Biotech Daily

Monday October 14, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMPEDIMED UP 9%; ATOMO DOWN 9%**

*** EBR RETAIL RIGHTS RAISE $4.2m; TOTAL $50m**

*** AND HEALTH $3.25m FOR 5 BIOTECHS**

*** LTR 'SPONTAN NASAL SPRAY BEATS VARDENAFIL FOR DYSFUNCTION'**

*** CLARITY TO START PIVOTAL US PROSTATE CANCER IMAGING TRIAL**

*** IMRICOR: FDA REVIEWS DEVICE MODULE; EU FACILITY AUDITED**

*** NANOSONICS 493k CEO RIGHTS AGM**

*** PRESCIENT CONDITIONAL BOARD SPILL, 1.4m DIRECTOR OPTIONS AGM**

*** BIOTRON RECEIVES $1.8m FEDERAL R&D TAX INCENTIVE**

*** AUSTRALIAN ETHICAL INCREASES, DILUTED TO 17% OF AUSTCO**

*** ARCHER LOSES CEO DR CHOUCAIR TODAY**

*** CLARITY CCO MICHELLE PARKER APPOINTED CEO; DR COLIN BIGGIN**

*** AROVELLA APPOINTS CLINICAL ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 0.47 percent on Monday October 14, 2024, with the ASX200 up 38.3 points to 8,252.8 points. Sixteen of the Biotech Daily Top 40 companies were up, 18 fell and six traded unchanged. All three Big Caps were up.

Impedimed was the best, up 0.55 cents or 9.2 percent to 6.5 cents, with 3.3 million shares traded. Imugene improved 8.2 percent; Curvebeam climbed 7.4 percent; Dimerix and Nova Eye were up more than five percent; Nanosonics improved 4.5 percent; Genetic Signatures was up 3.4 percent; Avita and Cynata rose more than two percent; CSL, Emvision, Micro-X, Resmed and Telix were up by more than one percent; with Clinuvel, Cochlear, Neuren, Pro Medicus and SDI up by less than one percent.

Atomo led the falls, down 0.2 cents or 9.1 percent to two cents, with 745,695 shares traded. Cyclopharm shed 8.2 percent; Prescient and Syntara fell more than four percent; Actinogen, Amplia, Opthea, Orthocell and Proteomics lost more than three percent; 4D Medical, Aroa and Starpharma shed more than two percent; Clarity, Compumedics, Medadvisor, Polynovo and Resonance were down one percent or more; with Mesoblast down by 0.7 percent.

EBR SYSTEMS

EBR says its fully-underwritten, one-for-20 retail rights offer at 82 cents per CDI raised $4.16 million, taking the total raised to $50 million.
Last month, EBR said it had raised $45.8 million at 82 cents per Chess depository interest (CDI) through a $37.4 million placement and the institutional component of its one-for-20 rights offer, with a $4.2 million retail offer to follow (BD: Sep 18, 20, 2024).
Today, the company said it received valid applications from eligible shareholders for 3,736,403 CDIs, raising about $3.06 million.
EBR said the remaining 1,339,330 CDIs not taken up by eligible retail shareholders, worth about $1.1 million, would be placed to the underwriters Bell Potter Securities, Morgans Corporate and E&P Capital Pty Ltd.
EBR fell two cents or 1.9 percent to $1.05 with one million shares traded.

AND HEALTH (AUSTRALIA'S NATIONAL DIGITAL HEALTH INITIATIVE)

