Biotech Daily

Friday November 3, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 1.14 percent on Friday November 3, 2023, with the ASX200 up 78.5 points to 6,978.2 points. Twenty-two of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and one was untraded.

Next Science was the best, up 6.5 cents or 26.5 percent to 31 cents, with 1.8 million shares traded. Both Actinogen and Cynata climbed 12.5 percent; Compumedics and Imugene improved more than 11 percent; Atomo was up 9.5 percent; Neuren rose 8.5 percent; Opthea was up 7.8 percent; Genetic Signatures improved 5.3 percent; Impedimed and Orthocell were up more than four percent; Clinuvel, Emvision and Polynovo were up more than three percent; Avita, CSL, Pro Medicus, SDI and Universal Biosensors rose more than two percent; Mesoblast, Nanosonics, Prescient and Telix were up more than one percent; with Cochlear up by 0.7 percent.

Dimerix led the falls, down 1.5 cents or 7.9 percent to 17.5 cents, with 7.5 million shares traded. Cyclopharm lost 5.3 percent; Antisense and Pharmaxis were down more than three percent; Nova Eye and Volpara shed more than two percent; with Amplia, Proteomics and Resmed down by more than one percent.

GLAXOSMITHKLINE
THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Glaxosmithkline says that the Walter and Eliza Hall Institute's Prof David Komander has won its $100,000 Research Excellence award.

Glaxosmithkline said that Prof Kommander was a leader in ubiquitination "a process that marks proteins for destruction and plays a crucial role in helping our cells stay healthy and functional".

The company said that Prof Kommander's work on 'kiss of death' proteins led to numerous drug discovery projects across a range of diseases, including Parkinsons disease.

Glaxosmithkline said that the award would support further research into ubiquitination with potential to impact a range of health conditions.

AUSBIOTECH

Ausbiotech says that Dr Iris Depaz will replace Serg Duchini, Geoffrey Kempler and Linda Peterson as a member of its board.

Ausbiotech said that Dr Depaz was Sanofi Australia and New Zealand's head of vaccines and was elected to the board at yesterday's annual general meeting in Brisbane.

Ausbiotech said Dr Depaz had more than 20 years of industry experience and was integral in developing Sanofi's Translational Science Hub, a $280 million partnership with the Queensland Government, University of Queensland and Griffith University.

Ausbiotech interim chair Dr James Campbell thanked the departing board members for their service "drive, passion, and considered guidance".

"I would also like to acknowledge Graham McLean for his input and advice as board observer," Dr Campbell said.

Ausbiotech said its current board comprised Dr Campbell, Dr Depaz, Erica Kneipp, Dr Megan Baldwin, Dr Dean Moss, Dr Marthe D'Ombrain and Lorraine Chiroiu.

DR BOREHAM'S CRUCIBLE: PARADIGM BIOPHARMACEUTICALS

By TIM BOREHAM

ASX code: PAR

Share price: 43 cents

Shares on issue: 281,756,625 (pre capital raise)

Market cap: $121.2 million

Executive chair: Paul Rennie

Board: Mr Rennie, Dr Donna Skerrett (chief medical officer), Amos Meltzer, Helen Fisher (John Gaffney resigned on October 20, 2023)

Financials (year to June 30 2023): revenue from continuing operations $46,760 (down 41%), loss of $51.9 million (previous deficit $39.2 million), cash $69.4 million (proforma, post capital raising excluding options exercise).

Identifiable major holders: Paul Rennie and related entities 7.3%.

The golden rule of biotech is never to waste a positive announcement - let alone two of them - by shunning the opportunity to fill the coffers.

On October 10, Paradigm released a clinical update that confirmed the efficacy of its repurposed wonder drug Zilosul (pentosan polysulphate sodium) for dodgy knees and joints.

A week later the company released data from magnetic resonance imaging (MRI) scans that suggests Zilosul results in 'functional' improvement to the joints - an outcome well beyond the previous known effects of relieving pain and improving function.

The key findings were that cartilage reduction had not just been halted but the volume of this connective tissue had increased, with bone lesion damage reducing.

OK, the study was based on a small active cohort of 15 patients, but it marks the first time that any drug has been shown to have such an effect.

Before you could say 'trick or treat', on October 30 the company was doing the rounds for $30 million by way of a placement and underwritten entitlement issue.

Spooky, eh?

