Biotech Daily

Thursday December 21, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTISCAN UP 7%; PRANA DOWN 10.5%**

*** 2017 - BIOTECH DAILY'S YEAR IN REVIEW**

*** CERTARA, MDGH FILE MOXIDECTIN APPLICATION FOR RIVER BLINDNESS**

*** LIVING CELL: 'LONG-TERM DATA KEEPS NTCELL PRIMARY FOCUS'**

*** NICE FAILS TO RECOMMEND CLINUVEL SCENESSE FOR NHS REBATE**

*** US FDA GRANTS MESOBLAST RMAT FOR LVAD TRIAL**

*** ACCC ENDS REVIEW OF CRYOSITE AND CELL CARE MERGER**

*** ITL, MYHEALTHTEST LAUNCH CHOLESTEROL TEST**

*** ONCOSIL: '20th BRACHYSIL PANCREATIC CANCER PATIENT IN JANUARY'**

*** STARPHARMA FILES 4th VIVAGEL BACTERIAL VAGINOSIS FDA MODULE**

*** HYDROPONICS TO SELL NANOLUX MARIJUANA GROWING PRODUCTS**

*** UP TO 27% OPPOSE PSIVIDA DIRECTOR OPTIONS**

*** GENETIC TECHNOLOGIES PLEADS SCHULTZ TO ASX 78% QUERY**

*** AURORA TAKES 22% OF CANN, CHAIR ALLAN MCCALLUM DILUTED**

*** MESOBLAST TO RELEASE 20m ESCROW SHARES**

*** CSL COUNSEL EDWARD BAILY QUITS CO SEC ROLE, JOHN LEVY**

MARKET REPORT

The Australian stock market fell 0.25 percent on Thursday December 21, 2017, with the ASX200 down 15.2 points to 6,060.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Optiscan was the best, up 0.6 cents or 7.1 percent to nine cents with 245,000 shares traded. Genetic Signatures climbed 6.9 percent; Actinogen improved 4.8 percent; Avita and Oncosil were up more than three percent; Impedimed, Pro Medicus, Telix, Uscom and Volpara rose more than two percent; with Airxpanders, Compumedics, Ellex, Orthocell and Reva up more than one percent.

Prana led the falls, down 0.8 cents or 10.5 percent to 6.8 cents with 47,075 shares traded. Universal Biosensors lost 8.8 percent; Opthea fell 4.3 percent; Benitec, Medical Developments and Neuren shed more than two percent; with Clinuvel, Cochlear, Nanosonics, Polynovo, Sirtex and Starpharma down more than one percent.

BIOTECH DAILY EDITORIAL: 2017 - THE YEAR IN REVIEW

The year started on a real high with a dozen marijuana companies competing for oxygen and confusing investors, seasoned reporters and speculators. Nearly all have been on a roll since listing.

During the year, several more jumped onto the cannabis caravan and it became increasingly difficult to understand which were biotechnology companies developing medical marijuana for human health purposes, which were developing cannabis products for cosmetics or food additives and which were nobly identifying themselves as pursuing a straight – or should that be bent ? – recreational market.

But it was Stemcell United that impressed the most: soaring 8,941.7 percent from 1.2 cents to $1.085 in May on the hire of marijuana consultant and "king of cannabis" Nevil Schoenmakers, but clinging to its Dragon's Blood Chinese herbal remedy, despite the disclaimer that it probably didn't work for anything, then tumbling back to 2.5 cents when the king abdicated in September. And we can't even begin to comment on cannabis beer, dope-infused honey and marijuana-flavored chocolate. Really? People don't smoke that stuff for its taste.

One thing that became increasingly certain was the some of the marijuana companies required trading halts for every announcement - not just for every mouse recruited, but for even more mundane purposes such as signing a previously flagged agreement. Some of the announcements read like the writer had been sampling the product.

The ASX should fine companies calling unnecessary trading halts.

