



Biotech Daily

Monday November 2, 2020

Daily news on ASX-listed biotechnology companies

- * OCTOBER BDI-40 DOWN 5%, ASX200 UP 2%, BIG CAPS UP 3%, NBI DOWN 4%
- * TODAY: ASX UP, BIOTECH DOWN: TELIX UP 29%; PATRYS DOWN 12.5%
- * US FDA APPROVES PHARMAXIS BRONCHITOL FOR CYSTIC FIBROSIS
- * TELIX, CHINA GRAND UP-TO \$450m RADIOTHERAPY PARTNERSHIP
- * IMUGENE: US FDA IND APPROVAL FOR PHASE I PD1-VAXX CANCER TRIAL
- * EMYRIA RECEIVES \$954k R&D TAX INCENTIVE
- * MEDADVISOR \$45m CAPITAL RAISE FOR ADHERIS ACQUISITION
- * NEUROTECH \$2.5m PLACEMENT; POSITIVE PRE-CLINICAL RESULTS
- * POLYNOVO APPOINTS BIOGENESYS GREEK NOVOSORB BTM DISTRIBUTOR
- * PAINCHEK, MEDI-MAP PARTNER FOR NZ AGED CARE PAIN MANAGEMENT
- * CELLMID LYRAMID MIDKINE DIVESTMENT AGM
- * RECCE 7.65m DIRECTORS OPTIONS AGM
- * NEUROSCIENTIFIC 3m DIRECTORS OPTIONS AGM
- * OPYL 1.2m DIRECTORS 'INCENTIVE' OPTIONS AGM
- * THORNEY, TIGA TAKE 9.3% OF ANATARA
- * KAROLIS ROSICKAS REPLACES REGENEUS CEO LEO LEE

MARKET REPORT

The Australian stock market was up 0.4 percent on Monday November 2, 2020, with the ASX200 up 23.7 points to 5,951.3 points. Seven of the Biotech Daily Top 40 stocks were up, 25 fell and eight traded unchanged.

Telix was the best, up 48.5 cents or 28.96 percent to \$2.16, with 4.1 million shares traded. Pharmaxis climbed 25 percent; Actinogen improved 4.8 percent; Oncosil and Paradigm were up three percent or more; with Cochlear, Opthea and Optiscan up by less than one percent.

Patrys led the falls, down 0.3 cents or 12.5 percent to 2.1 cents, with 7.3 million shares traded. Antisense lost 10 percent; Amplia fell 9.1 percent; Cynata shed 8.5 percent; Alterity was down 6.9 percent; Avita, Impedimed, Orthocell, Osprey, Starpharma and Uscom fell five percent or more; Polynovo lost 4.6 percent; Clinuvel, Dimerix, Prescient, Universal Biosensors and Volpara were down more than three percent; Cyclopharm, Genetic Signatures, Medical Developments, Nanosonics, Next Science, Proteomics and Resmed shed one percent or more; with CSL, Mesoblast and Pro Medicus down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

In the month of October, the Biotech Daily Top-40 Index (BDI-40) fell \$834 million or 5.0 percent to \$15,746 million.

A harsh reading could attribute it all to Mesoblast falling \$1,196 million or 39.3 percent following a US Food and Drug Administration complete response letter, requiring further trials of Remestemcel-L for graft-versus-host disease.

It is true to say that had Mesoblast not fallen, the BDI-40 would be up, but it is a composite index of many stocks. Some fell and others climbed.

By comparison, the benchmark S&P ASX200 was up 1.9 percent in October to 5,928 points but 11.0 percent below October 31, 2019.

The BDI-40 was up 4.5 percent for the year to October 31, 2020, while the Nasdaq Biotechnology Index (NBI) fell 3.7 percent in October but was up 21.6 percent for the year.

Most unusually, the collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed 2.7 percent in October despite the behemoth CSL retreating 1.4 percent to \$132,624 million.

Resmed was responsible for most of the improvement, up 16.9 percent to \$40,140 million on its first quarter report showing that its response to the Covid-19 pandemic was a positive for investors. Cochlear was up 7.5 percent to \$14,326 million.

For the month of October, 16 of the BDI-40 companies were up, nine by more than 10 percent and 23 fell, with 12 down by more than 10 percent.