The MRI results could pave the way for earlier provisional approval from Australia's Therapeutic Goods Administration (TGA), bearing in mind that more than 600 patients have been treated under the agency's special access scheme (SAS).

In 2018, the FDA knocked back the company's approval application and demanded a phase III trial.

There are more than 530 million osteo-arthritis (OA) sufferers worldwide, including 30 million in the US.

It's a dog's life

PPS is an anti-inflammatory, heparin-like compound made from beechwood hemicellulose and has been used as to treat a bladder condition and deep-vein thrombosis.

The manufacturing involves not just chucking bark in a vat, but a complex process to produce the final formulation.

Currently, osteo-arthritis commonly is treated with non-steroidal anti-inflammatory drugs or opioid-based painkillers, which are either ineffectual or undesirable.

Janssen Pharmaceuticals (Johnson & Johnson) sells an oral formulation of PPS under the name Elmiron, to treat a painful bladder disease called interstitial cystitis.

Paradigm has an exclusive 25-year exclusive supply deal with the only approved PPS maker, Germany's Bene Pharmachem.

Paradigm also has relevant patents (see below).

The deal pertains to human osteo-arthritis (OA) applications and not veterinary purposes. For some years PPS has been used to treat canine joint pain, including on Biotech Daily's editor David Langsam's faithful hound, Ripley.

Ripley is now deceased - believe it or not - but as far as we know this sad event had no causal link with the treatment.

Paradigm shifts

Paradigm was founded by Paul Rennie and Graeme Kaufman and listed on the ASX on August 18, 2015, having raised $8 million at 35 cents apiece.

Mr Rennie was Mesoblast's head of product development. Mr Kaufman was CSL's chief financial officer through the plasma behemoth's privatization and was Mesoblast's vice prez. Mr Kaufman stepped down as a Paradigm director (and chair) in June 2020 for health reasons.

In November 2021, Mr Rennie ceded his chief executive role and continued as chair. But in November last year he returned to the CEO role while continuing as (now executive) chair.

Mr Rennie replaced US-based healthcare exec Marco Polizzi, who came on as CEO in July last year but didn't last the gestation period, having clocked off on February 20 this year.

Where's the evidence?

Paradigm's evidence so far consists of two phase II trials - Para 005 and Para OA 008 - and the 600 'real world' patients. Many of the latter are former footballers, including Paradigm's investor relations guy Simon White.

Ten former US National Football League players have also been treated under a US special access scheme.

Para 005 achieved a primary endpoint of reduction in pain and improved function among its 121 subjects.

Covering 61 patients, Para 008 kicked off in 2021 with the remit of measuring the change in the synovial fluid biomarkers associated with pain, inflammation and osteo-arthritis disease, relative to placebo.

Having tabled positive results at days 56 and 168, Paradigm last month reported "clinically meaningful outcomes" at 365 days compared to placebo.

These included significant pain reduction and functional improvements and durable improvements in stiffness, as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (Womac) questionnaire.

The company also reported reduced use of pain medication, with the placebo group resorting to paracetamol (or such) five times more than the treated group.

The participants received two milligrams per kilograms of bodyweight, twice weekly for six weeks and the company now believes this regimen is ideal.

Moving to phase III

The first phase III program, Para-OA-002 is designed to maximise the potential of PPS for osteo-arthritis pain.

Granted FDA fast-track approval, the trial recruited 468 healthy volunteers for the first dosing stage, now completed, across 120 sites in seven countries.

In early 2024, the company expects to confirm the 2.0mg/kg dosing as optimal.

The trial then moves to a pivotal stage, covering 900 patients with a top-line data readout expected in mid-2025.

The program then moves to a confirmatory trial, dubbed - you guessed it - Para-OA-003 with enrolment starting by July 2024.

The company is eyeing a new drug application to the FDA by the end of 2025.

MRI data really resonates

With 15 active patients and 22 on placebo, the magnetic resonance imaging (MRI) sample was small, but it still showed a significant difference between these arms.

The analysis saw an increase in cartilage volume and thickness from baseline, by an average 0.06 millimetres. Among the placebo group, the cartilage loss averaged 0.04 millimetres.

The improvement was most notable in the medial compartment, where most knee osteo-arthritis occurs.

There was also a 17 percent reduction in bone marrow lesion volumes - compared with a two percent increase for the placebo cohort - and a reduction in synovitis inflammation.

