



Biotech Daily

Wednesday April 27, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: UNIVERSAL BIO UP 8%, AIRXPANDERS DOWN 8%**
- * **VICTORIA BUDGET 2016: SOME BENEFITS, 'NO CUTS' TO BIOTECH**
- * **VOLPARA OPENS AT 50c, CLIMBS 7% TO 53.5c, CLOSES AT 50c**
- * **PRO MEDICUS \$7m FRANCISCAN HEALTH SYSTEM CONTRACT**
- * **ACRUX, ELI LILLY AXIRON SALES DOWN 3% TO \$48.5m**
- * **ALL CHANGE AT SIMAVITA, \$3m RAISED, \$3.4m TO GO**
- * **RESMED Q3 REVENUE UP 7% TO \$595m, PROFIT DOWN 3% TO \$116m**
- * **DORSAVI Q3 REVENUE UP 33% TO \$657k**
- * **BIOXYNE Q3 PROBIOTICS REVENUE UP 132% TO \$647k**
- * **ANTEO PLEADS SCHULTZ TO ASX 31% QUERY**
- * **OBJ, PROCTER & GAMBLE EXTEND COLLABORATION 5 YEARS**
- * **EX-ACUVAX DR WILLIAM ARDREY APPEALS 4 YEARS GAOL**

MARKET REPORT

The Australian stock market fell 0.63 percent on Wednesday April 27, 2016 with the ASX200 down 32.9 points to 5,187.7 points. Twelve of the Biotech Daily Top 40 companies were up, 17 fell, 10 traded unchanged and one was untraded.

Universal Biosensors was the best, up two cents or 7.7 percent to 28 cents with 80,861 shares traded. Tissue Therapies climbed 5.3 percent; Genetic Technologies was up 4.8 percent; Bionomics was up 3.2 percent; Medical Developments, Prana, Prima, Pro Medicus and Starpharma rose more than two percent; Anteo, Living Cell and Sirtex were up more than one percent; with Cochlear up 0.1 percent.

Airxpanders led the falls, down eight cents or 8.4 percent to 87 cents with 144,880 shares traded. Neuren retreated a further 6.25 percent; Actinogen, Admedus, Benitec and IDT fell more than four percent; Avita, Biotron, Compumedics, Nanosonics, Resmed and Viralytics lost three percent or more; Clinuvel, Mesoblast, Opthea, Pharmaxis and Reva shed two percent or more; Polynovo lost 1.75 percent; with CSL down 0.3 percent.

VICTORIA GOVERNMENT

In a series of media releases, the Victoria Government says new funds will be available for sectors including biotechnology and the payroll tax threshold will be raised.

A senior officer of the Department of Economic Development told Biotech Daily there were “no cuts” to the biotechnology sector in the Budget, with further announcements to come.

The State Budget, delivered by Treasurer Tim Pallas, included “a new dedicated Investment Attraction and Assistance Fund” of \$116 million to attract investors and seize upon business opportunities in overseas markets.

A media release entitled ‘More Jobs: New Investment And New Industries’ said that \$66 million would be made available to expand the network of Victorian Government business offices, including the appointment of a new deputy commissioner for Western China.

The State Government said that \$10 million would be provided to ensure Victoria was “the destination of choice for the best global business talent” and \$24 million would be invested into the state’s outbound and inbound trade programs.

The media release said that the Budget provided \$111 million in additional funding for the six “fast-growing sectors where Victoria is poised to lead the [world]: medical technologies and pharmaceuticals, international education, professional services, new energy technologies, food and fibre, and new technology in construction, transport and defence” which was an expansion of the \$200 million Government’s Future Industries Fund established in last year’s Budget.

The Government said that the tax-free payroll threshold would be raised incrementally from the current \$550,000 to \$650,000 by June 30, 2020, with the first increase to \$575,000 effective from July 1, 2016.