Regulation

Speaking of the ASX, Biotech Daily learnt during 2017 that the Australian Stock Exchange has heeded some of our complaints and we have been responsible for two changes to ASX policy, with a third hopefully on the way.

Listing Rule 3.1 has adopted "the reasonable person" test for what is material – a very welcome change from the previous ASX in Wonderland "what the company believes to be material" test.

The ASX has also introduced Guidance Note 8 to Listing Rule 3.1 that says companies can no longer bury important information like a failed or delayed trial or the loss of funds under the title "Investor Update" or "Announcement".

The next target is mandatory separate announcements for any board change.

A tale of two Prime Ministers' 1st degree relatives

Biotech Daily was most surprised to discover from an Appendix 3Z announcement that Prima (now Immutep) had lost the services of seven-year chair Lucy Turnbull, whose husband Malcolm is currently Australia's Prime Minister.

That the announcement was made to those few people able to attend the annual general meeting and was in the chair's address posted on the ASX is nowhere near as clear as the separate stand-alone announcement that Ms Turnbull was appointed to the position seven years earlier, entitled 'Prima Biomed Appoints Lucy Turnbull as Chairman', as compared to '2017 Chairman's AGM Address'.

If an appointment, trial, distribution agreement or capital raising deserves a stand-alone announcement at the beginning, it deserves the same treatment at the end.

Ironically for the Turnbulls, the day after Lucy filed her 3Z, GI Dynamics posted the attention-attracting 'Change to Board of Directors' saying that director Anne Keating had tendered her resignation. Ms Keating's big brother Paul was the Prime Minister of Australia from 1991 to 1996 and Treasurer from 1983 to 1991.

It's called transparency.

Feeding the chooks

A new biotech lurk popped up during the year: feeding stories to tame reporters who then claim "Scoop Exclusives" ahead of the company telling investors and the ASX.

It is a breach of Listing Rule 15.7 and re-publishing a public relations company's spin is about as far from a journalism scoop as one can get.

Biotech beats ASX, Big Caps boom

As we reported in July, for the 10 years to June 30, 2017, the Biotech Daily Top 40 Index (BDI-40) climbed 79.6 percent compared to the ASX200 down 8.8 percent, with the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up 270.4 percent.

The 11-year data shows the significance of specific time points, with the BDI-40 up 166.6 percent, the ASX200 up 12.8 percent and the three Big Caps up 400.1 percent.

Highs and lows

There were some outstanding rises and falls over the past 12 months along with a great deal of solid progress by companies not rewarded by share price movements.

Starpharma's market capitalization climbed 113.6 percent to $519 million in the year to December 1, while Phylogica started from a much lower base climbing 206.7 percent to $92 million, with Benitec recovering 135.3 percent, MMJ up 194.1 percent and Noxopharm up 160.0 percent.

The three Big Caps of CSL, Cochlear and Resmed climbed a collective 44.3 percent in the year to November 30 and all are at record high market capitalizations.

The deepest dollar fall was Mayne Pharma losing $1.4 billion or 58.4 percent to $989 million, making Sirtex's 46.0 percent retreat look almost respectable, but failed trials cost Innate 96.4 percent, Resapp 78.5 percent and Living Cell 63.0 percent.

Anteo fell 71.1 percent (see below), Adherium lost 71.1 percent for no apparent reason, IDT fell 57.4 percent, while the biotech formerly known as Biota was down 53.4 percent on its way to American obscurity.

The good news

Companies that announced significant advances through the year included Avita, Bluechiip, Botanix, Compumedics, Cynata, Dorsavi, Ellex, ITL, Memphasys, Nanosonics, Nuheara, OBJ, Patrys, Probiotec, Pro Medicus, Rhinomed, Uscom and Zelda; with the unlisted Atomo, Clarity and Clinical Genomics all reporting good news. Reva won Conformité Européenne (CE) mark approval for its Fantom stent and began sales, Mesoblast passed its phase III cardiac trial futility test and Cynata graduated from pictures of a mouse re-growing a leg to a clinical trial of its stem cells for graft versus host disease, as well as foreshadowing cancer and asthma studies.

