resigned on February 9, 2011, meaning he was the chief executive officer at the time of the fraud (BD: Aug 29, 2006; Feb 9, 2011).

Justice Levy said that Phoenix Eagle, the victim company, was a small biotech health sciences company which was first incorporated in June 2002.

In a sentencing transcript provided by the Court, Justice Levy said the a director of Phoenix Eagle Tom McArthur had invented a process “whereby when any fruit or vegetable was heated and then had its pH changed by the addition of sodium bicarbonate, the end product appeared to have therapeutic effects”.

“The product resulting from this process was called Opal A or Opal 001 [and] the product ultimately was a cream that was applied topically,” Justice Levy said.

Justice Levy said that the State's case was that Dr Ardrey diverted the company away from its then project to another project called ‘Project Big Pharma’ and in doing so there were a number of deceits and/or fraudulent means perpetrated by Dr Ardrey on the company.

Justice Levy said that the prosecution alleged that Dr Ardrey, well knowing that a level of science not possessed by the company was necessary to achieve an effective licencing package, represented to the company that he could, with employment of consultants, produce such a package within varying but short timeframes and throughout his employment reassured the company they were on track to have a licencing package when he knew that an effective package could not be produced and the work his consultants were producing and being paid for was not suitable for incorporation in such a package and that the work claimed for in respect of each invoice had not been done.

Justice Levy sentenced Dr Ardrey to 18 months imprisonment on seven counts and to two years gaol on a further 11 counts.

“It's my view when I consider issues of concurrency and cumulation and totality your criminality can properly be reflected by ordering that count 13; that is, a term of two years' imprisonment, and count 15, another term of two years' imprisonment, are to be served cumulatively,” Justice Levy said.

“All other terms are to be served concurrently,” Justice Levy said. “That makes an effective total sentence of four years' imprisonment.”

“In my view given that you're 49 years old, the consequences of your offending and subsequent sentence to be imposed would not be destructive of a useful life after your release,” Justice Levy said.

“I consider that the seriousness of the offences, including the period over which you offended, the overall amount involved and the gross breach of trust are such that the only appropriate disposition for these offences is an immediate term of imprisonment; in other words, a term of imprisonment to be immediately served,” Justice Levy said.

“The offences are in my view in combination too serious,” His Honor said.

Justice Levy backdated the sentence to begin on March 3, 2015 and ordered that Dr Ardrey pay compensation to Phoenix Eagle Company Pty Ltd in the sum of \$394,759.38.

“That makes a total effective sentence of four years' imprisonment [and] you are declared eligible for parole,” Justice Levy said.

## ALCHEMIA

Alchemia fell as much as 57.8 percent to 3.5 cents on a lower than expected revenue and a dispute with fondaparinux distribution partner Dr Reddy's.

Alchemia said that its share of profit revenue for the three months to March 31, 2015 was \$US980,000 (\$1.25 million) down 34.9 percent compared to the three months to December 31, 2014 and 47.0 percent below the revenue for the three months to March 31, 2014.

The company previously said that the previous payments were prior to deductions of \$US500,000 towards yield and cost of goods improvement activities to Dr Reddy's which ended on December 31, 2014, so today's payment did not have that deduction.

Today, Alchemia said that Dr Reddy's had proposed a change in methodology for the provision of potential future sales returns, which, if accepted, would have had a very material impact on the net profit share for this quarter.

The company said it was unwilling to accept the proposed change in methodology and the trading halt and suspension were required while it worked with Dr Reddy's to agree on the net profit share due for this quarter and after lengthy discussions, Dr Reddy's agreed to calculate the net profit share using the previously agreed methodology.

Alchemia said that the fall in net profit share was largely attributable to a 27.5 percent fall in gross sales and rebates, including sales returns, offered to customers as a proportion of sales had increased, resulting in a 17.2 percent reduction in the net selling price for the three months, contributing to a 31.8 percent fall in net sales compared to the previous three months.

The company said that Dr Reddy's market share of fondaparinux sales volume in the US improved from 37.2 percent to 42.8 percent but overall fondaparinux sales volume fell by 10.3 percent and sales experienced "pricing pressure as evidenced by Dr Reddy's increase in rebates offered to customers".

Alchemia said that Dr Reddy's had taken measures such as increased rebates "to at least maintain market share of fondaparinux in the face of a decline in the total market for fondaparinux and aggressive marketing from Mylan which entered the generic fondaparinux market this quarter in replacement of Apotex".

The company said that the fondaparinux market decreased by 56.8 percent since the launch of Alchemia's generic by Dr Reddy's and unit prices have fallen by 50.1 percent over the last two years.

