# Biotech Daily

Friday December 15, 2017

*Daily news on ASX-listed biotechnology companies*

*** ASX DOWN, BIOTECH EVEN: VIRALYTICS UP 6%; PSIVIDA DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: DORSAVI**

*** TIGENIX PAYS MESOBLAST UP TO $30m FOR STEM CELL IP**

*** PSIVIDA PILOT TRIAL BACKS DURASERT DEXAMETHASONE FOR OA**

*** MEDIBIO READY FOR MAYO CLINIC DEPRESSION TRIALS**

*** ATCOR WINS $1m HEART FAILURE TRIAL CONTRACT**

*** CELLMID RAISES $1m FROM ADVISOR DENNIS ECK**

*** ORTHOCELL EUROPEAN PATENT FOR ORTHO-ATI MANUFACTURE**

*** PHOSPHAGENICS TPM-CHICKEN FEED BEATS HEAT STRESS**

*** USCOM RECEIVES $492k R&D TAX INCENTIVE; CAPITAL RAISING HALT**

*** EPAT EGM TO CHANGE NAME TO PAINCHEK**

*** RESPIRI 29% REMUNERATION 1st STRIKE; BOARD SPILL DEFEATED**

*** REGAL FUNDS DOWN TO 7% OF AVITA**

*** AUSCANN LOSES EXECUTIVE DIRECTOR HARRY KARELIS**

## MARKET REPORT

The Australian stock market fell 0.24 percent on Friday December 15, 2017 with the ASX200 down 14.3 points to 5,997.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded.

Viralytics was the best, up 3.5 cents or 5.8 percent to 63.5 cents with 93,579 shares traded. Mesoblast climbed 5.2 percent; Avita and Immutep (Prima) improved more than four percent; Admedus and Reva were up more than three percent; Benitec, Compumedics, Polynovo and Starpharma rose more than two percent; with Cyclopharm, Medical Developments and Prana up more than one percent.

Psivida led the falls, down 15 cents or 9.4 percent to $1.45 with 10,000 shares traded. Genetic Signatures lost 8.3 percent; LBT and Optiscan fell more than four percent; Telix was down 3.3 percent; Airxpanders, Clinuvel and Sirtex shed more than two percent; with Bionomics, Ellex, ITL, Nanosonics Neuren and Pharmaxis down more than one percent.

# DR BOREHAM'S CRUCIBLE: DORSAVI

**By TIM BOREHAM**

**ASX Code:** DVL

**Share price:** 28 cents

**Shares on issue:** 167,876,971

**Market cap:** $47.0 million

**Chief executive officer:** Dr Andrew Ronchi

**Board:** Greg Tweedly (chairman), Andrew Ronchi, Ashraf Attia, Dr Michael Panaccio, Caroline Elliott.

**Financials (2016-'17 year):** revenue $3,897,882 (up 20%), loss of $3,876,248 (previously $5,237,000 loss), cash of $8.6 million (up 43%)

**September quarter:** revenue $958,000 (down 4.6%), cash outflows $1.35 million (previously $219,000), estimated current quarter outflows $2.309 million, cash balance $7.06m *****

***** The company subsequently received a $832,000 R&D Tax Incentive

**Identifiable holders:** Starfish Tech Fund/Starfish Ventures/Michael and Christiana Panaccio/Micana Family Trust 43.43%; Gabrielle Banay 2.17%, Andrew Ronchi 1.43%.

Well before the advent of the Apple Watch, Dorsavi paved the way in the "wearables" sector with its first sensor-based wireless device to measure human movement.

The instruments are small but intricate, containing gyroscopes, accelerometers and magnetometers to assess the way that people twist and step.

Dorsavi operates in the occupational health and safety sector (the Visafe division), clinical measurement (Vimove) and the sports market (Viperform).

The flagship workplace product Myvisafe has been launched in the Australian, US and UK markets.

"With regulatory approval behind us our focus is now firmly on execution and scalability," says chief executive officer Dr Andrew Ronchi.

The next-gen clinical product Vimove2 has been launched in Australia and in July the company gained Food and Drug Administration 510k (device) clearance to launch in the US.

## In the beginning

The underlying technology was devised by physiotherapist Andrew Ronchi and his brother Dan in 2000.