Actinogen is now one of the few companies to have a serious trial underway for Alzheimer's disease, but that's because so many others have failed with the notoriously impossible to treat indication.

The Burnet Institute made several key discoveries, the Walter and Eliza Hall Institute pulled off a $405 million-plus coup with Venetoclax, and the Murdoch Children's announced hope for peanut allergies, as well as a 100,000-baby long-term study.

Learnings

Prescient gave us a paradigm case in the hardship of biotech, with the death of one very sick patient halting four trials and taking six months to have all studies back on-track.

And not so good news

In the not-so-good news department, the once-great Acrux finally lost all on-going revenue from Axiron. (Despite being an investor this writer always had concerns about selling testosterone to American men.)

Genetic Technologies has struggled for many years, with the sale of its "heritage" genetic testing business the harbinger of the unhappy changes and goes into 2018 with a board spill extraordinary general meeting.

Politics

The world of politics largely left us alone this year, apart from the sour after-taste of the penny-pinching 1.5 percent cut to the R&D Tax Incentive.

The worst Federal Government decision was Prime Minister Turnbull blithely scrapping the 457 temporary skilled work visa, including six life science categories in April, but backing down to industry pressure and reinstating them in July. Pats on the back to the industry organizations who lobbied so well.

IPOs, funding and capital raisings

This year saw at least 10 ASX biotech initial public offers, as well as Immuron trying its luck on the Nasdaq, compared to last year's 11, but just two of the floats, Telix for $50 million and Visioneering for $33 million easily outweighed all the previous year's combined.

Then Cann Group, which raised a measly $13.5 million in April to supply the Victoria Government marijuana epilepsy trial, among other targets, raised a further $58.7 million in the past few weeks, with $19.3 million more expected in January.

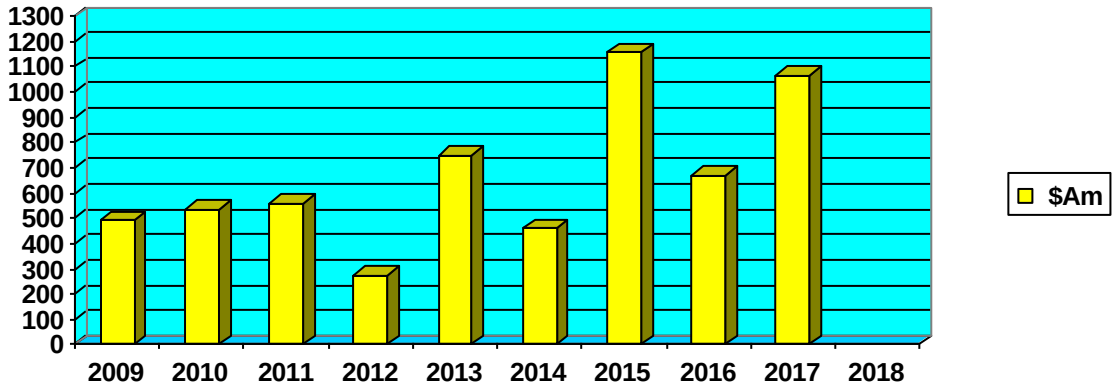
While the Federal Government has finally released $66 million from the Tony Abbott-Joe Hockey thought-bubble of a proposed $20 billion Medical Research Future Fund, Andrew Forrest's Minderoo Foundation shelled out an easy $75 million for the Eliminate Cancer project.

The Victoria Government and the Federally funded MTP Connect have also contributed millions of dollars to the sector.

Uniseed and the Brandon Capital-managed Medical Research Commercialisation Fund along with a raft of other funds including One Ventures and Bioscience Managers have pumped more than $100 million into Australian biotech this year.

The year was a bumper one for capital raising, with $1,066 million raised so far, second only to the record-breaking $1,153 million in 2015 and well above the nine-year average of $661 million.