Under normal conditions, cartilage reduces by four percent a year and the standard- of-care treatments such as corticosteroids are known to accelerate cartilage loss.

“Nothing else has shown the ability to halt disease progress, let alone regenerate cartilage,” broker Bell Potter chimes.

What’s next?

TGA provisional approval is extended to drug candidates with decent phase II data, for cases of high unmet needs for significant diseases.

“The TGA was impressed with the phase II data out to day-86 and wants to know the duration effect,” Mr Rennie says.

Naturally, the company would be obliged to continue a phase III trial and seek full approval down the track.

Australia has around three million osteo-arthritis sufferers - and the company reckons about 80 percent are unhappy with their current medication.

That implies an addressable market of hundreds and millions of dollars.

The company is confident of approval in early 2025.

Meanwhile, FDA approval remains Paradigm’s key priority, with the MRI data potentially supporting a disease-modifying indication.

“Pain and function is a huge market but if we can increase the label to ‘disease modifying’ it not only increases the price, but potentially how early it is bought forward by prescribing doctors in disease progressions,” Mr Rennie says.

Finances and performance

Three weeks ago, Mr Rennie asserted a capital raising at the prevailing subdued share price would be “too dilutive and devalue the asset”.

But the share valuation partially reflected the market’s expectation of a raising, so it gets a bit chicken-and-eggy.

Paradigm announced an $18 million institutional placement, followed by the $12 million non-renounceable rights offer of one share for every 10 shares held, with both struck at 43 cents a share, a hefty 30 percent discount to the prevailing price.

The rights leg also included a sweeter of three options for every four shares subscribed, exercisable at 65 cents by November 30, 2024.

Underwritten by lead manager Bell Potter, the raising takes the company’s pro forma cash position to $69 million, with the exercise of the options potentially adding $33.8 million.

Assuming the options are exercised, the proforma $103 million of cash is enough to fund the company to mid-2025 (and the phase III read-out).

The company also expects to pocket a $7.3 million Federal Research and Development Tax Incentive in the current quarter.

In August last year, Paradigm raised $66 million in a placement and rights issue, at $1.30 apiece. Paradigm shares are trading at close to their five-year low point, well adrift of the peak of $4.17 in January 2020.

How watertight are the patents?

While Paradigm has made great strides in proving that Zilosul might be a wonder drug for osteo-arthritis patients, there’s always the question of the strength of the company’s patent position.

The exclusive supply deal with Bene Pharmachem aside, Paradigm has patents on the relevant indications in injected oral or topical form, expiring in 2035 and 2040.

Nonetheless, Bell Potter opines that the validity of these patents is “highly likely” to be challenged, especially if the drug succeeds commercially.

The firm adds the supply contract is a “crucial piece of the company’s value as it effectively prevents, or delays, the creation of generics”.

Mr Rennie notes that Elmiron has been off-patent for years and has never had generic competition.

Paradigm highlights collaborative research that shows Zilosul differs to other available PPS drug substances “both with respect to their respective structure and biological characteristics”.

This means a generic PPS manufacturer would need to perform their own clinical efficacy and safety studies to gain marketing approval.

That takes care of third parties, but could Bene Pharmachem be so cheeky as to put out their own osteo-arthritis drug?

“They can’t and they wouldn’t,” Mr White says. “Their skills set lies in manufacturing and their sole focus it to produce as much PPS as they can. As part of the exclusivity deal, we do the clinical trials and they refer to us as their clinical arm.”

Dr Boreham’s diagnosis:

A former footballer for the AFL club Carlton, Mr White endured no fewer than eight knee surgeries - and multiple reconstructions - over his eight-year, 87-game playing career.

When Mr White retired in 2017 his knees were shot, but now he can “still kick a footy and run around on hard surfaces”.

“If you have had it [PPS], you are certainly a believer,” he says. “Patients don’t want to go back to where they were.”

Another true believer is principal investigator (and Carlton Football Club chief medical officer) Dr Philip Bloom, who has prescribed PPS to more than 300 patients under the special access scheme.

“I have seen myriad people seeing positive changes to their lifestyles and getting back to things they previously may have been unable to do due to the pain and dysfunction caused by their disease,” he trills.

Paradigm certainly is at an interesting juncture, with the potential TGA provisional approval promising some early revenues. But the limp share valuation shows that many investors think the Paradigm story is too good to be true.