At the time, Andrew was working both in private practice and for AFL football club Melbourne and was becoming frustrated at the use of visual and subjective data to make important patient decisions. He teamed up with IT guy Dan to devise the first wireless sensor monitoring systems.

Eight years later, the venture had evolved enough to attract the support of Dr Michael Panaccio's Starfish Technology Fund, which remains the company's key backer (Dr Panaccio sits on the board).

Dorsavi was formed to acquire the intellectual property from the brothers Ronchi in 2008. By the time Dorsavi listed in December 2013, $10 million had been spent on development.

## Move to the Vimove groove

Vimove2 measures, records and analyzes movements and muscle activity in the lower back and is slated to be launched in the UK this calendar year and in the US in the June quarter next year.

As well as being a pain in the lumbar region, dodgy lower backs are said to cost the US economy $US100-200 billion a year.

Dorsavi cites clinical trials that suggest Vimove has reduced the incidence of back pain by 45 percent and improved functionality by 73 percent for chronic back pain sufferers.

The devices turn algorithms picked up from the sensors into usable data; and suggest an exercise and treatment regime for the patient.

Relative to the first iteration of the device, Vimove2 has cut the start time from three minutes to 10 seconds and reduces user training time from four hours to 10 minutes.

Vimove2 also has 'run' and 'knee' modules, with Japanese shoe maker Mizuno using the run and analysis function to help customers choose their shoes.

Vimove currently is used by the US clinical trial group Select Medical across 45 locations.

## Sporting chance of success

The sports version is used by all the major US acronyms: the NBA, the NFL and NHL.

It's also deployed by the AFL, the NRL, Cricket Australia and the Australian Institute of Sport, here.

The company bashfully adds that it's used by the New England Patriots, winner of this year's Super Bowl (and National Hockey League champs Philadelphia Flyers).

The most popular module, the Athletic Movement index, allows sports administrators to benchmark players in terms of susceptibility to injury.

Adding to Dorvasi's local sporting cred, Australian running hero Herb Elliott was chairman until he retired at last month's AGM. In another boardroom change, Caroline Elliott - daughter of John 'Pigs Arse' Elliott and no relation to Herb - gained a board seat.

**Promoting a safe workplace**

In the occupational health and safety sector, Visafe enables managers to measure and mitigate high-risk activities based on actual data, rather than gut-feel and opinion.

Dorsavi directly sells Visafe in the UK and Australia and uses seven agents to tap the $US200 billion US occupational health and safety market.

While Dorsavi gleaned almost half of last year's revenue from workplace safety consulting, the latest version is pitched more at a do-it-yourself approach.

"Senior management is most interested in the ability to remotely monitor their workforce through an easy-to-use dashboard," Dr Ronchi says.

Customers include Crown Casino, Heathrow Airport, the London Underground, the Snowy Hydro Scheme, Coles, Woolworths, BHP Billiton and box maker Orora.

**Crown Casino gambles on Dorsavi workplace solution**

How many Crown Casino workers does it take to change seven million light globes a year across the gambling den's vast facilities?

Sorry about the lack of a decent punch line, but the answer is: lots.

As with so many other tasks across Crown's Melbourne and Perth facilities, renewing the globes must be done manually, as do 700 other tasks. With 15,600 employees and contractors and a rocketing workers' compo bill, Crown was an ideal candidate to become Dorsavi's first dinki-di client.

According to Crown's general manager (health and wellbeing) Tony Graham, the use of Dorsavi resulted in subtle but important changes to the layout of gaming tables to reduce the incidence of back and other strains suffered by croupiers.

Despite Crown's palpable enthusiasm for the product - the company has even dubbed its health and safety program the Dorsavi Way - the company has only bought eight sensor kits to date, but expects to purchase up to 100.

**Financially speaking**

In December last year Dorsavi raised $7 million in a private placement and share purchase plan.

Last month the company secured a $1.1 million Federal Government grant, under Canberra's advanced manufacturing incentive program.

True to the gist of the program, Dorsavi will invest in robotic loaders and optical tracking and calibration equipment.

While Dorsavi's revenue trajectory has been solid - it's more a Herb Elliott middle distance stayer than a Stawell Gift winner - we get the impression that potential workplace clients are reluctant to be first movers.

But sales leads have strongly increased in six months, in line with the company's bolstered marketing push that includes engaging more resellers and other parties such as insurers and health and fitness networks.