Capital Raising Chart 2009 -2017



Chairman of the Year

This is a new award to give credit to those admirals of the fleet who give strategic directions to the captains of their ships. If the objective is unclear, the mission will fail.

In previous years the award clearly belonged to “Chairman Mel”, Dr Mel Bridges of Too Many Companies to List, but he has been divesting his biotech interests, at least as long as he can until someone begs him to join a new board. The current ones, Anatara and Oventus, are early stage.

The runner-up for 2017 is Paul Hopper, who has juggled several companies to the brink of success. Viralytics is his fleet’s flagship, but all three ventures are in the difficult world of drug development, with Imugene and Prescient (of which he is a mere director), also pursuing a range of cancer trials.

The Chairman of the Year award goes to the corporate advisor who brought Vegemite back to Australia for Bega Cheese, the irrepressible David Williams who appointed last year’s CEO of the Year John Sharman to turn around Medical Developments and Paul Brennan to do the same at Polynovo.

Medical Developments was at 19 cents when Mr Williams gave it a kick-start and is currently trading at $7.00. Polynovo has improved from 14 cents when Mr Brennan started three years ago and following its first US contracts is now at 44 cents with some saying the company has only just begun its sales and marketing.

(Biotech Daily takes some credit for advising Mr Williams to do exactly what he did: dump the Essendon Football Club-killing peptide AOD9604 and focus on the brilliant CSIRO bio-resorbable polymer Novosorb.)

CEO of the Year

This has been a hard choice given the sector is on the rise and the large number of companies working hard at developing technologies.

Pharmaxis chief executive officer Gary Phillips and chief financial officer David McGarvie have turned their company around and taken back a technology, rather than having the technology thrown back at them. Optiscan’s Archie Fraser has done a similarly good turnaround job, not reflected in the share price, yet.

Again, Dr Sam Hupert has continued to build Pro Medicus and the two runners-up should be very proud of standing out from the crowded space biotech has become.

Dr Jackie Fairley has taken Starpharma into the $500 million market capitalization club and deserves congratulations for unflaggingly promoting Vivagel, or SPL7013, and continuing to maintain big pharma interest in her company.

Paul Perreault at the Magic Pudding we call CSL has led a new round of innovation in the already successful former Federal Government monopoly and we like everything about the company.

But the award has to go to the one person who has tirelessly worn out shoe-leather, defied all critics and taken a drug all the way to European approval and sales, and finally rewarded investors with a maiden profit – take a bow Dr Philippe Wolgen of Clinuvel, who once told Biotech Daily that he would NEVER prescribe a systemic drug for cosmetic purposes, despite some of his shareholders champing at the bit for Scenesse to get US approval for very rare sun-tolerance indications, so that it can be sold as a once-monthly injectable sun-tan.

Philippe, you really have performed a miracle. Mazal Tov from Biotech Daily.

Kamikaze of the Year

There were a few contenders in 2017. Biotech Daily prefers the years when the award is withheld, but with the highs come the lows.

To be fair to both New Zealand companies, Innate Immunotherapeutics' Simon Wilkinson and Living Cell's Dr Ken Taylor undertook rigorous phase II trials in the most difficult of indications, multiple sclerosis and Parkinson's disease, respectively, and when the trials showed their drugs did not work, honorably and honestly told us so in plain language.

Resapp, once the "most improved" stock on the ASX jumping 13,650 percent from 0.4 cents to 55 cents before tumbling to 5.5 cents took a trading halt, a suspension and 10 days from July 31 to August 9, as well as four paragraphs into the announcement to admit similarly non-significant results. Okay, there were problems in the methodology and supervision. We understand.

But Biotech Daily knows that contract research organizations send the results with headline figures and we only ever have trading halts, and especially suspensions, for the bad news trials while the companies go data mining to find something – anything – they can spin for investors. You lose points for doing this.