Alchemia said that Dr Reddy's had advised that, based on their assessment of actual sales returns of fondaparinux to date, "the current level of sales returns provision used in calculating the net profit share is unlikely to be sufficient to cover future returns of product".

Alchemia said it would work with Dr Reddy's "to review and negotiate a mutually acceptable methodology for the estimation of sales returns going forward".

"To the extent that any changes in methodology are agreed, and such changes lead to an increase in the provision for future sales returns, this may have a materially adverse impact on Alchemia's net profit share and therefore Alchemia's revenues for future quarters," Alchemia said.

"In addition, the actual volume of sales returns in the current and future quarters may also have a materially adverse impact on Alchemia's net profit share and therefore Alchemia's revenues, for those quarters," the company said.

Alchemia fell 4.3 cents or 51.8 percent to four cents with 50.1 million shares traded.

## GORDAGEN PHARMACEUTICALS

Gordagen says that Adelaide private ethics review company Bellberry has approved its 60-patient, Western Australia, phase I study of natural tocotrienols.

Gordagen said that the single ascending dose study would assess the safety, tolerability and plasma pharmaco-kinetics of its tocotrienol melt and swallow tablet formulation.

Last year, Gordagen raised \$6 million for the first stage of its over-the-counter and regulatory-directed trials of vitamin E-derived tocotrienols (BD: Feb 4, 2014).

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily at that time that vitamin E was composed of tocotrienols and tocopherols and by removing the tocopherols and administering the tocotrienols sub-lingually, or below the tongue, the company had seen increased pharmacokinetic activity, tocotrienols had shown potential against cancer, inflammatory disease, hypertension and diabetes but the results to date had been "very patchy" and Gordagen would complete trials of tocotrienols, initially for over-the-counter supplements, while identifying compounds for potential regulatory-directed trials.

Today, Gordagen said the phase I study was applicable across all of its target indications and might eliminate the need for subsequent phase I studies.

The company said that dosing was expected to begin in June 2015, be completed in 30 days and it expected results by the end of 2015.

Gordagen said the study was an open randomized controlled trial consisting of four cohorts of 12 subjects in the melt and swallow arms and two cohorts of six subjects in the oral arms and would compare several different doses of its tocotrienol formulation, administered either orally or via its melt and swallow technology, in fed and fasted states.

The company said it intended to begin a multiple ascending dose trial following the study and the combined studies would provide bioavailability information about the tocotrienol tablet formulation for a planned 2016 phase II program in exercise performance.

Gordagen said that Unison Nutraceuticals would manufacture the tablets.

Gordagen is a private company.

## NOVOGEN

Novogen says it has lodged with the US Patent and Trademark Office a patent covering a novel family of compounds within its anti-tropomyosin platform.

Novogen drug discovery and manufacture vice-president Dr Andrew Heaton told Biotech Daily that the patent was entitled '1,2,3,5-tetrasubstituted indoles and their use in the treatment of proliferative diseases' and assuming the company filed the patent under the international Patent Cooperation Treaty on May 27, 2016, the expiry date of national patents would be May 27, 2036.

In a media release, Novogen said the structurally novel compounds in the patent application were related to the original anti-tropomyosin compounds, including IAnisina.

Dr Heaton said the company's versatile approach to library based iterative design (VAL-ID) strategy had been executed on the anti-tropomyosin technology platform.

"This process has allowed us to extend the chemistry around our original [anti-tropomyosin] hit compounds, generating an entirely new family of compounds designed to target the tropomyosin protein," Dr Heaton said.

"The new family ... not only extends potential patent coverage around the [anti-tropomyosin] technology platform, but also allows us to start the design and discovery process for the next generation of [anti-tropomyosin] lead candidates," Dr Heaton said.

"We are already starting to see exciting initial in vitro data for this new family of compounds," Dr Heaton said.

Novogen fell 1.5 cents or 4.9 percent to 29 cents with 2.4 million shares traded.

### SIRTEX MEDICAL

Sirtex has requested a trading halt pending the presentation of the Sirflox clinical study results at the American Society of Clinical Oncology meeting in Chicago, Illinois.

Sirtex said the presentation and discussion on May 30, 2015 (US time) was “anticipated to yield important new information on the Sirflox study and interpretation of the results”.

In March, Sirtex requested a trading halt pending an announcement regarding the company’s Sirflox study and the following day, fell as much as 62.05 percent on news that SIR-Spheres with chemotherapy “does not result in a statistically significant improvement in the overall progression-free survival” (BD: Mar 16, 17, 2015).

Last year, Sirtex completed the 500-patient trial comparing SIR-Spheres with standard-of-care to standard-of-care alone (BD: Oct 9, 2014).