“By the time the measure is fully implemented, businesses with annual Victorian payrolls between \$4.8 million and \$31.5 million will have the lowest payroll tax burden anywhere in Australia,” the Budget media release said.

The media release said that up to 5,000 apprentices and trainees were displaced from training each year and a payroll tax exemption on their wages from July 1, 2016 would “encourage businesses to re-employ those who wish to complete their qualifications”.

The Budget said that \$59 million would assist the redevelopment of the Parkville Orygen Youth Mental Health clinical and research facility for younger people with mental illness.

The Budget said that \$28.5 million would support the establishment of the Office of Medicinal Cannabis and an independent medical advisory to expedite availability.

VOLPARA HEALTH TECHNOLOGIES

Volpara opened on the ASX at its \$10 million initial public offer price of 50 cents a share climbing seven percent to 53.5 cents in early trading.

Volpara has listed on the ASX under the code VHT to commercialize digital health products for the early detection of breast cancer.

The Wellington, New Zealand-based Volpara has previously said that its US Food and Drug Administration-cleared software was able to analyze breast density, which was a risk factor for cancer, indicating a likely higher incidence of breast cancer and a characteristic which could hide cancer in a mammogram (BD: Apr 18, 2016).

The company said the software transformed a digital mammogram from any supported x-ray vendor, into standardized information about the breast, to inform decision-making about next steps in cancer detection, including controlling radiation doses for scans.

Volpara said the offer was managed and fully-underwritten by Morgans Corporate.

Biotech Daily editor David Langsam participated in the initial public offer.

Volpara closed unchanged at 50 cents with 875,376 shares traded.

PRO MEDICUS

Pro Medicus says it has signed a \$7 million, seven-year contract with the Baton Rouge, Louisiana-based Franciscan Missionaries of Our Lady Health System.

Pro Medicus said that the contract was “based on a transaction licencing model” and would see its Visage 7 technology implemented at the Health System’s five acute care and specialty hospitals.

The company said that when it was fully implemented Visage 7 would be “a key component” of the Health System’s viewing platform and would be used for primary diagnoses, distribution and access to radiology images by more than 2,000 physicians through the system’s electronic health record.

Pro Medicus said that the Franciscan Health System was a shareholder of the St Louis, Missouri-based Resource Optimization and Innovation health care supply-chain organization and this was the second deal completed under the Visage ROI agreement (BD: Apr 4, 2016).

The company said that planning for the project was scheduled to begin by October 2016, with the first phase of implementation by July 2017, to coincide with the rollout of the Health System’s electronic health record system and take about 12 months to complete. Pro Medicus chief executive officer Dr Sam Hupert said the deal “demonstrates the benefits of the group purchasing deal we recently made with ROI”.

“By having the agreement in place we were able to significantly streamline the sales and contracting processes with [the Franciscan Health System] saving both parties a large amount of time and resources,” Dr Hupert said.

“It also means we will expand our footprint to the southern states of the US quicker than would otherwise be the case enabling us to build on our recent successes in the North American market,” Dr Hupert said.

Pro Medicus climbed nine cents or 2.3 percent to \$4.05.

ACRUX

Acrux says Axiron net sales for the three months to March 31, 2016 fell 5.4 percent to \$US37.0 million (\$A48.5 million) compared to the previous corresponding period.

Comparing the sales in US dollars, the fall was 5.4 percent compared to the \$US39.1 million for the three months to March 31, 2015, but in Australian dollar terms the fall was 3.4 percent.

In 2014, Acrux said that net sales for the three months to March 31, 2014 fell 26.7 percent compared to the three months to December 31, 2013, following a US Food and Drug Administration announcement that it was investigating the risk of stroke, myocardial infarction, and death in men taking testosterone products (BD: Feb 4, Apr 28, 2014).

In a separate presentation today, Acrux said that despite the FDA cardiac concerns the “testosterone replacement therapy market remains attractive and substantial in size”.

The company said that the FDA and sponsors were “working towards [a] collaborative long-term safety trial”.