Resapp is far from alone in this. Even Sirtex needed a couple of one-day trading halts to tell us bad news this year.

These are the mere runners up.

The Real Kamikaze Award for 2017 must go to Anteo Diagnostics for buying Belgium's Diasource for $34 million, changing its reporting into Euros causing everyone headaches, taking an equity finance facility that drove the price down from 9.5 cents to 2.3 cents, and then a capital raise primarily to fund salaries including that of the former chief executive officer who joined the raisings, only to flog off the Belgium subsidiary for $24 million, to return as an Australian company reporting in Australian dollars and hiring a new chief executive officer with expertise in lithium – no not carbonate for bipolar depression but ion for batteries. Well, that was a fun couple of years, wasn't it?

Australian financial reporting

While on the topic of reporting currencies, Biotech Daily is increasingly of the view that reporting in foreign currencies is more to do with defensive egos on the board and in management than anything practical.

Come on, guys (it's still mainly guys, isn't it?) grow a back-bone. Australia is a serious country in its own right. Do your deals in Australian dollars and stop kowtowing to the US. If President Trump destroys the US economy will you then report in Chinese renminbi?

You are Australian companies, listed on the ASX with most of your investors in Australia. How about reporting in our currency, rather than someone else's? Last week, Mesoblast did a deal in Euros and bizarrely translated the amount into US, but not Australian, dollars. How does that impress shareholders?

If Cochlear and Sirtex can, you can.

Summer holiday publishing schedule

Biotech Daily has published about 250 editions for the year. For the first few years it was a reasonable five to 10 articles a day, but with the new listings it is now more like 15 to 20 a day, every day. That's about 4,000 announcements for the year.

In 2017, we added the services of Tim Boreham writing the weekly Crucible and are currently training journalism cadets, who will hopefully graduate to permanent part-time or full-time staff.

We expect 2018 to be an even bigger year and in preparation for the next marathon Biotech Daily will shut down for the long, hot, Australian Summer tomorrow, December 22 and be back on deck refreshed and recharged on January 22, 2018.

Given the whole country stops at this time, we urge all companies NOT to put out any announcements - that no-one will read anyway - for the next month. Go to the beach.

That said, we shall monitor all announcements and publish a Summer Holiday Catch-Up edition, highlighting any companies posting bad news after the market closes on Christmas Eve (technically tomorrow) and New Year's Eve.

Biotech Daily would like to thank its team of advisers: Prof George Fink, Dr Stuart Garrow, Marc Sinatra and Michael Ibbott for invaluable wisdom, insights and cautions throughout the year.

We wish everyone an excellent Southern Hemisphere Summer break, a Merry Christmas, a Happy Hogmanay/New Year and see you all in 2018.

David Langsam
Editor

CERTARA, MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

Certara says the Medicines Development for Global Health (MDGH) has filed a new drug application to the US Food and Drug Administration for moxidectin for river blindness.

Certara D3 president Dr Craig Rayner told Biotech Daily that his group supported the work undertaken by the Melbourne-based not-for-profit Medicines Development for Global Health and the development of oral moxidectin for river blindness, or onchocerciasis, was originally a D3 program with team members in Washington DC and Princeton, New Jersey.

Certara said that river blindness was a debilitating tropical disease and the FDA granted moxidectin priority review on December 16, shortening its review timeline from 10 months to six, triggering a tropical disease priority review voucher, should the submission be approved.

“Product development relationships are critical for advancing medicines for unmet global health needs and MDGH has got the model right,” Dr Rayner said. “We are delighted to be an integral part of MDGH’s team for the development of moxidectin.”

“This is another significant step towards making this important medicine available to the millions of people afflicted with river blindness, which is a terrible disease, and we are proud to play a pivotal role in this process,” Dr Rayner said.

Certara said that onchocerciasis was caused by the filarial worm Onchocerca volvulus which was transmitted through the bites of infected black flies.