Trading will resume on June 2, 2015 or on an earlier announcement.

Sirtex last traded at \$26.68.

### REVA MEDICAL

All resolutions at the Reva annual general meeting were passed, but with up to 17.57 percent opposition to the re-election of Gordon Nye as a director.

Reva said that 16,838,190 votes (82.43%) supported Mr Nye, with 3,587,849 votes (17.57%) “withheld”.

The meeting used the US system of voting in which shareholders cannot vote against directors but “withhold” their votes and votes were counted in US shares, rather than Australian Chess depository interests (CDIs).

All other resolutions passed easily with up to 3.63 percent dissent against the issue of options and shares to directors.

Reva’s most recent Appendix 3B said the company had 33,579,778 US shares on issue meaning that the votes withheld from Mr Nye opposition amounted to 10.7 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

Reva was up half a cent or one percent to 51 cents.

### PRIMA BIOMED

Wayne Holman, Ridgeback Capital Investments and Ridgeback Capital Management have become substantial shareholders in Prima with 100,206,500 shares (5.86%).

The Miami Beach, Florida-based Rudgeback parties said they bought the shares on May 15 and 27, 2015 for \$1,809,172 or 1.8 cents a share.

Prima fell half a cent or 4.55 percent to 10.5 cents with 35.8 million shares traded.

### REPRODUCTIVE HEALTH SCIENCE

Rod Gibson and Rosherville Pty Ltd say they have become substantial shareholders in Reproductive Health with the acquisition of 2,600,000 shares (5.48%).

The Redesdale, Victoria-based Mr Gibson said Rosherville acquired the shares between April 22, 2014 and May 22, 2015 for \$489,034 or an average price of 18.8 cents a share. Reproductive Health was untraded at 13.5 cents.

### REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says Ray Ridge has replaced Donald Stephens as chief financial officer and company secretary.

Reproductive Health said that Mr Stephens would continue as a non-executive director.



## IMPEDIMED

Impedimed says that Prof Leigh Ward has won the Clunies Ross National Science and Technology Award for his work on bio-impedance spectroscopy. for lymphoedema. Impedimed said that the Australian Academy of Technological Science and Engineering Clunies Ross Award was “one of the most prestigious innovation awards in the country, given in recognition of the outstanding application of science and technology that provides economic, social and/or environmental benefit to Australia”.

The company said that Prof Ward was employed by the University of Queensland’s School of Chemistry and Molecular Biosciences and received the award in recognition for his contribution to the development of the bio-impedance spectroscopy application for lymphoedema assessment, the technology platform behind its L-Dex device.

Impedimed chief executive officer Richard Carreon said the company congratulated Prof Ward on the award.

“In the spirit of the Clunies Ross Award, Leigh’s research is a commercial success story, as well as a scientific one, and is improving the lives of many cancer patients around the world,” Mr Carreon said.

“At Impedimed we are very proud to work with such a ground-breaking technology and will continue to honor Prof Ward’s lifelong research and contribution to the development of bio-impedance spectroscopy application for lymphoedema assessment”.

Impedimed was up one cent or 1.05 percent to 96 cents.

## VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster (STC) says that five finalists have been selected to receive \$20,000 each in seed funding and prizes in its Medtech’s Got Talent competition. The Cluster said the finalists in the Victoria Government supported competition would continue to the accelerated technology road-mapping training and mentorship program and the final selection, to be held on August 7, 2015.

The STC said that the finalists included Jennifer Tang and Jarrel Seah for their project Eynaemia, making anaemia screening as simple as taking a selfie; Kyle Slater, David Sly and Luke Campbell for Nuraloop, a non-invasive, rapid and portable hearing diagnostic device; Shane Battye, Indra Kurniawan and Raven Erata for Pathobin, enhancing patient diagnosis with digital pathology; Jacqueline Savage and James Bell for Medpro, a remote drug delivery and patient monitoring system using a portable drug infusion and patient monitoring device for improved chemotherapy delivery management; and Andrew Yap and Bernard Duchesne for Medtasker, a medical communication platform that enabled task management, escalations and proactive critical alerts.

The Cluster said that the inaugural people’s choice award went to Shane Battye.

STC said that Medtech’s Got Talent was part pitch competition, part accelerator offering resources, skills development and seed funding to high-potential early-stage medical technology start-ups.

STC said that the program’s intense timelines provided “a fast and soft fail approach to rapidly get projects ready and able to attract seed investment” and would culminate in an investor boardroom pitch, which would select an overall winner, who would receive an additional \$40,000.

STC chief operating officer Dr Laura Faulconer said there were “more fundable ideas than there were finalist positions, meaning that the five finalist positions were selected by the narrowest of margins”.

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