"We can't forecast revenue but these are strong indicators," Dr Ronchi says.

At Dorsavi's recent AGM, chairman Greg Tweedly said the US clinical market was critical, as the health sector there was more willing to accept data-driven decision making.

Current Visafe contracts range from $40,000 to $300,000 each. The clinical and sports deals involve an up-front sum of $2,000 to $3,000 and then a similar ongoing annual leasing payment.

**Dr Boreham's diagnosis:**

Dorsavi is often compared to the listed wearables play Catapult Group (ASX code CAT, $1.41), which has developed sports performance monitoring devices and boasts a similar list of big-league clubs as clients.

But while Catapult shares have, well, catapulted since listing in December 2014 at 55 cents apiece, Dorsavi shares are stuck below their December 2013 listing price of 40 cents a share.

Still, there's no denying Dorsavi is now doing the heavy-lifting and back-breaking work of selling a range of fully-developed products.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He avoids problems by moving very slowly and very gently at all times***

## MESOBLAST

Mesoblast says it will earn up to $30.7 million for licencing patents to support the commercialization of Tigenix NV's Cx601 fat-derived stem cells for fistulae.

Mesoblast said the Leuven, Belgium-based Tigenix' adipose-derived mesenchymal stem cell product Cx601 for the Crohn's disease complication of perianal fistulae had completed a European phase III trial and was in a phase III trial to support a US biologic application.

The company said that the agreement included the right for Tigenix to grant sub-licences to affiliates and third parties, including Tigenix's current development and commercialization partner, Tokyo's Takeda for countries other than the US.

Mesoblast said it would receive up to EUR20 million ($A30.7 million) in payments, with EUR5 million upfront, EUR5 million within 12 months, and up to EUR10 million in product regulatory milestones as well as single digit royalties on net sales of Cx601.

Tigenix chief executive officer Eduardo Bravo said his company was "delighted to have concluded this exclusive licence agreement with Mesoblast, which will broaden our … protection for Cx601 as we move closer to commercialization in Europe".

"Tigenix now has a stronger intellectual property position that supports the use of Cx601 for treatment of all fistulae," Mr Bravo said.

Mesoblast chief executive Prof Silviu Itescu said the agreement "highlights the strength of Mesoblast's extensive intellectual property portfolio covering mesenchymal lineage cells".

"When consistent with our strategic objectives, Mesoblast may consider providing third parties with commercial access to our valuable patent portfolio," Prof Itescu said.

Mesoblast said it was developing its bone marrow-derived allogeneic expanded mesenchymal stem cell candidate for patients with biologic-refractory Crohn's disease.

Mesoblast was up seven cents or 5.2 percent to $1.42 with 3.4 million shares traded.

## PSIVIDA CORP

Psivida says a six-patient pilot trial at New York's Hospital for Special Surgery shows potential for its Durasert dexamethasone for knee osteoarthritis pain.

Psivida said the phase I safety and exploratory efficacy pilot study for a sustained release implant integrating its Durasert delivery technology and a Hospital-designed implantable device showed that subjects experienced an average 3.8 point reduction in average weekly pain, on a zero to 10 point pain scale, by week-4 that did not diminish over the 24 week period, with 4.7 points and 5.0 point reductions at weeks 12 and 24, respectively.

The company said that using a "strict responder" scale, four subjects were considered strict responders by week-4, with all six subjects strict responders on weeks 12 and 24.

Psivida said that the implant was designed to deliver a continuous-low dose of dexamethasone into the knee joint for several months.

The company said the six subjects with radiologically-confirmed and symptomatic osteoarthritis of the knee were studied for six months, with safety monitoring including serial radiographs and plasma dexamethasone concentrations.

Psivida said that plasma dexamethasone concentrations were lower than those reported by other standard-of-care treatments and no adverse events were reported, the implant was well-tolerated and showed potential analgesic effects through the six-month study.

Hospital for Special Surgery principal investigator Dr Mark Figgie said the system had "the potential to fill a much-needed therapeutic gap for knee [osteoarthritis] patients".

Psivida chief executive officer Nancy Lurker said the "positive phase I data demonstrates that Durasert technology has applications beyond our core back-of-the-eye disease markets".