AND Health says it will provide a total of $3.25 million to five companies following a grant from the Federal Government's Medical Research Future Fund.
AND Health said the funding was awarded to Eugene, Atmo Biosciences, Immunosis, Metabolic Health Solutions and Humanetix to "conduct further studies and scale their businesses to solve health challenges across genomics and genetic testing, gut and metabolic health, immune deficiencies and improving clinical efficiencies".
The organization said the five companies were part of the third cohort of its AND Health+ program, which began in August last year (BD: Aug 25, 2023).
AND Health said that since the start of the program recipients have had "support from local and international advisors, experts and investors to strengthen their businesses, as well as preliminary funding for key stage one projects".
The organization said Eugene was a genomics company that would use the funds to conduct a health and efficiency benefits study, and further scale its genetic risk testing platform "to allow greater variety and volume of genetic testing applications".
AND Health said Atmo Biosciences would use the funds for the commercialization of its gas-sensing capsule for gut health and the diagnosis of motility disorders as well as expanding the device to further clinical indications.
The organization said Immunosis would use the funds for clinical studies of its immune deficiency tests, Metabolic Health Solutions would develop its patient metabolism management software and Humanetix would run further assessments of its care management software for residential aged care and home care.
AND Health managing-director Bronwyn Le Grice said the funding would "support these high-growth potential companies to tackle major health issues impacting Australians on a daily basis."
"The funded projects will not only look at the commercial and clinical milestones these Australian health businesses need to meet, but provide expert support and advice, access to global partnerships and critical non-dilutive funding to ensure these solutions make it into the hands of patients, clinicians and care teams as swiftly as possible," Ms Le Grice said.
"Funding and support through grant programs is more important than ever," Ms Le Grice said.
"Our most recent sentiment survey of digital health start-ups revealed that grant funding was seen as their most likely source of future funding, with access to capital and experienced digital health investors their top challenge to commercialization," Ms Le Grice said.

LTR PHARMA

LTR says its 18-patient study shows its 5mg Spontan nasal spray for erectile dysfunction had a 78.6 percent faster absorption time than a 10mg vardenafil tablet.
In June, LTR said its open-label, 18-patient, randomized study of 5mg Spontan nasal spray vardenafil (marketed as Levitra) compared to vardenafil 10mg tablets for erectile dysfunction met its primary and secondary endpoints (BD: Mar 29, 2023; Jun 7, 2024).
Today, LTR said final study results showed Spontan achieved a mean time-to-maximum plasma concentration, or T-max, of 12 minutes, compared to the oral tablet's 56 minutes.
The company said that 5mg Spontan nasal spray had a half-life of 4.15 hours compared to 10mg vardenafil's 4.23 hours half-life.
LTR chair Lee Rodne told Biotech Daily that the "duration of effect is slightly longer than the half-life, for both Spontan and vardenafil".
The company said that the rapid onset of Spontan offered patients "greater spontaneity and convenience compared to traditional oral [erectile dysfunction] medications".
LTR said Spontan showed "a comparable bioavailability to the oral tablet on a dose-normalized basis" and that despite a lower 5mg dose, the nasal spray showed 111.8 percent dose dose-normalized bioavailability relative to the oral tablet.
The company said Spontan's maximum plasma concentration, or C-max, was comparable on a dose-normalized basis, reaching 155.6 percent of the oral tablet's concentration.
LTR said Spontan was well-tolerated with no adverse events reported and that all treatment-related adverse events were "mild-to-moderate and transient … [and] consistent with the known safety profile of vardenafil".
LTR chief medical officer Prof Geoffrey Strange said that the results were "highly encouraging from a clinical perspective" and the data supports our belief that Spontan may represent a meaningful advancement in erectile dysfunction management.
Mr Rodne said the study results were "a significant milestone for LTR Pharma".
LTR fell five cents or 2.6 percent to $1.88 with 2.45 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has provided "positive feedback" for a pivotal, 220-patient, phase III trial of copper-64 Sar-Bis-PSMA for prostate cancer.
Earlier this year, Clarity said its 52-patient, phase I/II trial showed that copper-64 Sar-Bis-prostate specific membrane antigen, or PSMA, was "safe and highly effective in detecting tumors, and later said it could detect "much smaller lesions than anticipated" including a lesion with a less than 2.0mm diameter (BD: Feb 15, Mar 6, 2024).
In August, the company said the FDA had awarded it fast track status for copper-64 Sar-Bis-PSMA to expedite its development (BD: Aug 22, 2024).
Today, Clarity said the non-randomized, single-arm, open-label, phase III trial would study the diagnostic's ability to detect the recurrence of prostate cancer, with evaluation occurring over two days.
The company said data from the phase III trial was intended to support an application to the FDA for copper-64 Sar-Bis-PSMA as a diagnostic imaging agent in prostate cancer.
Clarity said it expected to begin patient recruitment in early 2025.
Clarity executive chair Dr Alan Taylor said the company was "very excited to progress our second phase III trial with Clarity's lead product and appreciate the valuable guidance the FDA has provided in relation to our copper-64 Sar-Bis-PSMA program to date".
"The data we have seen so far for this product has been incredibly favorable and we believe copper-64 Sar-Bis-PSMA to be best-in-class," Dr Taylor said.
Clarity fell seven cents or one percent to $6.90 with 1.6 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says the US Food and Drug Administration has reviewed its first application module and the European regulator has audited its facility.

