



Biotech Daily

Tuesday October 10, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ATOMO UP 18%; ACTINOGEN DOWN 12.5%**
- * **PARADIGM CLAIMS PPS 'SIGNIFICANT' OA PAIN REDUCTION**
- * **EMVISION BRAIN SCANNER IDENTIFIES STROKE PATIENTS**
- * **NUHEARA RIGHTS FOR \$10m**
- * **VISIONEERING RIGHTS TO RAISE \$4.1m**
- * **BLUECHIIP 3-MONTH REVENUE UP 117% TO \$163k**
- * **KAZIA TAKES 'ASX DELISTING FOR NASDAQ' HALT TO SUSPENSION**
- * **PERENNIAL REDUCES TO 10% OF MICRO-X**
- * **RHYTHM AGM 13% OPPOSE CHAIR OTTO BUTTULA RE-ELECTION**
- * **OPTISCAN: TIM ROWE, SHAYRA LEON FOR US BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market was up 1.01 percent on Tuesday October 10, 2023, with the ASX200 up 70.4 points to 7,040.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Atomo was the best, up 0.4 cents or 18.2 percent to 2.6 cents, with 1.6 million shares traded. Cyclopharm climbed 13.3 percent; Imugene improved 11.1 percent; Alcidion, Mesoblast and Opthea were up more than four percent; Avita, Polynovo, Prescient and Starpharma were up more than three percent; Emvision rose 2.5 percent; Clinuvel, Paradigm and Resmed were up more than one percent; with Cochlear, CSL, Pro Medicus and Telix up by less than one percent.

Actinogen led the falls, down 0.3 cents or 12.5 percent to 2.1 cents, with 5.9 million shares traded. Pharmaxis fell 7.7 percent; Dimerix lost 5.9 percent; 4D Medical and Proteomics fell four percent or more; Impedimed and Neuren were down more than three percent; Compumedics, Next Science, Nova Eye and Resonance shed more than two percent; Antisense and Volpara were down more than one percent; with Medical Developments down by 0.6 percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says at one year its 61-patient phase II trial of injectable pentosan polysulfate sodium (PPS) for osteoarthritis shows reduced pain and improved function.

In 2021, Paradigm said it had dosed the first of 60-patients in its randomized, double-blind, placebo-controlled, phase IIb trial of PPS, or Zilosul, for synovial fluid biomarkers in knee osteoarthritis pain (BD: Apr 14, 2021).

At that time, the company said the trial's primary purpose was "to measure the change in synovial fluid biomarkers associated with pain, inflammation and osteoarthritis disease progression" following treatment with PPS compared to placebo.

Last year, Paradigm said patients with knee osteoarthritis receiving PPS showed "statistically significant improvement" in pain and stiffness scores at day-56, with a change in one or more synovial fluid biomarkers achieved; and earlier this year, said 168-day data showed that PPS may slow disease progression (BD: Oct 4, 2022; Apr 4, 2023).

Today, Paradigm said patients received 2.0mg/kg of PPS twice weekly for six weeks and reported "clinically meaningful outcomes at 12-months, compared to placebo".

The company said these outcomes included "significant pain reduction ($p = 0.054$); significant functional improvement ($p = 0.048$); durable improvements in stiffness; and significant improvement in Womac scores ($p = 0.054$)".

Paradigm said the durable improvements to stiffness results led to cumulative pain medication use, such as paracetamol and other rescue medications for pain treatment, to be more than five times higher in the placebo group than the treated group after one year, or 28,947 milligrams of pain relief medication compared to 5,147 milligrams, respectively.

Paradigm said patient global impression of change results showed "highly statistically significant improvements for PPS" for treatment compared to placebo ($p = 0.005$).

The company said the trial "confirmed that the once weekly regimen of iPPS did not demonstrate meaningful improvement over the placebo control ... [and] the optimal dose regimen for further development is likely to be 2.0mg/kg twice weekly".

The company said it would work "on the best pathway forward for introducing this dose regimen into the registration programs".

Principal investigator Dr Phillip Bloom said "the mainstays in managing osteoarthritis pain are simple analgesics like paracetamol or aspirin, along with more anti-inflammatory types of analgesics like ibuprofen or diclofenac, along with changes to diet and movement".

"We see osteoarthritis patients in the clinic when the simple analgesics have failed, the anti-inflammatories are failing, they're not progressing with physiotherapy and their lifestyles are starting to be affected," Dr Bloom said.

