



Biotech Daily

Monday October 30, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: CYNATA UP 12.5%; NEXT SCIENCE DOWN 10%**
- * **PARADIGM HOPES TO RAISE \$30m**
- * **LUMOS PLACES \$2.65m; TOTAL \$8.1m**
- * **CONTROL BIONICS RIGHTS TO RAISE \$2.7m, \$1m UNDERWRITTEN**
- * **4D: INTEGRAL DIAGNOSTICS TO SELL XV LVAS IN AUSTRALIA, NZ**
- * **AMPLIA AMP945 'SAFE, WELL TOLERATED, INITIAL EFFICACY'**
- * **ORTHOCELL 1.7m SHARES FOR UWA ROYALTIES**
- * **EMYRIA: ETHICS COMMITTEE 'ENDORSES' MDMA PRESCRIBERS**
- * **MESOBLAST 7.5m CEO, CMO DIRECTOR OPTIONS AGM**
- * **BLUECHIIP 3m CEO 'PERFORMANCE' RIGHTS AGM**
- * **REGAL TAKES 5.6% OF BLUECHIIP**

MARKET REPORT

The Australian stock market fell 0.79 percent on Monday October 30, 2023, with the ASX200 down 54.0 points to 6,772.9 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and three were untraded.

Cynata was the best, up 1.5 cents or 12.5 percent to 13.5 cents, with 12,408 shares traded. Micro-X climbed 7.7 percent; both Actinogen and Dimerix were up 6.25 percent; 4D Medical and Proteomics were up more than five percent; SDI improved 3.6 percent; Amplia, Imugene, Neuren and Universal Biosensors rose two percent or more; Emvision, Immutep, Nanosonics, Opthea, Resmed and Telix were up more than one percent; with Polynovo and Pro Medicus up by less than one percent.

Next Science led the falls, down two cents or 9.8 percent to 18.5 cents, with 922,784 shares traded. Impedimed lost eight percent; Prescient was down 6.6 percent; Kazia shed 5.9 percent; Atomo and Medical Developments fell more than four percent; Alcidion, Clinuvel, Cyclopharm and Starpharma were down three percent or more; CSL and Genetic Signatures were down one percent or more; with Avita, Cochlear and Volpara down by less than one percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it hopes to raise \$30 million through an \$18 million institutional placement and a \$12.1 million one-for-10 entitlement offer, at 43 cents a share.

Paradigm said the accelerated, non-renounceable entitlement offer would be conducted through both an institutional and a retail offer and included three attaching options for every four shares subscribed for, exercisable at 65 cents each by November 30, 2024.

The company said the share price was a 31 percent discount to the last traded price of 64 cents a share on October 27, 2023.

Paradigm said that the retail component of the entitlement offer had a record date of November 1, would open on November 6 and close November 20, 2023.

Paradigm said the funds would be used to fund its general working capital expenses through to June 30, 2023 without additional licensing revenue, including the top-line readout from its pivotal phase III osteoarthritis clinical trial.

The company said it had appointed Bell Potter Securities Ltd as lead manager to the raise, with neither the placement nor the entitlement offer underwritten.

Paradigm said it had requested a trading halt pending an announcement in relation to the capital raising with trading to resume on November 1, 2023, or an earlier announcement.

Paradigm last traded at 61.5 cents.

LUMOS DIAGNOSTICS

Lumos says it has raised a further \$2.65 million through a private placement at seven cents a share to existing institutional shareholders.

In July and August, Lumos said that its share plan had raised \$690,000 of a hoped-for \$4.75 million, taking the total raised with the \$4.75 million placement in July to \$5.44 million (BD: Jul 10, Aug 3, 2023).

Today, the company said following the “relatively modest uptake by shareholders” in the share purchase plan, it had offered institutional shareholders the ability to take up its remaining placement capacity at the same price as the unsubscribed share plan shares.

Lumos said the price was a 10 percent discount to its closing share price on October 27, 2023, and that the funds would be used for the commercialization of its Febridx and Viradx diagnostics in the US as well as existing and potential partnership opportunities.

Lumos fell 0.4 cents or 5.1 percent to 7.4 cents with 9.9 million shares traded.

CONTROL BIONICS

Control Bionics says it hopes to raise up-to \$2.73 million in a two-for-three, non-renounceable rights offer at 4.0 cents a share, with more than \$1 million underwritten.