Psivida fell 15 cents or 9.4 percent to $1.45.

## MEDIBIO

Medibio says it will begin an up to 120-patient trial of its cardiac rhythm for depression diagnostic with the Rochester Minnesota-based Mayo Clinic in January.
In October, Medibio signed a five-year master clinical trial agreement with the Mayo Clinic, following a May three-year development agreement (BD: May 10, Oct 4, 2017).
Today, Medibio chief executive officer Jack Cosentino told Biotech Daily that he expected the first patient to be enrolled in January 2018 with final results expected by October 2019.
Mr Cosentino said the trial would investigate depression sub-types as well as unipolar compared to bipolar depression and pave the way for further regulatory submissions.
In a media release, Medibio said the trial would be a prospective diagnosis and longitudinal monitoring of both unipolar and bipolar depression, along with the depressive subtypes melancholic and atypical.
The company said that the primary goal was to characterize longitudinal autonomic, circadian and sleep patterns, as classified by its analytics platform, following the initiation of a standard pharmacological treatment for a new or recurrent, moderate-to-severe major depressive episode of both the unipolar and bipolar type.
Medibio said its analytics platform would be used to characterize patterns unique to the bipolar type depression.
Medibio fell 0.5 cents or 1.4 percent to 34.5 cents.

## ATCOR MEDICAL

Atcor says it has a $1.0 million contract with an unnamed pharmaceutical company to supply its Sphygmocor systems and support services for a phase II heart failure trial.
Atcor said the pharmaceutical company was anew customer and the cardiac trial would be conducted at several European sites.
The company said the trial would run for up to 24 months with the majority of revenue recognized in the year to June 30, 2019.
Atcor chief executive officer Craig Cooper said the contract was “further validation of our core technology in large pharmaceutical trials for the treatment of heart failure and related disorders”.
Atcor executive director Duncan Ross said there was “increasing interest in utilising Sphygmocor in heart failure trials and in the clinic”.
“Heart failure is a high-cost disease state where drug selection, dosing and patient monitoring are of critical importance,” Mr Ross said.
“This is our second heart failure trial to commence in the past six months and discussions are underway for additional trials,” Mr Ross said.
Atcor was unchanged at 2.9 cents.

## CELLMID

Cellmid says it has raised $1 million in a placement at 38 cents a share to US investor Dennis Eck.
Cellmid said that Mr Eck had 40 years’ management experience in the retail sector including beauty products and would advise the company on US retail strategy in 2018 for its Evolis-branded FGF5 inhibitor hair loss products.
Cellmic chief executive officer Maria Halasz said it was “very exciting to secure support from a strategic investor of Dennis Eck’s industry experience and wisdom”.
“We are looking forward benefiting from his insights,” Ms Halasz said.
Cellmid was up 1.5 cents or 3.95 percent to 39.5 cents.

## ORTHOCELL

Orthocell says it has been granted a European Patent protecting the method of manufacture of its Ortho-ATI tendon regeneration cells.

Orthocell said the patent, entitled 'Culture medium, culturing method and use of tenocytes' covered its Ortho-ATI autologous tenocyte implantation product until 2027 and provided additional intellectual property to protect its tendon repair applications, granted in the EU, US, China, Australia, Singapore, Hong Kong and New Zealand.

" Orthocell managing director Paul Anderson said that "securing this patent for tendon repair in Europe is another milestone in strengthening our [intellectual property] position as we drive our novel, world-leading, tendon repair product into the global market".

Orthocell was unchanged at 35 cents.

## PHOSPHAGENICS

Phosphagenics says an independent, second poultry study shows that adding tocopheryl phosphate mixture (TPM) to feed has benefits for birds under stress.

Phosphagenics said that additives were included in poultry feed to improve growth, laying capacity and to prevent diseases and the trial "confirmed the optimum TPM dose in broilers and demonstrated significant additional benefits associated with adding TPM to the diet of birds under additional stress conditions [such as] heat stress".

The company said that adding phosphorylated vitamin E, or TPM, to feed in previous studies focussed on increasing the absorption of vitamins and minerals from standard feed, thereby improving the performance of the animals on the feed.

Phosphagenics said that the new study in broiler chickens investigated the potential positive impact of TPM-enhanced feed on broiler growth during heat stress, a common problem in many parts of the world.