Within the next two years we should know whether the sceptics or the true believers are right.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was once offered a shot of Zilosul but happily he has no kneed – yet.

NEUREN PHARMACEUTICALS

Neuren says sales of Daybue for the three months to September 30, 2023 was $US66.9 million ($A104.1 million), providing $10.4 million in royalties.

Neuren said the third quarter sales of Daybue, or trofinetide, for Rett syndrome, were up 188.4 percent compared to the three months to June 30, 2023.

The company said that it expected royalties from sales for the three months to December 31, 2023 to be between $12.5 million and $13.7 million, providing total royalties for the year to December 31, 2023, between $26 million and $28 million.

Neuren said there were 800 patients currently being treated with Daybue at September 30, 2023, that "the surge in initial demand [had] exceeded pre-launch expectations".

The company said 81 percent of patients remained on Daybue after four months, 80 percent of patients were covered by formal reimbursement plans, 75 percent to 80 percent of patients complied with the labelled dose at three months and physicians and caregivers continued to report benefits.

Neuren chief executive officer Jon Pilcher said the launch of Daybue had "been exceptional, with all metrics exceeding expectations and we are delighted to see the positive impact in the Rett community".

"The first full quarter of sales has achieved an annual run-rate of more than US$250 million," Mr Pilcher said.

"For Neuren, in addition to very significant royalty revenues, this brings into focus the potential sales milestone payments," Mr Pilcher said.

Neuren was up 96 cents or 8.5 percent to $12.25 with 2.1 million shares traded.

NANOSONICS

Nanosonics says its Coris device is superior to manual cleaning for removing unwanted biofilms from endoscope air and water channels.

In its annual general meeting presentations, Nanosonics said that the Coris system was "significantly more effective at removing cyclic build-up biofilm from simulated endoscope [air/water channel] lumens compared to manual cleaning".

The company said that preliminary study results, presented at conferences, but not in standalone announcements to the ASX, showed that in simulated endoscopes, the biofilm built-up within 30 to 60 days, despite the endoscopes being cleaned and disinfected immediately after each use.

Nanosonics said that in three-metre-long segments of a 1.4 millimetre lumen channel the study grew biofilm then stained it and measured protein levels to test for cleanliness after manual cleaning and comparing that to the use of its Coris device.

The company said that considering the protein results, manual cleaning "essentially had no effect" in removing protein, but its Coris "reduced it down to the limit of detection".

Nanosonics said it had "very similar results on other markers measured, [including] total organic carbon and colony forming units".

The company said that "clearly, this data demonstrates the opportunity for Coris to set a totally new benchmark in cleaning but more importantly, improved patient safety".

Nanosonics said the efficacy data was being presented at a number of international conferences, at the National Infection Prevention conference in the US, at the World Federation of Hospital Sterilisation Services in Europe and the Irish Decontamination Institute with much "positive feedback".

Nanosonics said it expected to submit a US Food and Drug Administration de-novo submission for Coris by the end of March 2024.

Nanosonics was up four cents or one percent to $3.91 with 898,872 shares traded.

IMPEDIMED

Impedimed says Unitedhealthcare will reimburse its Sozo bio-impedance spectroscopy for lymphedema assessment in the US.

Impedimed said Unitedhealthcare was “the largest private payer in the US’ and that it had changed its policy on bio-impedance spectroscopy for detecting lymphedema from “unproven and not medically necessary”, or experimental, to silent coverage.

Impedimed managing-director Rick Valencia said it was a “very exciting step for patients at risk of lymphedema”.

“We expect this change to mean that we will have silent coverage from Unitedhealthcare, when the policy goes into effect in January 2024,” Mr Valencia said.

“With this change, Unitedhealthcare will be the second top-five national payer to cover Sozo testing for lymphedema … [as] Cigna was the first,” Mr Valencia said.

“Silent coverage is not uncommon,” Mr Valencia said.

“US Medicare and 27 other private payers currently cover our technology through silent coverage,” Mr Valencia said.

“With the addition of Unitedhealthcare, we will achieve six states at critical mass to start the calendar year,” Mr Valencia said.

Impedimed was up half a cent or 4.35 percent to 12 cents with 4.2 million shares traded.

AUSTCO HEALTH

Austco says it has an $3.8 million contract to refresh the Tacera Nurse Call platform at Singapore’s Ng Teng Fong General Hospital and Jurong Community Hospital.