"After prescribing PPS to more than 300 patients via the TGA's Special Access Scheme I've seen a myriad of people seeing positive changes to their lifestyles and able to get back to things they previously may have been unable to do due to the pain and dysfunction caused by their disease," Dr Bloom said.

Dr Bloom said most people had meaningful pain relief for 18 months to two years, so PPS could be used "as an earlier stage intervention to help maintain and preserve joint health and normal life activities, rather than only when the disease has significantly progressed".

Paradigm chief executive officer Paul Rennie said that "to achieve clinically meaningful and significant results with [injectable] PPS at a dose of 2.0mg/kg twice weekly compared to placebo at 12 months in only a small number of subjects per treatment arm shows clear strength in this treatment regimen over placebo".

"The 12-month durability of effect on [osteoarthritis] pain and function following one six-week course of treatment is truly an outstandingly positive trial outcome and separates [injectable] PPS from all currently available therapies for knee OA," Mr Rennie said.

Paradigm was up one cent or 1.7 percent to 60 cents with 7.7 million shares traded.

[EMVISION MEDICAL DEVICES](#)

Emvision says a 15-patient interim analysis from a stage two clinical trial of its portable brain scanner shows the device can identify stroke, non-stroke and haemorrhagic patients.

In May, Emvision said it had begun its up-to 150 patient, stage two, multi-site trial of its electro-magnetic microwave imaging-based portable brain scanner for stroke and stroke mimic patients at emergency departments (BD: May 29, 2023).

Today, the company said that to assess the scanner's accuracy it tested five haemorrhagic stroke patients, two ischaemic stroke patients and eight non-stroke patients, with the scanner correctly identifying all patients with and without haemorrhagic stroke. Emvision said the haemorrhagic stroke detection algorithm, called "blood or not" was developed based on simulated scan data and augmented real scan data to act like non-contrast computer tomography imaging in acute stroke care to rule out brain bleeding. Emvision said a total of 100 patients had been recruited for the trial, including 10 haemorrhagic stroke patients, 43 ischaemic stroke patients and 47 stroke mimic patients, with recruitment of the remaining 50-patients expected to be complete before 2024. The company said the analysis served as an "encouraging indicator of the robustness of the model and ability of simulation data to accurately represent real-world clinical scenarios" but that the sample size was too small to draw definitive conclusions on the algorithm's performance.

Emvision said following this analysis it would use the complete clinical data from the stage two clinical trial to train and or test the full suite of artificial intelligence algorithms.

The company said the results were published in an abstract for the International Journal of Stroke as part of the 15th World Stroke Congress in Toronto, Ontario, October 10-to-12, 2023.

Emvision chief executive officer Scott Kirkland said the company was "very encouraged by this early analysis, albeit from a small sample set".

"Using simulation data is an effective way to accelerate our [artificial intelligence] algorithm development alongside the patient data we are capturing from stage two of our clinical trial which will support algorithm training and testing, dialogue with prospective partners and our planned engagement with the [US Food and Drug Administration]," Mr Kirkland said. "The recruitment process for stage two is progressing well, which we are on track to complete this quarter," Mr Kirkland said.

Emvision was up four cents or 2.5 percent to \$1.64.

[NUHEARA](#)

Nuheara says it hopes to raise about \$10 million in an accelerated, one-for-2.64, non-renounceable, non-underwritten entitlement offer at 13 cents a share.

Nuheara said the offer price was a 3.7 percent discount to the last closing price on October 9, 2023.

The company said that rights offer would be conducted in two parts with an institutional offer today and the retail rights offer having a record date of October 12, opening on October 17 and closing on October 30, 2023.

The company said the funds would be used for sales and marketing investments, working capital including materially increasing production and external pre-launch costs for its single-chip hearing aid product expected to be commercially launched in January, 2024. Nuheara said Bell Potter Securities would act as lead manager and bookrunner to the offer.

Nuheara was in a trading halt for the institutional rights offer and last traded at 13.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it hopes to raise \$US2.5 million (\$A3.9 million) in a Chess depository interest rights offer at 22 cents and \$US120,000 (\$A187,000) in a directors' placement. Visioneering said the five-for-nine, non-underwritten, non-renounceable rights offer's Chess depository interest (CDI) issue price was a 34 percent discount to its 30-day volume weighted average price.

