



Biotech Daily

Friday November 21, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: ACRUX UP 22.5%, OPTISCAN DOWN 14.5%**
- * **DORSAVI EARNs FIRST US REVENUE**
- * **CALZADA: 'METABOLIC, AOD9604 FOR SALE - SPEED PREFERRED'**
- * **UP TO 29% OF STARPHARMA OPPOSE CEO RIGHTS**
- * **UP TO 16% DISSENT AGAINST INVION DR MITCHELL GLASS OPTIONS**
- * **NOVOGEN IDENTIFIES LEAD ANTI-CANCER CANDIDATE AS ATM-3507**
- * **MEDICAL AUSTRALIA TO RELEASE 18.3m ESCROW SHARES**

MARKET REPORT

The Australian stock market fell 0.22 percent on Friday November 21, 2014 with the S&P ASX 200 down 11.9 points to 5,304.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and two were untraded.

Acrux was the best, up 23.5 cents or 22.5 percent to \$1.28 with 4.8 million shares traded.

Benitec and Psivida climbed more than eight percent; Alchemia was up 6.26 percent; Impedimed rose 5.3 percent; Admedus was up 4.55 percent; Ellex, Nanosonics and Universal Biosensors were up more than three percent; Medical Developments rose 2.5 percent; Bionomics and Biotron were up one percent or more; with CSL and Resmed up by less than one percent.

Optiscan led the falls, down 1.1 cents or 14.5 percent to 6.5 cents with 16.9 million shares traded.

Compumedics fell 9.1 percent; Avita lost 6.3 percent; IDT, Patrys and Prana shed five percent or more; Anteo fell 4.2 percent; Analytica was down 3.6 percent; Clinuvel fell 2.5 percent; Cochlear, Sirtex, Starpharma and Tissue Therapies were down more than one percent; with Osprey down by 0.9 percent.

DORSAVI

Dorsavi says revenue is increasing and has sold its first human movement diagnostic in the US, which has a potential market of 26 million people with low back pain.

In a presentation to investors and dealers at Cannacord in Melbourne, Dorsavi chief executive officer Dr Andrew Ronchi and Dorsavi US president John Kowalczyk described the multiple uses of the movement analysis technology and the three key markets of elite sport, clinical diagnosis and therapy, and occupational health and safety.

Dr Ronchi said the technology was able to produce data immediately and a 112-patient low back pain clinical trial had shown that it reduced pain by 44 percent while increasing function by 70 percent.

He said that the low cost of the device and tests compared to \$50,000 for back surgery in Australia and about \$130,000 in the US.

Dr Ronchi said that the adoption of the Dorsavi Viperform by elite sports including Australian Rules Football clubs gave it validation, but the major markets were clinical use for low back pain patients and use in occupational health and safety.

Dr Ronchi said the company had revenue of \$359,117 for the three months to September 30, 2014, nearly half of the total of \$767,031 for the year to June 30, 2014.

Mr Kowalczyk said that the company had US Food and Drug Administration 510k clearance for the Vimove as a diagnostic for low back pain and would be seeking label extensions to include the use of the system for low back therapy.

Mr Kowalczyk said that there were more than 600 elite sporting teams in the US, the country spent \$US635 billion on the 116 million people with chronic pain, of which 26 million had low back pain.

Dorsavi's presentation said that "the national annual price tag of occupational injuries and illnesses [was] \$US250 billion" with a significant component back injuries.

Dr Ronchi said that apart from low back injuries the sensor strips could be used on all limbs to diagnose movement.

He showed a video of an athlete undertaking hamstring assessment, with the diagnostic defining the difference between the injured leg and uninjured leg to determine whether the athlete was ready to return to the team.

Dr Ronchi said that the diagnostic unit was licenced at \$5,000 to \$7,500 per year in Australia and \$US8,100 per year in the US, with the disposable strips costing \$2 to \$15 per test.

He said that doctors and physiotherapists were taught how to analyze the data.

Dr Ronchi said that the system was affordable to elite sports clubs and he expected it would be taken up by amateur clubs as well.

Dr Ronchi said that Melbourne Girls Grammar school had licenced the diagnostic for its rowing team.

Mr Kowalczyk said that he had been with Medtronic for 19 years most recently as its vice-president of sales.

When he was first introduced to the Dorsavi technology he said he called about 30 physicians and asked them to assess important was the ability to provide accurate movement data for chronic pain "and all 30 said this is something we need and can't provide".

Mr Kowalczyk said that chronic pain was "very subjective so you need a baseline assessment and how they are performing".

Mr Kowalczyk said that being able to demonstrate efficacy would be key to gaining reimbursement from insurers as well as win the preventative and remedial occupational health and safety markets.

Dorsavi was unchanged at 42 cents.

CALZADA

Calzada says it will divest Metabolic Pharmaceuticals through a trade sale, licence or as a back-door listing, and “parties who can move quickly will be preferred”.

Calzada said that the future for Metabolic was in further developing AOD9604 “a peptide fragment derived from the C-terminus of human growth hormone, for application in the human and veterinary healthcare markets [and] Metabolic’s recent focus has been on the development of AOD9604 as a treatment for osteoarthritis”.

In 2007, Calzada, then named Metabolic, said a 536-patient trial of AOD9604 for obesity failed to meet its primary endpoint and since then the peptide has been reported to have been pirated in China for use by body-builders as well as being at the centre of a controversy for Victoria’s Essendon Football Club (BD: Feb 21, 2007).