Patrys was the best, on no major news at all, up \$13 million or 61.9 percent to \$34 million. Impedimed climbed \$20 million or 28.6 percent to \$90 million, followed by Amplia (26.3%), Imugene (19.9%), Pro Medicus (19.9%), Optiscan (18.4%), Polynovo (17.9%), Universal Biosensors (16.3%) and Genetic Signatures (11.1%).

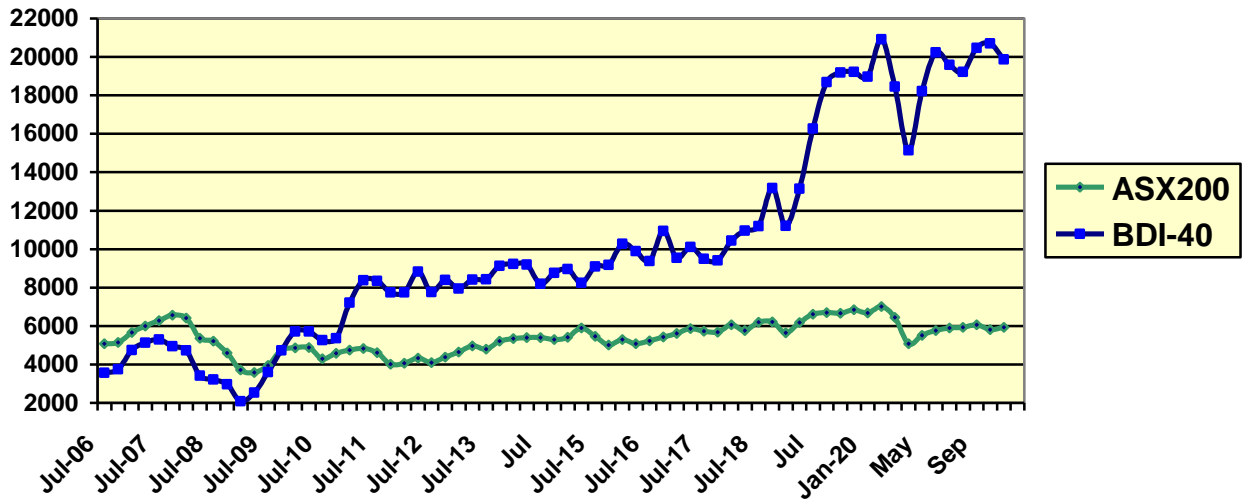
Mesoblast led the falls (see above) down \$1,196 or 39.3 percent to \$1,848 million, followed by Alterity down 27.8 percent to \$39 million, Antisense (23.9%), Actinogen (23.3%), Cynata (20.7%), Osprey (17.9%), Prescient (15.9%), Cyclopharm (15.5%), Dimerix (15.0%), Avita (14.0%), Orthocell (12.3%) and Clinuvel (12.2%).

Cannabis Corner fell a collective \$120 million in October to \$1,146 million, down 21.7 percent for the year to October 31.

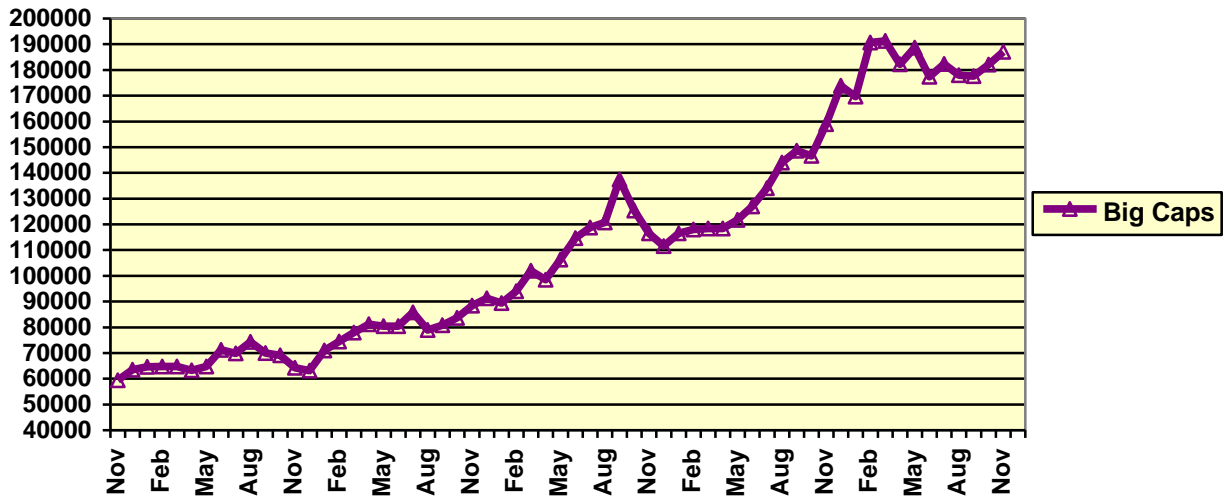
On the Nasdaq, Eyepoint (Psivida) fell 22.0 percent to \$71 million, down 79.6 percent for the 12 months, and its lowest market capitalization since March 31, 2018, when it left the ASX for the better valuations of the Nasdaq.