Control Bionics said the offer price was a 37.9 percent discount to the 30-day volume weighted average price and two of its three largest shareholders, Nightingale Partners Pty Ltd and Phoenix Development Fund, had underwritten a total of \$1 million.

The company said it would use the funds to gain additional regulatory approvals and commercialize its Drove autonomous wheelchair and Neurostrip physiological telemetry device products as well as working capital.

Control Bionics said its chief executive officer Jeremy Steele and directors Roger Hawke, Prof Rob Heard and Damian Lismore had collectively committed a total of \$140,000, consisting of their full entitlements plus an underwritten amount of \$77,032.

The company said the offer had a record date of November 2, would open on November 7 and close November 24, 2023.

Control Bionics fell 0.3 cents or five percent to 5.7 cents.

4D MEDICAL

4D Medical says Melbourne's Integral Diagnostics will distribute its XV lung ventilation analysis software (LVAS) in Australia and New Zealand.

In 2020, 4D said the Australian Therapeutic Goods Administration had approved the commercial sale of its XV LVAS (BD: Sep 30, 2020).

Today, the company said that Integral Diagnostics was a medical imaging services provider with 71 sites in Victoria, regional New South Wales, Queensland and Western Australia as well as 20 recently acquired imaging clinics in New Zealand.

4D Medical said Integral Diagnostics would offer its fluoroscopy-enabled XV LVAS software and computer-tomography (CT)-based LVAS software, beginning with a pilot program at two sites in Ballarat, Victoria.

4D Medical said that before a network-wide rollout, the two parties would jointly undergo a market and engagement campaign to build awareness and understanding amongst referring clinicians as distribution reach and patient catchment areas were expanded.

The company said Integral Diagnostic's 20 New Zealand clinics provided "a potential longer-term conduit for the first trans-Tasman availability of ... [its] unique XV technology".

4D Medical did not state the commercial terms of the agreement.

4D Medical managing-director Prof Andreas Fouras said the agreement meant "more patients and clinicians, particularly in regional Australia, will gain access to insights that only our proven XV technology can deliver".

"Commencing with operations in Ballarat demonstrates a commitment to increase the accessibility of XV technology and a commitment to improve healthcare across the regions," Prof Fouras said.

4D Medical was up 2.5 cents or 5.3 percent to 49.5 cents.

AMPLIA THERAPEUTICS

Amplia says its 14-patient phase Ib trial of AMP945 for pancreatic cancer with standard-of-care shows it is safe and well-tolerated with "very encouraging" activity.

In August, Amplia said it had begun dosing the final cohort of its phase Ib/IIa, dose-escalation trial of its oral focal adhesion kinase (FAK) AMP945, or narmafotinib, for pancreatic cancer with gemcitabine and nab-paclitaxel chemotherapy, designed to identify a dose for the phase IIa stage (BD: Aug 2, 2023).

Today, the company said the trial had identified a safe dose for the phase IIa study.

Amplia said although the phase Ib study was not powered for an efficacy readout, all patients were assessed and the initial data showed no patients had a complete response, five patients, or 35.7 percent had a partial response and eight patients, or 57.1 percent, had stable disease, with one patient unevaluable, which compared to an independent review of standard-of-care gemcitabine and nab-paclitaxel chemotherapy alone, which showed 23 percent of patients had a partial response and 27 percent had stable disease.

Amplia said the phase IIa trial would be held at seven trial sites across Melbourne, Sydney and Brisbane and five additional sites in Korea expected by 2024.

Amplia chief executive officer Dr Chris Burns said "completion of the phase Ib stage of the trial is an important milestone for the Accent trial".

"We have now identified a safe and well-tolerated dose of narmafotinib to take into the phase IIa stage of the trial and the preliminary efficacy signals we have seen to date, across three dose cohorts, are very encouraging," Dr Burns said.

"The team at Amplia are now focused on executing the next phase of the trial as quickly and efficiently as possible," Dr Burns said.

Amplia was up 0.2 cents or 2.4 percent to 8.5 cents.

ORTHOCELL

Orthocell says it will issue the University of Western Australia 1,714,286 shares in exchange for the University's royalty entitlements on sales of its products.