Austco said the contract with the 700-bed Ng Teng Fong Hospital and the 400-bed Jurong Hospital included its care communications system and real-time location system-enabled call points.

The company said the contract took its open sales orders to a record $40.7 million, and that a portion of the contract revenue would be recognized in 2023-’24, with the remaining balance anticipated to be delivered in 2024-’25.

Austco was up one cent or 5.7 percent to 18.5 cents.

ADALTA

Adalta says it hopes to raise $1.23 million in a placement at two cents a share, a 13.0 percent discount to the last traded price.

Adalta said that for every two shares purchased shareholders would receive one attaching option exercisable at three cents by May 29, 2024, and if the options were approved by shareholders at its extraordinary general meeting, would receive an additional option exercisable at the same terms.

The company said the funds would be used for final analysis of its phase I extension study of AD 214, progressing partnering and licencing discussions for AD-214, evaluating external technology and product opportunities, expanding its product pipeline and to the extent any funds remain for general working capital.

Adalta said it had appointed Peak Asset Management lead manager of the placement, and would issue it 12,000,000 options if the placement raised $1.5 million and a further 5,000,000 options for every additional $500,000 raised, subject to shareholder approval.

Adalta said the offer opened November 3 and would close on November 6, 2023.

Separately, Adalta requested a trading halt “in relation to a proposed capital raising”.

Trading will resume November 7, 2023, or on an earlier announcement.

Adalta last traded at 2.3 cents.

ANATARA LIFE SCIENCES

Anatara says hopes to raise about $1.055 million in a partially underwritten, two-for-five, pro-rata, non-renounceable entitlement offer, at 2.2 cents a share.
Anatara said the offer price was a 27 percent discount to the five-day volume weighted average price up-to and including October 31, 2023, of 3.01 cents a share.
The company said Taylor Collison Ltd would act as lead manager and would underwrite the offer up-to about $360,000, with executive chair Dr David Brookes and director John Michailidis committed to take up their entitlement and sub-underwrite the offer for $33,000 and $5,500, respectively.
Anatara said the funds would be used to progress its stage II clinical validation trial of Garp product for irritable bowel syndrome following stage I success.
The company said the offer had a record date of November 8, would open on November 13 and would close on December 1, 2023.
Anatara fell 0.2 cents or 6.7 percent to 2.8 cents.

NEXT SCIENCE

Next Science says a 423-patient study shows its Xperience for peri-prosthetic joint infection led to a zero percent infection rate for all patients within 90 days.
Next Science said the study was conducted over 12 months from June 2021 to June 2022 and included nine surgeons at two sites applying their own techniques and surgical approaches with 423 primary joint arthroplasty patients.
The company said there were 217 knee patients, 164 hip patients and 42 shoulder patients, and that the study endpoint was the rate of peri-prosthetic joint infection within 90 days of surgery according to Centre for Disease Control criteria.
Next Science said that about 95 percent of patients presented with at least one high-risk co-morbidity profile, that pre-disposed the patient to peri-prosthetic joint infection.
Next Science said the study, titled 'Novel Intra-Operative Surgical Irrigant in Preventing Periprosthetic Joint Infection in Primary Hip, Knee and Shoulder Arthroplasties: A Retrospective Analysis', was led by Dr Robert Harris.
The company said that typical incidence rates for peri-prosthetic joint infection ranged from one-to-two percent for hip or knee surgeries and 0.4-to-four percent for shoulder surgeries.
Next Science said a finding of zero percent infection across a patient cohort of this size "supports our view of the efficacy of our advanced surgical irrigation solution".
Next Science said Dr Harris "concluded that Xperience was efficacious at preventing [peri-prosthetic joint infection] at rates at or below historical incidence rates, which warranted further investigation as a sole anti-microbial irrigant".
The company said Dr Harris believed further studies should include "a robustly designed, controlled, blinded, prospective multi-centre clinical trial in joint arthroplasty surgeries to determine [the] potential utility of this novel irrigant to reduce the overall burden of [peri-prosthetic joint infection] and improve patient outcomes".
Next Science said Dr Harris had submitted the study data for publication.
Next Science managing-director Harry Hall said the study was "the first of three retrospective studies investigating the efficacy of our advanced surgical irrigation solution, Xperience into preventing surgical site infection in primary joint surgeries".
"This data set is encouraging and begins the process of building the clinical evidence base culminating in the major prospective study in infection prevention that commenced in Canada earlier this year and is targeting 7,600 patients," Mr Hall said.
Next Science was up 6.5 cents or 26.5 percent to 31 cents with 1.8 million shares traded.