Redhill (with Australian assets) retreated 16.5 percent from an all-time high of \$533 million to \$445 million, while Queensland's Protagonist slipped 1.2 percent to \$992 million.

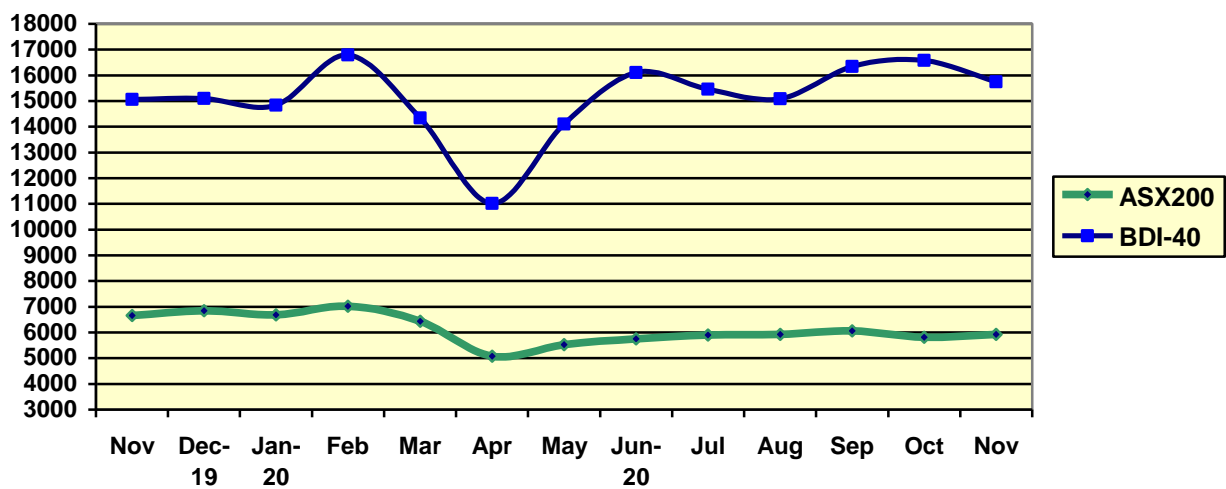
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2020- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Oct 31, 2015 – Oct 31, 2020



BDI-40 (\$m) v S&P ASX 200 – Oct 31, 2019 – Oct 31, 2020 (current, raw data)



PHARMAXIS

Pharmaxis says the US Food and Drug Administration has approved Bronchitol as “add-on maintenance therapy ... in cystic fibrosis patients 18 years of age and older”.

Pharmaxis said that US licensee, the Parma, Italy-based Chiesi Farmaceutici SpA, would pay a \$US7 million milestone with a further \$US3 million on shipment of commercial launch stock, inhaled mannitol dry powder, scheduled by April 2021.

In 2010, Pharmaxis said the FDA had provided guidance on its Bronchitol drug application which it expected to file by July 2011 (BD: Dec 15, 2010).

In 2011, the Australian Therapeutic Goods Administration approved Bronchitol, but the Pharmaceutical Benefits Scheme refused reimbursement two months later, followed by a European vote against approval (BD: Feb 8, Apr 21, May 25, Jun 24, 2011).

Following an appeal, Bronchitol was approved in Europe (BD: Oct 24, 2011).