The company said that adding TPM to broiler feed at 10 parts per million "significantly improves performance" and negates the three to five percent loss associated with heat stress on broiler growth.

Phosphagenics chief executive officer Dr Ross Murdoch said the company had been "working hard to build a body of data demonstrating the utility and flexibility of TPM in the animal health sector".

"We have maintained a multi-prong approach assessing TPM's potential across multiple species selecting … pigs, poultry and cattle to provide proof-of-concept data in mono-gastric [or single stomach] and ruminant species – although related, each being significantly valuable in their own right".

"To date we have demonstrated significant utility and value for TPM in both the pig and poultry feed sector," Dr Murdoch said. "Discussions with key potential partners have highlighted poultry as a key species of interest, increasing the importance of this result."

Phosphagenics said it was trialling TPM in dairy cattle feed with results expected before the end of the year.

Phosphagenics rose 0.1 cents or 6.25 percent to 1.7 cents with 14.2 million shares traded.

## USCOM

Uscom says it has received $491,732 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Uscom said the rebate related to research and development expenditure for the year to June 30, 2017.

Uscom was in a trading halt for a capital raising and last traded at 15 cents.

## EPAT TECHNOLOGIES

Epat says that an extraordinary general meeting will vote to change the company name to Painchek Limited, the same name as its pain detection software system.
Epat chief executive officer Philip Daffas told Biotech Daily that the name change would assist in branding and marketing recognition.
The company previously said its Painchek software had been developed for pateintes and aged care residents who could not verbalize their pain, as well as for young children.
The meeting will be held at Suite 401, 35 Lime Street, Sydney on January 17, 2018 at 10am (AEDT).
Epat fell 0.3 cents or 4.55 percent to 6.3 cents with 3.3 million shares traded.

## RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri has a remuneration report first strike with the annual general meeting voting 53,056,114 votes (28.8%) against the report and 131,384,135 votes (71.2%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill.
Respiri said that the re-election of executive chairman Leon L'Huillier, the issue of 34,000,000 options to directors Mr L'Huillier, Marion Gattino and John Ribot-de-Bresac and the issue of 1,000,000 shares for consulting fees to S3 Consulting faced similar levels of opposition (BD Nov 14, 2017).
The election of proposed board spill directors Samuel Herszberg and Nicholas Johansen had about 30 percent support and 70 percent opposition (BD: Oct 17, 2017.
Respiri's most recent Appendix 3B new issue announcement said that the company had 433,383,224 shares on issue, meaning that the largest opposition of 53,840,713 votes against options for Mr Gattino amounted to 12.4 percent of the company, sufficient to requisition extraordinary general meetings .
Respiri fell 0.7 cents or 15.6 percent to 3.8 cents with 1.3 million shares traded.

## AVITA MEDICAL

The Sydney-based Regal Funds Management says it has reduced its holding in Avita from 85,698,972 votes (8.16%) to 72,392,312 shares (6.89%).
In November Regal reduced its holding in Avita from 51,966,936 shares (6.71%) to 42,019,615 shares (5.43%) selling shares at prices between 5.2 and 5.9 cents a share and then increased its holding to 85,698,972 votes (8.16%) buying 51,892,954 shares at 4.5 cents a share at the time of the October placement and November share plan at 4.5 cents a share which raised $16.9 million (BD: Nov 2, 14, 2017).
Today, Regal said that between November 10 and December 12, 2017 it bought 5,000,000 shares at 4.5 cents a share and sold 10,498,725 shares at prices ranging from 4.5 cents to 6.9 cents a share.
Regal said a further 7,807,935 shares were due to "becoming aware the right entitlements were not fully received".
Avita was up 0.3 cents or 4.8 percent to 6.6 cents with 1.5 million shares traded.

## AUSCANN GROUP HOLDINGS

Auscann says that executive director Harry Karelis has resigned “to concentrate on his other business ventures”.

Mr Karelis is the executive chairman of Zelda Therapeutics, chairman of the public unlisted Clinicann and a director of the Perth-based advisory and investor firm Jindalee Partners.

Auscann said that Mr Karelis was a founding director, helping to establish the company in September 2014 and played an active role in the start-up funding and corporate development of the business.

Auscann thanked Mr Karelis for his contribution.

Auscann fell two cents or 2.9 percent to 69 cents.