The co-inventor of AOD9604 Dr Woei-Jia Jiang has been gaoled for his role in defrauding Phosphagenics of more than \$6 million (BD: Nov 7, 2014).

Today, Calzada said there was “a significant unfulfilled need for a new, safe and effective treatment for osteoarthritis that may be addressed by AOD9604 [and] Metabolic also has extensive data supporting AOD9604’s safety and tolerability”.

The company said AOD9604 had US generally recognized as safe status allowing it to be added as a supplement in foods, drinks and dietary supplements at up to 1.0mg per day.

Calzada said that to take Metabolic forward would require “significant additional funds to undertake critical pivotal trials to investigate the potential in animal and human for osteoarthritis as well as in other applications” and it needed to use its resources on the development and commercialization of Polynovo’s Novosorb for burns and wounds.

Calzada chairman David Williams said the company was “open to maintaining a minority interest in the Metabolic business should we identify the right buyer or partner”.

The company said that the divestiture process would be managed internally and interested parties should contact acting joint managing director Philip Powell at:

ppowell@calzada.com.au.

Calzada said it wanted to “conclude this matter expeditiously and parties who can move quickly will be preferred”.

The company said that Metabolic chief executive officer David Kenley had indicated that interests associated with him intend to make an offer to acquire Metabolic and he would step down from his position until the divestiture process was finalized.

Calzada was unchanged at nine cents.

STARPHARMA HOLDINGS

Starpharma says that 42,933,088 proxy votes (29.1%) opposed the grant of 1,500,000 performance rights to chief executive officer Dr Jackie Fairley.

Starpharma said that there were 104,754,521 votes (70.9%) in favor.

The company said that the remuneration report was opposed by 25,434,437 votes (17.4%) with 120,827,538 votes (82.6%) in favor.

The company said that the increase in the pool of directors by 22.2 percent to \$550,000 was opposed by 25,434,437 votes (16.4%) and supported by 120,827,538 votes (83.6%), with 3.3 million votes against the employee performance rights plan and 144.3 million in favor and all other resolutions passed overwhelmingly.

Starpharma’s most recent Appendix 3B new issue announcement said that Starpharma had 319,008,325 shares on issue, meaning that the 42,933,088 votes against Dr Fairley’s performance rights amounted to 13.5 percent of the company, sufficient to requisition extraordinary general meetings.

Starpharma fell one cent or 1.9 percent to 50.5 cents.

INVION

Invion's annual general meeting passed all resolutions easily except the grant of 8,812,500 options to chief medical officer Dr Mitchell Glass.

The resolution was opposed by 8,123,006 votes (15.6%) and supported by 44,091,599 votes (84.4%).

The company's most recent Appendix 3B said that Invision had 547,553,228 shares on issue meaning that the opposition to Dr Glass's options amounted to 1.5 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Invion was up 0.2 cents or 3.8 percent to 5.5 cents.

NOVOGEN

Novogen says it has identified its lead anti-tropomyosin drug candidate as ATM-3507 which is hoped to safely boost the anti-cancer activity of certain existing chemotherapies. Novogen said that the existing chemotherapies were in two classes of drugs, taxanes and vinca alkaloids, which targetted the skeletal structure of the cancer cells, known as the cytoskeleton.

The company said that taxanes and vinca alkaloids targetted the microtubules, blocking the cancer cell's ability to divide and survive.

Novogen anti-tropomyosin program director Dr Justine Stehn said that the microtubule inhibitors had been "the backbone of chemotherapy for the past 40 years, but they come with three main problems".

"One is that they are toxic because their inhibitory effect is not limited to cancer cells," Dr Stehn said.

"Another is that cancer cells rapidly develop resistance to these drugs," Dr Stehn said.

"A third is that many forms of cancer show no response to these drugs," Dr Stehn said.

"The strategy we adopted eight years ago was to find a way of knocking out the other main component of the cancer cell's cytoskeleton, the microfilaments," Dr Stehn said.

"The reasoning was that by comprehensively knocking out both parts of the cytoskeleton, that the anti-cancer effect would be considerably enhanced," he said. "We are delighted to see that this is the case".

Novogen said that ATM-3507 increased the sensitivity of cancer cells to the microtubule inhibitors, "resulting in much enhanced cancer cell killing with significantly lower amounts of drugs, an important step-forward in potentially reducing the toxic side-effects of those commonly-used chemotherapies".

The company said that ATM-3507 targetted the terminal end of the Tm5NM1 tropomyosin isoform, a form of tropomyosin that was prevalent in cancer cell's microfilaments and in the laboratory, ATM-3507 had proved to be highly effective in disabling the microfilaments of cancer cells, resulting in their death, across a broad range of cancer types, with the focus on prostate cancer and melanoma and the main solid cancer of children, neuroblastoma.

Novogen said it would bring ATM-3507 into the clinic in combination with taxanes or vinca alkaloids in the treatment of prostate cancer, melanoma and neuroblastoma with a target of a first-in-man study by early 2016.

The company said that ATM-3507 had been given the name Anisina, the Turkish word for 'in memory of', in memory of the children whose deaths were the stimulus that led to the development of the technology.

Novogen was up 0.6 cents or 7.1 percent to nine cents.

[MEDICAL AUSTRALIA](#)

Medical Australia says that it will release 18,333,333 shares from voluntary escrow on 6 December 5, 2014.

Medical Australia said the shares were issued as part consideration for the acquisition of Medivet.

The company's most recent Appendix 3B new issue announcement said that Medical Australia had 204,278,502 shares on issue,
Medical Australia was untraded at 7.4 cents.