In 2012, the company filed its Bronchitol for cystic fibrosis new drug application to the FDA, for which it had orphan drug designation and two-phase III trials, one of which showed Bronchitol (400mg mannitol) superior to placebo (50mg mannitol) but missing the significance endpoint ($p = 0.059$) (BD: Jun 23, 2010; May 21, Aug 2, 2012).

In 2012, the Pharmaceutical Benefits Scheme approved reimbursement for Bronchitol and later that year the UK National Institute for Health and Clinical Excellence (NICE) followed suit (BD: Jun 25, Oct 26, 2012)

In 2013, the FDA refused the Pharmaxis application, requiring an additional trial and the company began its third phase III trial, meeting its endpoint with other measures not statistically significant (BD: Mar 19, 2013; Oct 30, 2014; Feb 23, Jun 13, 2017).

Pharmaxis chief executive officer Gary Phillips said at that time that he believed the results were “sufficient to underpin a resubmission of the Bronchitol new drug application to the FDA ... in 2018” which the company did. (BD: Dec 20, 2018).

While the 16-person pulmonary-allergy drugs advisory committee backed Bronchitol the FDA required a further small trial to demonstrate that clinicians understood revised product packaging and user instructions (BD: May 9, Jun 20, 2019).

Pharmaxis filed the revised new drug application this year (BD: May 5, 2020).

Today, Pharmaxis said it expected US Bronchitol sales “to contribute strongly” to sales and profit, making the mannitol business cash flow positive from next year.

Pharmaxis chair Malcom McComas said the approval was “a very significant event for everyone who has worked hard to achieve this outcome”.

Pharmaxis chief executive officer Gary Phillips said the US made-up more than 60 percent of the cystic fibrosis market by value so the FDA “justifies the vision we shared with our partner Chiesi to commit to the final phase III study”.

Mr Phillips said that the additional Bronchitol volume “greatly increases capacity utilization and consequently radically improves the cost of goods”.

The company said that it expected to earn “high teens royalties” and three sales milestones totalling \$US15m were payable on annual sales thresholds.

“The FDA approval of Bronchitol is transformational for Pharmaxis because the milestone payments from Chiesi together with positive cash flows from the mannitol business segment allow us to move confidently ahead with the development of our lead clinical development asset PXS-5505 for the treatment of myelofibrosis,” Mr Phillips said.

“Clearing this last significant regulatory hurdle for the mannitol business also enables us to progress a number of restructuring initiatives to further extend the company’s cash runway,” Mr Phillips said.

The company said that PXS-5505 inhibited all the lysyl oxidase family of enzymes, which played a role in the development of severe fibrosis, as well as fibrotic cancers.

Pharmaxis climbed 2.2 cents or 25 percent to 11 cents with 157.5 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has an exclusive up-to \$US315 million (\$A450 million) plus royalties 10-year partnership with China Grand Pharmaceutical and Healthcare Holdings.

Telix said the development, sales, marketing and distribution agreement was for its prostate, renal and brain cancer imaging and therapeutic molecularly-targeted radiation products in Greater China.

The company said the Hong Kong-based China Grand would pay \$US25 million up-front and up-to \$US225 million in regulatory and commercial milestone payments, including up-to \$US69 million for marketing authorisation and up-to \$US156 million for commercial net sales milestones.

Telix said China Grand would pay an up-to \$US65 million program-related investment for clinical costs associated with TLX591 for prostate cancer and TLX250 for renal cancer in China and the agreement included minimum annual purchase obligations in order to maintain exclusivity in China.

The company said China Grand would also make a \$US25 million investment in Telix through a private placement at \$1.69 a share for 7.62 percent of the company.

Telix said the price was based on the 10-day volume weighted average price to October 28, 2020 and the shares would be subject to a holding lock for 12 months from issue.

Telix chief executive officer Dr Chris Behrenbruch said the company's "mission is to be a leading global oncology company and China is an important future market for our products".

"We are pleased to be working with [China Grand] to deliver our diagnostic imaging and therapeutic products to cancer patients in China," Dr Behrenbruch said.

"Considering the successful acquisition of Sirtex Medical with joint venture private equity partner CDH Genetech and subsequent approval of a new drug application filing for SIR-Spheres by the National Medical Products Administration of the People's Republic of China, we believe that [China Grand] possesses the technical experience and execution infrastructure to be an ideal clinical and commercial partner for Telix in China," Dr Behrenbruch said.