Imricor said the FDA pre-market approval module was submitted ahead of schedule and covered its devices including the Vision-magnetic resonance (MR) ablation catheter 2.0 as well as its RF-5000 ablation generator, irrigation pump, tubing set and remote-control unit.

The company said the module content included pre-clinical animal study data, bio-compatibility and sterilization validation, and that it had received FDA notice that the module was accepted and considered closed.

Imricor said Germany's Technischer Überwachungsverein, or Technical Inspection Association, had given it positive audit results for its factory manufacturing the Vision-MR ablation catheter, and that it would be "recommended for certification to manufacture these products under the new stringent medical device regulation (MDR) regime".

Imricor chief executive officer and chair Steve Wedan said that "the FDA review process for our first module went very smoothly and in a time frame that exceeded our own expectations".

"That's not to say there won't be challenges in the other module reviews, but this was a challenging module and we are very pleased with FDA's punctuality and efficiency," Mr Wedan said.

"In addition, we are navigating the process of approval for the Vision-MR Ablation Catheter 2.0 under the new MDR regime with success and with timelines that also exceed our original expectations," Mr Wedan said.

"Importantly, the 2.0 catheter is the one used in the 'Visabl-VT' and 'Visabl-AFL' trials, so everything is coming together nicely worldwide," Mr Wedan said.

"It's hard to overstate how impressive this all is [especially for an industry insider], and it is only possible because of Imricor's world-class quality and regulatory teams, formed and operating under the equally impressive leadership of our vice president, Jennifer Weisz," Mr Wedan said.

Imricor was up three cents or 5.4 percent to 59 cents.

NANOSONICS

Nanosonics says investors will vote to issue chief executive officer Michael Kavanagh 21,914 service rights and 470,877 performance rights at its annual general meeting.

Nanosonics said, the service rights were part of Mr Kavanagh's short-term incentive, while the performance rights were part of his long-term incentive, in addition to his $882,601 yearly base pay.

The company said the service rights equalled the remaining $76,440 of Mr Kavanagh's short-term incentive, would vest on August 31, 2025 and were subject to an exercise restriction until August 31, 2026.

Nanosonics said the performance rights were subject to performance milestones, had a value of about $1,642,560, would potentially vest on September 30, 2027 and had a term of 10 years from the grant date.

The company said the meeting would vote to re-elect director Marie McDonald, pass its remuneration report and re-insert the proportional takeover provisions in its constitution.

The meeting will be held online and at Level 1, Building A, 7-11 Talavera Road, Macquarie Park, Sydney on November 12, 2024 at 11am (AEDT).

Nanosonics was up 16 cents or 4.5 percent to $3.69 with 795,982 shares traded.

PRESCIENT THERAPEUTICS

Prescient says investors will vote on its remuneration report and a potential second-strike board spill and the issue of 1,415,000 options to director Dr Gavin Shepherd.
Last year, Prescient said its shareholders at its annual general meeting voted 72.2 percent against the remuneration report, with the 10 percent placement capacity defeated by 59.7 percent (BD: Nov 17, 2023).
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.
Prescient said investors would vote to issue Dr Shepherd's long-term incentive options, in addition to his $60,000 a year fees, exercisable at a 43 percent premium to the five-day volume weighted average price to the grant date, within four years.
Prescient said the meeting would vote to elect Dr Shepherd and Dr James Campbell as directors, renew takeover provisions and approve its 10 percent placement facility.
The meeting will be held online on November 14, 2024 at 12pm (AEDT).
Prescient fell 0.2 cents or 4.35 percent to 4.4 cents.