Acrux said that Axiron’s market share remained consistent at about 14 percent of the total US market with quarterly net sales around the \$US40 million mark.

The company has previously said that it would be entitled to a \$US50 million royalty milestone, believed to be when global sales reached more than about \$US200 million in one calendar year (BD: Jan 31, 2014).

Acrux was unchanged at 64 cents.

SIMAVITA

Simavita says it is raising \$6.4 million with Michael Spooner and Dr Gary Pace replacing chairman Michael Brown and chief executive officer Philippa Lewis.

Simavita said that Mr Spooner had been appointed a non-executive chairman, Dr Pace would be a non-executive director, and the role of chief executive officer or managing director was redundant.

The company said that Peta Jurd had resigned as interim chief financial officer but she would remain chief commercial officer and a chief financial officer would be appointed "shortly".

In 2013, Simavita raised \$14 million to list on the ASX to commercialize its smart incontinence management (SIM) system but failed to report significant revenues with \$350,831 in revenue for the six months to December 31, 2015 and \$778,574 for the 12 months to June 30, 2015, with the 2015 annual report saying that Ms Lewis was paid \$601,448 for the year to June 30, 2015 (BD Dec 3, 2013, Aug 20, 2015).

In February, Simavita said that a review identified cost containment, revenue uplift and capital management as priorities, directors Ari Bergman and Damien Haakman would retire, Ms Lewis would reduce her annual salary by 30 percent and chairman Michael Brown's Integrated Equity Pty Ltd would be engaged for corporate advisory services for up to 16 consulting days a month for two months at a fee of \$2,500 a day (BD: Feb 16, 2016).

Today, Simavita said that it had issued secured notes raising \$3,063,000 to meet immediate obligations and provide a runway for "a major restructuring of the company's operations and implementation of a new strategy" and the notes would automatically convert into Chess depository instruments (CDIs) at five cents per CDI, on the company obtaining shareholder approval as an extraordinary general meeting to be convened as soon as reasonably possible.

The company said it was "in final discussions with other major shareholders [and] investors with the objective of raising further funds" of about \$3.4 million at the same price, subject to prior shareholder approval to the extent it exceeded the placement capacity and regulatory approval, including the approval of the Toronto Stock Exchange.

Simavita said it needed to build sales in the short term, particularly in the US and to reduce and refocus costs away from overheads, "immediately and materially".

The company said that directors Craig Holland and Warren Bingham would remain on the board for a transitional period pending the appointment of new directors.

Simavita said that Mr Spooner was company director with a track record in international finance and in the rapid growth of publicly listed companies and was currently a director of Mesoblast and was formerly a director of Pelin.

The company said that Dr Pace was a biopharmaceutical executive with more than 30 years experience in the industry and was currently a director of Resmed.

Simavita said it held a secured note deed for \$2,063,000 with Dussman Pty Ltd as trustee for the Devonia Investment Trust and entities associated with Mr Holland, Mr Bingham and Mr Brown and had issued notes for an aggregate amount of \$1 million to other non-related investors on the same terms.

The company said it had agreed to pay up to \$100,000 in reimbursement of note-holder transaction costs, except for costs incurred by Mr Holland, Mr Bingham and Mr Brown and entered a general securities deed poll granting a first ranking charge over all of Simavita's assets and undertakings in Australia in favor of each holder under the agreement.

Simavita said that Dussman held about 36 percent of its issued and outstanding CDIs and the other related note-holders were currently directors of the company.

Simavita was unchanged at 4.5 cents.

RESMED

Resmed says that revenue for the three months to March 31, 2016 was up 7.4 percent to \$US453,879,000 (\$A594,683,330) with net profit after tax down 2.8 percent to \$US88,458,000.

Resmed said diluted earnings per share was 63 US cents for the three months, down 1.6 percent compared to the three months to March 31, 2015.