In 2014, before it listed on the ASX, Orthocell said it acquired intellectual property for its tendon stem cell treatment from the University of Western Australia, including the manufacture of Ortho-ATI for degenerated tendon tissue and its Celgro collagen platform technology which helped repair soft tissue damage (BD: May 14, 2014).

Today, the company said its Celgro medical device and Ortho-ATI cell therapy were invented by its chief scientific officer and University of Western Australia academic Prof Ming Hao Zheng, and it had acquired the intellectual property relating to the products in 2014 in exchange for ongoing royalties on sales.

The company said the University would hold 2.36 million shares (1.19%) of its shares.

Orthocell chair John Van Der Wielen said the agreement allowed the company "to retain all revenue benefits of its intellectual property".

Orthocell was unchanged at 33 cents.

EMYRIA

Emyria said an ethics committee has "endorsed" its lead psychiatrists as authorized prescribers of 3,4 methylene-dioxy-meth-amphetamine (MDMA) for therapy.

Emyria said the approval from an unnamed National Health and Medical Research Council-accredited ethics committee was the first stage of a two-step evaluation, with final approval from the Australian Therapeutics Goods Administration still in progress.

The company said that with ethics committee endorsement it could progress its authorized prescriber applications with the TGA for final consideration.

Emyria fell 0.2 cents or 2.9 percent to 6.8 cents.

MESOBLAST

Mesoblast says its annual general meeting will vote to issue 2,693,070 chief executive officer options, 1,960,765 chief medical officer options and 2,838,889 director options. Mesoblast said it would issue 2,420,000 milestone-based options to chief executive officer Prof Silviu Itescu under his long-term incentive plan, and a further 1,273,070 options in lieu of 30 percent of his base yearly salary of \$1,010,000.

The company said it would issue 740,000 milestone-based options to chief medical officer Dr Eric Rose under his long-term incentive plan and 1,220,765 options in lieu of 30 percent of his base annual pay of \$US615,000 (\$A967,000).

Mesoblast said Prof Itescu and Dr Rose's long-term incentive options were exercisable at 37 cents each and the options in lieu of salary at 38 cents each.

Mesoblast said in lieu of 50 percent of their director fees it would issue Joseph Swedish, William Burns, Jane Bell and Philip Facchina a total of 1,853,889 options and 985,000 milestone-based options to director Dr Philip Krause.

The company said the options in lieu of fees were exercisable at 38 cents each and Dr Krause's milestone-based options were exercisable at 39 cents each.

Mesoblast said the meeting would vote to adopt the remuneration report, make amendments to its constitution, re-elect directors Mr Facchina and Mr Burns and ratify the issue of securities to institutional investors.

The meeting will be held online and in-person at Minter Ellison, Collins Arch, Level 20, 447 Collins Street, Melbourne, on November 28, 2023 at 12pm (AEDT).

Mesoblast was unchanged at 36.5 cents.

BLUECHIIP

Bluechiip says its annual general meeting will vote to issue 3,000,000 performance rights to chief executive officer Andrew McLellan.

Bluechiip said in addition to his \$309,796 yearly pay, Mr McLellan was entitled to an up-to 30 percent short-term cash incentive and an up-to 50 percent long-term incentive, subject to achieving measurable market standard performance indicators.

The company said Mr McLellan's performance rights would vest in three equal tranches on August 30, 2024, 2025 and 2026.

Bluechiip said shareholders would vote to approve the issue of 6,380,953 shares to chair Iain Kirkwood, 714,286 shares to Mr McLellan and 1,190,477 shares to director Michael Ohanessian pursuant to two placements (BD: May 29, Oct 18, 2023).

Bluechiip said the meeting would vote to adopt the remuneration report, re-elect director Andrew Cox, approve an additional 10 percent placement capacity and ratify the issue of 157,417,615 placement shares.

The meeting will be held at Phillips Ormonde Fitzpatrick, Level 16, 333 Collins Street, Melbourne, on November 30, 2023 at 2pm (AEDT).

Bluechiip was untraded at 2.6 cents.

BLUECHIIP

Regal Funds Management Pty Ltd says it has become substantial in Bluechiip with the purchase of 43,809,524 shares, or 5.57 percent.

The Sydney-based Regal said that on October 25, 2023 it bought the shares for \$920,000, or 2.1 cents a share.