The company said that each adult female worm could live for up to 15 years in the human body, producing millions of microfilariae that migrate through the skin, eyes, and lymph nodes.

Certara said that symptoms included severe skin inflammation, intense itching, enlarged lymph nodes and, in some patients, visual impairment that can ultimately lead to blindness.

The company said that onchocerciasis infections occurred in tropical climates, with 99 percent of cases in 31 countries in sub-Saharan Africa and more than 25 million people infected worldwide.

Certara is owned by Sweden’s EQT VII Fund.

LIVING CELL TECHNOLOGIES

Living Cell says that three-year data from its phase I/IIa trial of NTCell for Parkinson’s disease shows improvements in some patients.

Living Cell said that the encapsulated pig choroid plexus brain cell NTCell remained the primary focus of its research and development efforts.

In November, Living Cell said that its 18-patient, phase IIb trial of NTCell had demonstrated no statistically significant efficacy for Parkinson’s disease at 26 weeks post implant (BD: Nov 10, 2017).

Today, Living Cell said that to determine if there was efficacy in its phase IIb trial would require longer than the 26-week follow-up reported in November, with one-year follow-up to be announced in May 2018.

Living Cell said it was collaborating with the University of Auckland’s Centre for Brain Research to identify the secretions from NTCell to develop a drug that would protect against human brain pericytes, cells thought to be central in the origin of neurodegenerative disease.

The company said it planned to explore further applications for NTCell and its components for eye and ear disease.

Living Cell climbed 0.4 cents or 17.4 percent to 2.7 cents with 1.2 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says that its Scenesse for erythropoietic protoporphyria (EPP) has not been recommended for reimbursement by the English National Health Service.
Clinuvel said that the National Institute for Health and Care Excellence (NICE) published its draft assessment with Scenesse, or 16mg afamelanotide, not recommended for reimbursement, subject to a final report.
Clinuvel said that NICE made recommendations for use of medical technologies by the English National Health Service (NHS) and a final recommendation was expected in May 2018, which, if not appealed against by the company, could be upheld.
The company said Scenesse was the only approved treatment for EPP patients in Europe and was currently under review as a highly specialized technology (HST) in England.
Clinuvel said that Scenesse had been authorized by the European Commission and while not currently reimbursed in England had been adopted as the standard-of-care for adult EPP patients in surrounding European reference countries.
Clinuvel UK general-manager Lachlan Hay said the company was “very disappointed with the preliminary assessment” but the assessment process was “still ongoing and NICE’s preliminary assessment [was] only a first draft”.
Mr Hay said that “NICE’s publication did not include the critical budget impact test showing that the annual cost of Scenesse falls well within the budget threshold set by NHS England and NICE for novel technologies”.
Clinuvel fell 12 cents or 1.5 percent to $7.73.

MESOBLAST

Mesoblast says it has US regenerative medicine advanced therapy designation for its mesenchymal precursor cells for cardiac patients with left ventricular assist devices.
Mesoblast said that the US Food and Drug Administration regenerative medicine advanced therapy (RMAT) designation under the 21st Century Cures Act aimed to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions.
This company said the designation allowed for multi-disciplinary, interactions with the FDA to support the development of and potential accelerated approval pathway for its allogeneic mesenchymal precursor cells in the treatment of heart failure patients with left ventricular assist devices (LVAD) and offered eligibility for priority review.
Mesoblast said that once the biologics licence application was approved the FDA could require post-approval confirmatory commitments.
Mesoblast chief executive Prof Silviu Itescu said the designation “speaks to the strength of the clinical data generated to date using our cell-based therapy in these heart failure patients with LVADs who are at risk of high mortality and have extremely limited treatment options”.
The company said that the RMAT designation came from a 30-patient randomized, blinded, placebo-controlled pilot trial of its MPCs at a dose of 25 million cells, which suggested the product improved native heart function, prolonged the time post device implantation of a first hospitalization for a non-surgical, major gastro-intestinal bleeding event and improved early survival rates.
Mesoblast said that a phase IIb trial of MPCs at a 150 million cells dose was currently being conducted in 159 patients with heart failure and LVADs with the primary endpoint expected to be reached by April 2018.
Mesoblast was up one cent or 0.7 percent to $1.46 with 1.45 million shares traded.