Telix climbed 48.5 cents or 28.96 percent to \$2.16 with 4.1 million shares traded.

IMUGENE

Imugene says it has investigational new drug approval from the US Food and Drug Administration for a 32-subject phase I trial of PD1-Vaxx for non-small cell lung cancer. In September, Imugene said it had ethics approval for the trial at New Jersey's Hackensack University Medical Center (BD: Sep 3, 2020).

The company said the multi-centre trial would test different doses of PD1-Vaxx as a monotherapy and in combination with immune checkpoint inhibitor drugs to determine safety, optimal dosage, efficacy and immune response.

Imugene said it could begin recruitment and additional sites would be opened at the Phoenix, Arizona-based Mayo Clinic and the Ohio State University Medical Center.

Imugene was unchanged at 5.6 cents with 11.8 million shares traded.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says it has received \$954,180 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Emyria said the rebate related to expenditure for the year to June 30, 2020.

Emyria fell 0.4 cents or 5.4 percent to seven cents with 1.2 million shares traded.

MEDADVISOR

Medadvisor says it hopes to raise \$45 million at 45 cents a share to fund the \$US27.5 million (\$A39.2 million) acquisition of Adheris Health from Syneos Health US Inc.

Medadvisor said it had paid Syneos a \$US1,375,000 deposit and would pay a further \$US21,125,000 at closing and a deferred \$US5 million payment by May 2021.

The company said the acquisition would be subject to raising a minimum of \$35 million in a hoped-for \$27.9 million placement and \$17.1 million one-for-2.5 entitlement offer.

Medadvisor said the Adheris acquisition would add a distribution and analytics capability to the company, including 15 patents for proprietary technology and patient delivery solutions.

The company said the Adheris patient communications systems included Patient Inoffice to deliver prescriber messaging, Patient Inpharmacy for pharmacists to directly engage with patients, Patient Inhome for supportive education and resources and Patient Inmotion to securely message patients.

Medadvisor said it expected to complete the acquisition on or around November 16, 2020. The company requested a trading halt and voluntary suspension pending the acquisition and capital raising.

Medadvisor last traded at 40 cents.

NEUROTECH INTERNATIONAL

Neurotech says it hopes to raise \$2.5 million in a placement at 2.2 cents for its Mente software and clinical trials of marijuana for autism, epilepsy and attention disorders.

Neurotech said it had interim results from pre-clinical laboratory studies of four marijuana strains, which found that full spectrum strains provided a potent "neuroprotective" effect.

The company said the strains reduced brain cell inflammation, improved mitochondrial viability, increased cell health and viability and increased the number of mitochondrial cells without toxic insult.

Neurotech said the strains were between 30 and 80 percent more potent than cannabidiol isolate in all tests and did not have any negative effects on cell health.

The company said studies were underway with Monash University and the Royal Melbourne Institute of Technology, with results expected by the end of November 2020.

Neurotech said that chair Brain Leedman had committed to subscribe for \$50,000 of shares and it would issue 10 million options exercisable at three cents within two years to Max Capital as lead manager to the placement.

Neurotech fell 0.2 cents or 7.7 percent to 2.4 cents with 8.5 million shares traded.

POLYNOVO

Polynovo says it has appointed Biogenesys as its Novosorb biodegradable temporizing matrix (BTM) for burns injuries distributor in Greece.

Polynovo said the Ioannina, Greece-based Biogenesys had an established network of leading hospitals and surgeons.

Polynovo managing director Paul Brennan said that Greece was "the first of the Mediterranean markets to join the Polynovo family".

"With Melbourne having such a close connection to Greece we are pleased that our life changing Novosorb BTM is now available to the wider Greek family".

"Biogenesys brings significant local knowledge and connections to facilitate penetration of this market," Mr Brennan said.

Polynovo fell 12 cents or 4.6 percent to \$2.48 with 2.6 million shares traded.

PAINCHEK

Painchek says it has partnered with the Christchurch, New Zealand medication management system, Medi-map, for aged care providers in New Zealand.

Painchek said that Medi-map would promote its pain assessment tool to aged care clients and integrate Painchek results into the platform to enhance delivery of care.