IMMUTEP

Immutep says its phase II trial of efti for non-small cell lung cancer (NSCLC) shows "statistically significant increases" in biomarkers linked to improved outcomes.
Last year, Immutep said data from its 114-patient, Tacti-002 phase II trial of eftilagimod alpha, or efti, with pembrolizumab for NSCLC had an 'encouraging' overall response rate of 40.4 percent, or 46 patients (BD: Nov 11, 2022).
Today, the company said increased interferon-gamma and C-X-C motif chemokine ligand 10 (CXCL-10) serum biomarkers were seen at three months and six months of therapy.
Immutep said six-of-seven patients with a partial or complete response showed a more than or equal to 1.4-fold change of interferon-gamma and all seven showed a more than 1.4-fold change in CXCL-10 after the first efti dosing.
Immutep said an early increase of lymphocyte count was reported and greater in overall, and progression-free survival, complete response, partial response or stable disease.
Immutep said an early increase in absolute lymphocyte count correlated to the positive overall survival results in non- small cell lung cancer patients it presented at a conference in 2023, and was a potential on-treatment biomarker for clinical benefit.
The company said blood-based gene expression profiling analyses showed "significant enrichment of genes involved in immune activation and cytotoxicity, including CD8 T-cells, in patients with a favorable tumor response".
Immutep said it would present that data at the Society for Immunotherapy of Cancer's annual meeting at San Diego Convention Centre from November 1-to-5, 2023.
Immutep chief scientific officer Dr Frederic Triebel said the data further confirmed "efti's unique stimulation of the immune system, which may help patients live longer".
Immutep was unchanged at 30 cents with one million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has pre-clinical data showing its ARG-007 "significantly inhibits the cellular uptake … of tau protein in two different in victor Alzheimer's disease models".
Argenica said the first study at New York's Creative Biolabs tested its ARG-007 in mice incubated with human Alzheimer's patient tau proteins, which showed a 68.2 percent reduction in cellular uptake at a 0.0375 microgram concentration.
The company claimed statistical significance in the study of three groups of five-to-six mice at different doses and a 12 mouse no treatment control group.
Argenica said the second study was by chief scientific officer Prof Bruno Meloni at Perth's Perron Neuroscience Research Institute using laboratory models incubated with tau seeds, which showed a 48.7 percent inhibition in cellular uptake.
Argenica said the studies showed ARG-007 had the "capacity to significantly reduce the uptake of abnormal tau into brain cells … thereby potentially limiting the spread of abnormal tau between brain cells".
The company said the studies confirmed that ARG-007 inhibited "intracellular tau aggregation by up to 89 percent in the first study and 35 percent in the second study".
Argenica cited an article titled 'The complexity of tau in Alzheimer's disease', published in Neuroscience Letters in 2019, which said the spread of abnormal tau was "thought to be a significant cause of Alzheimer's disease".
The article is at: https://pubmed.ncbi.nlm.nih.gov/31028844/.
Argenica managing-director Dr Liz Dallimore said "the ability of ARG-007 to reduce tau cellular uptake and abnormal aggregation of tau within neurons in these two pre-clinical studies is extremely encouraging".
Argenica was up 3.5 cents or 11.3 percent to 34.5 cents with 1.2 million shares traded.

PYC THERAPEUTICS

PYC says it has dosed all three patients in cohort two of its single-ascending dose phase I clinical trial of VP-001 in patients with retinitis pigmentosa type 11 (RP11).
In September, PYC said it had safety review committee approval for a second three-patient cohort in its trial of VP-001 (BD: Sep 22, 2023).
Today, the company said the safety review committee overseeing the trial would meet in December to review the initial data generated for patients in cohorts one and two and consider approval to escalate to dosing in cohort three.
PYC said subject to approval it remained on track to begin dosing patients this year.
The company said it expected to transition to a multiple ascending dose study of VP-001 in retinitis pigmentosa type 11 patients by July 2024.
PYC said both the currently ongoing single ascending dose study and the planned multiple ascending dose study would contribute to initial human safety and efficacy read-outs with data expected across both sets of endpoints in 2024.
PYC was unchanged at 5.6 cents.