CRYOSITE, CELL CARE PTY LTD

The Australian Competition and Consumer Commission says it will discontinue its review of the merger of Cryosite and Cell Care Australia (BD: Aug 4, Nov 8, 2017).
The ACCC said Cryosite and Cell Care were the only two providers of umbilical cord blood and tissue collection, processing and storage in Australia outside the public health system.
ACCC chairman Rod Sims said the Commission would continue to "investigate the circumstances surrounding entry into the agreement and the closing of Cryosite's cord blood and tissue collection operations".
Mr Sims sad the ACCC was "concerned by the closure of Cryosite's cord blood and tissue marketing, collection and processing operations for new customers and the failure of the parties to approach the ACCC for clearance".
Mr Sims said that "while parties are not obliged to approach the ACCC for clearance, it is concerning that an acquisition in a highly concentrated market such as this would not prompt the parties to contact the ACCC".
The ACCC said Cryosite had publicly stated that it would maintain its cord blood and tissue operations for existing customers who had blood or tissue in storage.
In a separate announcement, Cryosite said the extraordinary general meeting for shareholders to vote on the transaction would proceed on January 15, 2018.
Cryosite was untraded at 12.5 cents.

ITL HEALTH GROUP

ITL says its wholly-owned subsidiary Myhealthtest Pty Ltd has launched a direct-to-consumer cholesterol test.
ITL said customers could monitor their cholesterol on the Myhealthtest secure website and that the test was available through its online shop.
The company said high cholesterol was a major issue and that "63 percent of adult Australians had abnormal levels of cholesterol in Australia and 89 percent of those with high cholesterol are not taking cholesterol-lowering medication".
ITL said that the recommended cholesterol test frequency was once every five years for adults under 45 years, and every year for adults who are more than 45 years or have a family history of heart disease.
The company said the cholesterol test was its third test, following its diabetes and thyroid tests, with a prostate test to launch in early 2018 (BD: Jul 14, 2015; Nov 28, 2017).
ITL was unchanged at 47 cents.

ONCOSIL MEDICAL

Oncosil says it has enrolled 28 patients and expects to treat the twentieth patient next month in its 300 patient pivotal Brachysil for pancreatic cancer trial.
Oncosil said the trial incorporated its 20-patient Conformité Européenne (CE) mark application study (BD: Oct 23, 2017).
The company said that its Brachysil radiation treatment showed "excellent local disease control" with 100 percent control at week-8 and 90 percent at week-16, with no serious adverse events attributed to the device or implantation procedure.
Oncosil said that a 73 percent tumor volume reduction was observed at week-8, four weeks post-implant, and 72 percent at week-16, 12 weeks post implant.
Oncosil was up half a cent or 3.2 percent to 16 cents with two million shares traded.