BIOTRON

Biotron says it has received $1,814,495 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Biotron said the incentive was for research and development expenditure related to its antiviral drug development programs for the year to June 30, 2024.
Biotron was up 0.2 cents or 10.5 percent to 2.1 cents.

AUSTCO HEALTHCARE

Sydney's Australian Ethical Investment says it has increased but been diluted in Austco from 41,447,475 shares (17.81%) to 61,119,909 shares (16.79%).
Australian Ethical said its last substantial shareholder notice in Austco was filed seven years ago on October 6, 2017, and that on October 9, 2024 it sold 2,000,000 shares for $499,175, or 24.96 cents a share, but did not disclose the price it paid for the 21,672,434 shares it acquired since 2017.
In May, Austco said that it had raised $9,720,000 at 18.5 cents a share in a placement and rights offer $9,720,000 (BD: Apr 24, May 21, 2024).
Austco fell half a cent or 2.0 percent to 24 cents.

ARCHER MATERIALS

Archer says its chief executive officer Dr Mohammad Choucair has formally resigned, effective immediately.
In July, Archer said Dr Choucair, the co-inventor of its quantum and biosensor technologies, would resign in January 2025, for personal reasons (BD: Jul 15, 2024).
Today, the company said that it was "mutually agreed that now is the appropriate time for Dr Choucair to complete his role as [chief executive officer] of Archer" due to the recent commencement of its TMR quantum sensor project and its recently announced 'refreshed' corporate strategy.
Archer fell 1.5 cents or 5.6 percent to 25.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has promoted Michelle Parker to chief executive officer, from October 11, 2024, with Dr Colin Biggin continuing as executive director and chief operating officer.
Earlier this year, Clarity said it had appointed chief clinical officer Michelle Parker as an executive director (BD: Aug 26, Sep 20, 2024).
At the time, the company said Ms Parker was recently promoted to chief clinical officer, had worked in clinical operations for more than six years at Clarity and had more than 20 years of experience in nuclear medicine, positron emission tomography and pharmaceuticals including as head of clinical research operations at Novartis Australia.
Today, Clarity said Dr Biggin would remain an executive director and would return to the role of chief operating officer, having joined the company in 2017 as head of quality and promoted from chief operating officer to chief executive officer in 2019.
Clarity executive chair Dr Alan Taylor said the company remained "focused on continuing the rapid progression of Clarity's best-in-class assets to late-stage clinical development, as well as significant growth of the team and our business to support this goal".
"Due to Clarity's flat management structure, this latest shift in leadership will not impact the day-to-day operational or corporate functioning," Dr Taylor said.
"However, it will enable us to better focus on commercialization and being launch ready, with strong clinical data to back our applications for product approvals and a strong team to support our growth," Dr Taylor said.
"Ms Parker's insights and extensive experience in the radio-pharmaceutical field, along with her excellent leadership capabilities, will be highly valuable in further growing our company," Dr Taylor said.
"Her appointment reflects our increasing focus on progressing multiple late-stage clinical programs towards product approvals," Dr Taylor said.
"Dr Biggin will continue to add significant value at the senior executive and board levels as he has over the years, leveraging his strong skillset to advance our supply and manufacturing network," Dr Taylor said.

AROVELLA THERAPEUTICS

Arovella says it has appointed Dr Salvatore Fiorenza as chair of its clinical advisory board, with Prof Sattva Neelapu and director Dr Debora Barton appointed advisers.
Arovella said Dr Fiorenza was deputy director and medical lead of cell therapy at Melbourne's Epworth Healthcare and a post-doctoral research scientist at the University of Sydney and was recognized for his "expertise in the development and application of [chimeric antigen receptor] T-cell therapies".
The company said Dr Neelapu was professor and deputy chair at Houston's University of Texas MD Anderson Cancer Center.
Arovella said that Dr Barton was chief medical officer at several biotechnology companies as well as one of its non-executive directors.
Arovella was unchanged at 18.5 cents with 4.4 million shares traded.