ARTRYA

Artrya has told the ASX it became aware that its 510(k) filing for Salix US Food and Drug Administration approval had been delayed eight months on October 17, 2023.
The ASX said that in an announcement marked price sensitive, on May 3, 2023, Artrya said it had lodged a “Q-submission” to the US Food and Drug Administration for its Salix coronary anatomy system for coronary plaque identification (BD: May 3, 2023).
Biotech Daily reported at that time that the FDA website did not explain what the “Q” represented but said a ‘Q-Submission’ or ‘Q-Sub’ “refers to the system used to track the collection of interactions” and were opportunities for submitters to share information with the FDA and receive input beyond the submission of an application. Artrya said in May that the submission was a “key enabling step” in the US regulatory process and it expected a meeting with the FDA to present its approach to the Salix product’s development and clinical reader study within nine to 12 weeks.
The company said at that time that it “expected that the final 510(k) application will be able to be submitted to the FDA by the end of October 2023”.
The ASX said that in an Appendix 4C Quarterly Report dated October 19, 2023, Artrya it expected to file the 510(k) submission in “late June 2024”.
The ASX asked Artrya whether the information was “information that a reasonable person would expect to have a material effect on the price or value of its securities?” and if not why not and when it first became aware of information before the relevant date.
Artrya told the ASX that it did not consider the information material because the Q-sub was only “steps in a process for a decision by the FDA”.
The company said that at a board meeting held on October 17, 2023 the board was advised that the company “would not be in position to lodge a final FDA 510(k) submission around the end of October as all Q-Sub targets as guided by the FDA Q-Sub meeting would not be fully achieved”.
“To lodge a final FDA 510(k) submission without all FDA feedback being fully addressed would place at risk the quality of the submission and future timing of an FDA approval,” Artrya said
The company said that it “prepared the necessary disclosure promptly without delay and released the information to the market in its Quarterly Report lodged before market open on October 19, 2023”.
Artrya fell two cents or 9.1 percent to 20 cents.

CORRECTION: ATOMO DIAGNOSTICS

Atomo has told the ASX that the 10 percent placement annual general meeting resolution was not “carried” as stated yesterday (BD: Nov 2, 2023).
The additional placement capacity vote is a ‘special resolution’ requiring a 75 percent majority to pass and yesterday Atomo said the additional 10 percent placement capacity was opposed by 44.15 percent of the meeting.
No sub-editors were harmed in making this correction.
Atomo was up 0.2 cents or 9.5 percent to 2.3 cents.

POLYNOVO

Polynovo says its annual general meeting resolution to adopt the remuneration report was opposed by 58,425,329 votes (22.28%) with 206,192,443 votes (77.92%) 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 and if passed the directors must stand for re-election within 90 days.
The company said the resolution to approve the employee share option plan was opposed by 63,060,264 votes (21.24%), with the election of directors Robyn Elliot and Christine Emmanuel-Donnelly passed with more than 93 percent of votes.
According to its most recent notice, Polynovo had 690,232,751 shares on issue, meaning the votes against the share plan amounted to 9.1 percent of the company, sufficient to requisition extraordinary general meetings.
Polynovo was up 4.5 cents or 3.6 percent to $1.295 with 1.7 million shares traded.

RACE ONCOLOGY

Race says it has requested a trading halt to analyze and interpret data from its “phase II human clinical trial … [of] bisantrene … [for] acute myeloid leukaemia”.
Trading will resume on November 7, 2023, or on an earlier announcement.
Race last traded at 91.5 cents.

CLEO DIAGNOSTICS

Cleo says it has requested a trading halt pending an announcement “in connection with the publication reporting results of Cleo’s first clinical validation study for the triage test”.
Trading will resume November 7, 2023, or on an earlier announcement.
Cleo last traded at 16.5 cents.

LUMOS DIAGNOSTICS

Melbourne’s Planet Innovation says its 68,021,060 share-holding in Lumos has been diluted from 16.11 percent to 14.13 percent.
Planet Innovation said it was diluted in a share issue on October 30, 2023.
On Monday, Lumos said it had raised $2.65 million in a private placement at seven cents a share to existing institutional shareholders (BD: Oct 30, 2023).
Lumos was up 0.8 cents or 10.8 percent to 8.2 cents with 12.2 million shares traded.