The company said research and development expenditure for the quarter was up 4.0 percent to \$US28,109,000 or 6.2 percent of revenue.

Resmed fell 29 cents or 3.7 percent to \$7.59 with 6.4 million shares traded.

DORSAVI

Dorsavi says that revenue for the three months to March 31, 2016 was up 32.7 percent to \$657,000 compared to the previous corresponding period.

Dorsavi said that for the 12 months to March 31, 2016, the revenue from Australia, the US and the United Kingdom was up 139.3 percent to \$1,962,000 compared to the previous corresponding period.

The company said that it had \$7,666,000 in cash at March 31, 2016 compared to \$7,850,000 at March 31, 2015.

Dorsavi was untraded at 38 cents.

BIOXYNE

Bioxyne says revenue from sales of probiotics in the three months to March 31, 2016 was up 131.8 percent to \$647,000, compared to the previous corresponding period.

Bioxyne said that for the nine months to March 31, 2016, Bioxyne's revenue was up 38.2 percent to \$1,665,000, compared to the nine months to March 31, 2015.

In 2014, Bioxyne reported revenue for the three months to March 31, 2014 of \$933,000 with revenue for the nine months to March 31, 2014 of \$1,735,000.

Today, the company's Appendix 4C showed it was cash-flow positive with a net gain of \$258,000.

Bioxyne said that the increase in revenue "was the result of further sales of, and receipts of debtors from, its proprietary probiotic *Lactobacillus fermentum* VRI-003, PCC.

The company said that revenue from sales and royalties for the year to March was \$1,492,000, a 35.6 percent increase on the previous corresponding period.

Bioxyne said it had \$1,365,000 in cash at March 31, 2016 compared to \$1,150,000 at March 31, 2015.

Bioxyne was unchanged at 2.9 cents.

ANTEO DIAGNOSTICS

Anteo 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 rose 1.5 cents or 31.25 percent from 4.8 cents on April 20 to 6.3 cents on April 26, 2016 and noted an increase in trading volume.

Anteo was up 0.1 cents or 1.7 percent to 5.9 cents with 2.8 million shares traded.

OBJ

OBJ says Procter & Gamble has been extended their product development agreement for a further five years to 2021.

OBJ said the agreement was originally executed in 2014 and the renewal would encompass forthcoming licencing arrangements, covering multiple Procter & Gamble brands.

The company said that the terms of the agreement, including the relaxation of several provisions requested by OBJ, had been agreed and the agreement was awaiting final execution.

OBJ said that the renewed agreement extended the number of work plans for the original three to 10, with an additional work plan in negotiation and two new plans covering the licencing term sheet for the Wave I Eye Wand over two brands and the Wave II applicator to be used across multiple SK-II products.

The company said that Procter & Gamble was continuing to assess the results of the Bodyguard University of Queensland clinical trial in relation to their business and product needs on a non-exclusive basis and had requested additional time to consider the data, but as the exclusivity has expired it was in discussions with several major companies to determine how it could maximize its coverage of the market opened by Bodyguard.

OBJ fell 1.6 cents or 18.0 percent to 7.3 cents with 10.2 million shares traded.

AVANTOGEN, ACUVAX, ACTIVISTIC

Former Acuvax chief executive officer Dr William Ardrey has begun an appeal against his conviction and four year gaol sentence on 18 counts of fraud.

An officer of the Supreme Court of Western Australia told Biotech Daily that Dr Ardrey appeared before Justice Robert Mazza for a directions hearing, with a further directions hearing scheduled for April 28 and the appeal hearing set down for May 13, 2016.

Last year, Perth District Court's Justice Laurence Levy convicted Dr Ardrey following a five-week trial on 18 counts of fraud against Phoenix Eagle Pty Ltd and ordered he repay Phoenix Eagle \$394,759.38 (BD: May 29, 2015).

Dr Ardrey was appointed chief executive officer of the then Avantogen, later Acuvax 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).

Activistic is not involved in biotechnology.