The company said the Medi-map platform managed all aspects of medication in a facility-based environment to share medication charts between a prescriber, pharmacy and care organization staff.

Painchek said it would remain responsible for direct sales, implementation, training and technical support, with direct sales in New Zealand commenced on November 1, 2020.

Painchek fell 0.3 cents or 3.4 percent to 8.6 cents with 3.7 million shares traded.

CELLMID

Cellmid says its annual general meeting will vote on the divestment of its wholly-owned subsidiary Lyramid and its midkine assets.

In 2016, Cellmid said it established Lyramid to commercialize its midkine antibody assets for therapeutic indications in fibrotic diseases and cancer (BD: Apr 8, 2016).

In August, the company said revenue for the year to June 30, 2020 was up 2.4 percent to \$8,547,715, including royalty licence fees of \$1,110,515 from its Lyramid midkine division (BD: Aug 27, 2020).

Cellmid said Lyramid developed treatments for inflammatory diseases and cancer targeting midkine, an embryonic growth factor implicated in a number of indications.

Today, Cellmid said the sale resolution was advisory only to gauge the views of shareholders and following a divestment, it would retain its hair loss products and Covid-19 tests.

The company said the meeting would vote to issue 465,437 shares to Dennis Eck in lieu of director's fees for the period from March 27, 2020 to March 26, 2021, issued at 10.74 cents a share, along with the remuneration report, to re-elect Dr Martin Cross as a director and adopt its employee incentive plan.

The meeting will be held at Level 5, 126 Phillip Street Sydney on November 30, 2020 at 1pm (AEDT), and virtually with pre-registration available at:

https://us02web.zoom.us/webinar/register/WN_3PfLqOrISfyVf8wppNYnZg.

Cellmid was unchanged at 10 cents.

RECCE PHARMACEUTICALS

Recce says its annual general meeting will vote to issue 7,650,000 options and 60,000 shares to directors as incentives.

Recce said it would vote to issue 2,250,000 options to managing director James Graham, 2,175,000 options to chair John Prendergast, 1,500,000 options to executive director Michele Dilizia, 1,125,000 options to director Dr Alan Dunton and 600,000 options to executive director Justin Ward, exercisable at \$1.56 within five years.

Recce said the meeting would vote to issue 60,000 shares to Dr Dunton as part of his remuneration, alongside \$60,000 in cash, adopt the remuneration report, elect Dr Prendergast and Dr Dunton as directors, approve an additional 10 percent capacity, ratify the prior issue of shares and options and adopt its employee incentive plan.

The virtual meeting will be held on November 30, 2020 at 9am (AEDT) with registration at: https://us02web.zoom.us/webinar/register/WN_DJPUbzY8Q8-le7F_MyEzfQ.

Recce fell 7.5 cents or 7.3 percent to 95 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its annual general meeting will vote to issue 3,000,000 options to directors Brian Leedman, Matthew Liddelow, Dr Anton Uvarov and Stephen Quantrill. Neuroscientific said it would vote to issue 1,200,000 options to managing director Mr Liddelow, 800,000 options to executive director Dr Uvarov and 500,000 options each to chair Mr Leedman and director Mr Quantrill, exercisable at 40 cents within three years. The company said the meeting would vote to adopt its remuneration report, to re-elect Mr Leedman and Dr Uvarov as directors, approve the 15 percent placement capacity and adopt its incentive performance rights and option plan.

The virtual meeting will be held on December 7, 2020 at 11am (AWST) with registration at: https://us02web.zoom.us/webinar/register/WN_rkZSjb5dSBihG6XyRYmWnw.

Neuroscientific was up two cents or 7.1 percent to 30 cents.

OPYL

Opyl says its annual general meeting will vote to issue 300,000 unlisted "incentive" options each to Dr Julian Chick, Damon Rasheed, Marat Basyrov and Mark Ziirsen.

Opyl said the options would be exercisable in three equal tranches within five years, including at 30 cents one year from the issue date, 50 cents two years from the issue date and 75 cents three years from the issue date.

Opyl said the meeting would vote to adopt its remuneration report, elect Mr Rasheed and Mr Ziirsen as directors, ratify the prior issue of shares and approve the 10 percent placement capacity.