STARPHARMA

Starpharma says it will submit its Vivagel BV treatment clinical section of its new drug application to the US Food and Drug Administration tomorrow, December 22, 2017.
Starpharma said the clinical module was the fourth of five modules to be submitted under the rolling submission system.
The company said that the FDA had completed a preliminary review of the proposed clinical datasets and confirmed that the intended format and presentation of that data was acceptable.
Starpharma said the data included its two phase III treatment trials of Vivagel BV for bacterial vaginosis (BV) conducted in 2012 and said the efficacy data from the trials complied with the revised FDA guidance for the treatment of bacterial vaginosis issued in mid-2016.
The company said the revised FDA guidance recommended that the primary efficacy endpoint for products treating bacterial vaginosis should be assessed seven to 14 days after commencing treatment, aligning with its 2012 trials "which showed highly statistically significant clinical cure of [bacterial vaginosis] when patients were assessed two to five days after [the] end of treatment [or] nine to 12 days after commencing treatment".
In 2012, Starpharma said Vivagel failed to meet its phase III trial primary endpoint of clinical cure two to three weeks after the cessation of treatment but "achieved statistically significant clinical cure and resolution of patient-reported symptoms of [bacterial vaginosis] at the end of treatment visit (two to five days post treatment)" (BD: Nov 28, 2012).
In 2013, Starpharma said its phase II trial for BV recurrence was clinically, but not statistically, significant with a greater rate of adverse events (BD: Apr 3, 2013).
Starpharma said the one percent dose of Vivagel was close to statistically significant in reducing the risk of bacterial vaginosis at week-16 compared to placebo ($p = 0.0588$).
Today, Starpharma said its FDA application was submission for both treatment and prevention of recurrent bacterial vaginosis.
The company said the final clinical data module would be submitted "in the near future" with a review expected in about six to eight months.
Starpharma fell 1.5 cents or 1.1 percent to $1.35.

THE HYDROPONICS COMPANY

Hydroponics says it will distribute Nanolux Technology's lighting and ballasts for the hydroponic markets in Canada.
Hydroponics said its wholly-owned Canada-based business, Crystal Mountain-Dragon Vision would distribute the products adding to the inventory for "the rapidly growing Canadian marketplace for cannabis growth and production".
The company said that Nanolux had more than 40 years of experience and the product range controlled and regulated lighting to optimize growing conditions.
Hydroponics was up one cent or 1.6 percent to 63 cents

GENETIC TECHNOLOGIES

Genetic Technologies 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 77.8 percent from 0.9 cents on December 20 to 1.6 cents today and noted a significant increase in the trading volume.
Genetic Technologies closed up half a cent or 62.5 percent to 1.3 cents with 48.9 million shares traded.

PSIVIDA

Psivida's annual general meeting passed all resolutions, with up to 26.5 percent opposition to the issue of 380,000 options and 302,500 stock units to directors.
The strongest percentage dissent was against the issue of 20,000 options and 12,500 deferred stock units to director Douglas Godshall with 3,880,174 votes (26.5%) against the resolution and 10,778,443 votes (73.5%) in favor.
Psivida shareholders similarly opposed the grant of options and deferred stock units to chairman Dr David Mazzo, Dr James Barry, Michael Rogers, Jay Duker, and Kristine Peterson, as well as options, performance shares and restricted shares to chief executive officer Nancy Lurker and the company's executive compensation resolution.
The company said that the ratification of a previous share issue and the 10 percent placement capacity were passed by wider margins.
The company's most recent Appendix 3B said that Psivida had 45,256,999 US shares and Chess depositary interests on issue meaning that the opposition to Mr Godshall's options amounted to 8.6 percent of the company, sufficient to requisition extraordinary general meetings.
Psivida was untraded at $1.47.

CANN GROUP

The Vancouver, British Columbia-based Aurora Cannabis says it has increased its holding in Cann from 21,562,314 shares (19.9%) to 28,762,314 shares (21.8%).
Aurora said it bought 7,200,000 shares for $18,000,000 or $2.50 a share, the same price as the current $78 million capital raising.
In a separate announcement, chairman Allan McCallum said he was diluted below five percent in the capital raising.
Cann was unchanged at $2.52.

MESOBLAST

Mesoblast says that 20,044,771 shares will be released from voluntary escrow on January 6, 2018.
Mesoblast's most recent Appendix 3B new issue announcement said it had 470,601,826 shares in issue and a company executive told Biotech Daily that there were a further 158,901 shares held in voluntary escrow until October 6, 2018.

CSL

CSL says that company secretary and Australian general-counsel Edward Bailey has resigned as company secretary from today, December 21, 2017.
CSL said that Mr Bailey would continue as Australian general counsel and John Levy remained the sole company secretary.
CSL fell 56 cents or 0.4 percent to $141.06 with 1.5 million shares traded.