The company said that the record date would be October 13, it would open on October 18 and close on October 27, 2023.

Visioneering said its two largest Thorney and Regal Funds had both advised that they intend to take up their pro-rata entitlement through the rights offer, with Thorney's holding to remain below 50 percent of the company.

Visioneering said its non-executive directors would subscribe for a total of \$US120,000 of shares on the same terms, subject to shareholder approval at a meeting that would also ask shareholders to approve the conversion into shares of 1,120,000 convertible notes held by Thorney Technologies Ltd, Tiga Trading Pty Ltd and Jasforce Pty Ltd, with a face value of \$US1,120,000, convertible at 22 cents per share.

The company said funds would be used for its Project clinical trial, expanding markets, sales and business development, as well as supporting increased marketing and lead generation activities.

In a separate announcement from the ASX, trading in Visioneering securities has temporarily been paused pending a further announcement.

Visioneering fell 15 cents or 37.5 percent to 25 cents.

BLUECHIIP

Bluechiip says repeat revenue for the three months to September 30, 2023 was up 117.3 percent to \$163,000, compared to \$75,000 in the previous corresponding period.

Bluechiip said the number of laboratories using its technology had increased to 27, including two "top-20 [pharmaceutical] companies, an Ivy League research institution and several leading biopharma groups".

The company said the repeat orders included an additional five handheld sample readers, and other consumables from the New York Psychiatric Institute.

Bluechiip managing director Andrew McLellan said a second unnamed pharmaceutical company becoming a customer was a hugely significant step for the company and that the customer was "a world leader in cell therapies and wants to upgrade inventory management protocols for its valuable samples".

"Revenue is understandably a key driver for us in 2023-'24 and we are delighted with the trend and momentum that we are seeing in this area," Mr McLellan said.

"We remain confident that our advanced sample management solution will continue to gain currency with more of the world's top pharma companies," Mr McLellan said.

"They are increasingly acknowledging the increasing importance of tracking the samples, and the temperature history of those samples, in their safekeeping," Mr McLellan said.

Bluechiip was up 0.1 cents or three percent to 3.4 cents.

KAZIA THERAPEUTICS

Kazia has requested a suspension following Friday's trading halt regarding the "proposed delisting ... from ASX" (BD: Oct 6, 2023).

Trading will resume on October 11, 2023, or on an earlier announcement.

Kazia last traded at 16 cents.

MICRO-X

Perennial Value Management says it has reduced its substantial shareholding in Micro-X from 54,653,635 shares (11.25%) to 52,948,563 shares (10.23%).

The Sydney-based Perennial said it bought and sold shares between December 20, 2022 and September 28, 2023 with the largest sale of 1,149,745 shares on September 18 for \$132,043 or 11.5 cents a share.

Micro-X was unchanged at 14 cents.

RHYTHM BIOSCIENCES

Rhythm says all resolutions were passed at its annual general meeting, with up-to 13.4 percent dissent against the resolution to re-elect chair Otto Buttula.

Rhythm said 11,343,158 votes (13.37%) opposed Mr Buttula's re-election, with 73,508,059 votes (86.63%) in favor.

The company said that all other resolutions passed with less than 4.28 percent dissent.

According to its most recent notification, Rhythm had 221,142,589 shares on offer meaning that the votes against Mr Buttula amounted to 5.1 percent of the company, sufficient to requisition extraordinary general meetings.

Rhythm fell 1.5 cents or 4.7 percent to 30.5 cents.

OPTISCAN IMAGING

Optiscan appointed Tim Rowe and Shayra Leon US business development managers for the North American East Coast and West Coast, respectively.

Optiscan said the appointments were for "further growth and expansion of its subsidiary Optiscan Imaging Inc, in the US".

The company said Mr Rowe was previously Horiba Scientific's regional sales manager of fluorescence, Raman and custom optical spectroscopy and worked for PerkinElmer Health Sciences as a sales engineer.

Optiscan said Ms Leon was previously with Lumencor as business development manager Leica Biosystems sales executive for pathology.

Optiscan managing-director Dr Camile Farah said the appointments reflected "significant structuring and resourcing ... in the US".

"Their appointments signal the first stage of talent acquisition for our US operational structure, and we look forward to further expanding the team as our plans for US collaboration and commercialization continue," Dr Farah said.

Optiscan was unchanged at 7.3 cents.