The virtual meeting will be held on November 26, 2020 at 1pm (AEDT) with registration at: https://us02web.zoom.us/webinar/register/WN_MOkCKonAQGilpUFvsjirpw.

Opyl was unchanged at 15 cents.

ANATARA LIFESCIENCES

Thorney Technologies and Tiga Trading say they have increased their shareholding in Anantara from 2,787,773 shares (5.64%) to 5,328,514 shares (9.28%).

The Melbourne-based Thorney and Tiga said they acquired 2,540,741 shares in the \$1.67 million placement at 15 cents a share (BD: Oct 21, 2020).

Anantara was up half a cent or 2.6 percent to 19.5 cents.

REGENEUS

Regeneus says chief executive officer Leo Lee has resigned, replaced by Karolis Rosickas, effective immediately.

Regeneus said Mr Lee had left the company in order "to pursue a new role in a major Japanese pharmaceutical company" but would continue as a non-executive director.

The company said Mr Rosickas had more than 15 years' experience in healthcare, technology and finance, most recently as the chief executive officer and co-founder of London nutrition company Ome Health.

Regeneus said Mr Rosickas co-founded Singapore's Singcell and previously held senior positions at Hong Kong and Shanghai Banking Corporation, JP Morgan, Danone, Santander Group and Klynveld Peat Marwick Goerdeler.

The company said Mr Rosickas held a Master of Business Administration from the Barcelona-based University of Navarra's Institute of Higher Business Studies.

Regeneus fell one cent or 7.4 percent to 12.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT OCTOBER 31, 2020

| Company \$Am | Nov-19 | Oct-20 | Nov-20 |
|----------------------|---------------|---------------|---------------|
| Cochlear | 12,231 | 13,325 | 14,326 |
| CSL | 116,204 | 134,457 | 132,624 |
| Resmed | 30,565 | 34,346 | 40,140 |
| BDI-20 | | | |
| Avita | 1,114 | 741 | 637 |
| Clinuvel | 1,496 | 1,205 | 1,058 |
| Compumedics | 127 | 76 | 73 |
| Cyclopharm | 80 | 193 | 163 |
| Cynata | 134 | 121 | 96 |
| Ellex | 82 | 47 | 47 |
| Genetic Signatures | 102 | 244 | 271 |
| Immutep | 109 | 122 | 128 |
| Medical Developments | 384 | 346 | 356 |
| Mesoblast | 958 | 3,044 | 1,848 |
| Nanosonics | 2,042 | 1,748 | 1,580 |
| Neuren | 229 | 127 | 116 |
| Opthea | 876 | 781 | 750 |
| Paradigm | 572 | 623 | 612 |
| Pharmaxis | 79 | 34 | 35 |
| Polynovo | 1,494 | 1,514 | 1,785 |
| Pro Medicus | 2,772 | 2,861 | 3,431 |
| Starpharma | 432 | 598 | 576 |
| Telix | 415 | 422 | 425 |
| Volpara | 403 | 327 | 334 |
| Second 20 | | | |
| Actinogen | 37 | 30 | 23 |
| Alterity | 23 | 54 | 39 |
| Amplia | 4 | 19 | 24 |
| Antisense | 42 | 71 | 54 |
| Dimerix | 17 | 60 | 51 |
| Impedimed | 71 | 70 | 90 |
| Imugene | 85 | 206 | 247 |
| Kazia | 27 | 91 | 100 |
| LBT Innovations | 48 | 37 | 35 |
| Next Science | 438 | 236 | 221 |
| Oncosil | 66 | 108 | 116 |
| Optiscan | 19 | 49 | 58 |
| Orthocell | 100 | 74 | 65 |
| Osprey | 16 | 39 | 32 |
| Patrys | 20 | 21 | 34 |
| Prescient | 22 | 44 | 37 |
| Proteomics | 26 | 48 | 47 |
| Resonance | 53 | 73 | 69 |
| Universal Biosensors | 31 | 49 | 57 |
| Uscom | 17 | 27 | 26 |

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alcidion, Alterity, Amplia, BTC Health, Cochlear, Cynata, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Telix, Volpara and non-biotech stocks. Through Australian Ethical Superannuation he has an indirect interest in other companies: <https://www.australianethical.com.au/personal/ethical-investing/companies-we-invest-in/>. These holdings are liable to change.

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