Biotech Daily

Tuesday October 8, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PROTEOMICS UP 21%; ATOMO DOWN 9%**

*** LUMOS RETAIL RIGHTS RAISE $6.9m; TOTAL $10m**

*** AUDEARA EARNS $570k FROM CLINICO TAIWAN EARBUDS**

*** ORTHOCELL WINS REMPLIR SINGAPORE APPROVAL**

*** ECHO IQ: FDA APPROVES ECHOSOLV FOR AORTIC STENOSIS**

*** IMPEDIMED: US NABPC INCLUDES BIS FOR BREAST CANCER**

*** CLARITY, SPECTRONRX TO MANUFACTURE CU-64**

*** ANATARA ENROLS 36 OF 100 PHASE II GARP IBS PATIENTS**

*** PERCHERON RECEIVES $2.35m FEDERAL R&D TAX INCENTIVE**

*** IMAGION REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EPSILON COMPLETES SUBSIDIARIES DOCA**

*** RECCE CONDITIONAL BOARD SPILL, 11.5m OPTIONS AGM**

*** HERAMED: 'RECORD 3.8k ACCUMULATED HERACARE USERS'**

*** OPTHEA APPOINTS CMO, CFO, HEAD OF MARKETING**

MARKET REPORT

The Australian stock market fell 0.35 percent on Tuesday October 8, 2024, with the ASX200 down 28.5 points to 8,176.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell and six traded unchanged. All three Big Caps were up.

Proteomics was the best, up 14 cents or 21.2 percent to 80 cents, with 3.6 million shares traded. 4D Medical and Orthocell climbed more than seven percent; Dimerix, Medadvisor and Micro-X improved four percent or more; Actinogen was up 3.85 percent; Cyclopharm rose 2.65 percent; CSL, Genetic Signatures and Impedimed were up more than one percent; with Aroa, Cochlear, Resmed, SDI and Telix up by less than one percent.

Atomo led the falls, down 0.2 cents or 8.7 percent to 2.1 cents, with 203,425 shares traded. Syntara lost 6.7 percent; Percheron was down 5.7 percent; Neuren fell 4.15 percent; Amplia, Curvebeam, Mesoblast and Universal Biosensors were down three percent or more; Clarity, Emvision, Nanosonics, Paradigm and Polynovo shed more than two percent; with Avita, Clinuvel, Compumedics, Immutep, Medical Developments, Opthea, Pro Medicus and Starpharma down by less than one percent.

LUMOS DIAGNOSTICS

Lumos says it has raised $6.9 million at 3.8 cents a share in its one-for-1.82, retail entitlement offer, taking the total with the institutional offer to $10 million.
Last month, Lumos said its one-for-1.82 pro rata institutional entitlement offer had raised $3.1 million, with its retail offer to raise $6.9 million more (BD: Sep 6, 2024).
Today, the company said that $300,000 of the retail offer was raised from investors, with the remaining $6.1 million raised from underwriter, Bell Potter, as well as sub-underwriters Ryder Capital and Tenmile Ventures Pty Ltd, a company controlled by Dr Andrew Forrest.
Lumos said the remaining $500,000, which was not subscribed by valid retail investors, or the underwriters, had been placed to investors who participated in the institutional offer.
Lumos managing-director Doug Ward said attaining clinical laboratory improvement amendment (CLIA) waiver status in the US for Febridx was “high on our list of objectives” expected before the 2025 US influenza season.
Lumos was up 0.1 cents or 2.4 percent to 4.2 cents with five million shares traded.

AUDEARA

Audeara says it has received a $570,000 purchase order for Clinico-branded hearing earbuds from the Taipei-based Clinico Inc, Taiwan’s largest hearing aid retailer.
Earlier this year, Audeara said the Clinico had paid $180,000 in cash to develop and distribute its hearing earbuds in China and Taiwan (BD: Aug 5, 2024).
Today, the company said the earbuds would be marketed and distributed across Taiwan and China, with an official product launch expected by the end of 2025.
Audeara said the order underlined Clinico’s “commitment to expanding [its] audiology and health distribution network with Audeara’s innovative hearing [products]”.
The company said the partnership and launch with Clinico was part of its “strategic focus on expanding its international footprint and aligning with market leading brands”.
Audeara managing-director Dr James Fielding said the order shows “the strength of our ongoing partnership and the confidence Clinico has in Audeara’s products”.
“We look forward to expanding our footprint in major Asian markets,” Dr Fielding said.
Audeara was up 0.1 cents or 2.1 percent to 4.9 cents.

ORTHOCELL

Orthocell says it has Singapore Health Sciences Authority regulatory approval to sell its Remplir collagen wrap for use in peripheral nerve repair.
Orthocell said the Singapore approval was “the first major international approval of Remplir outside … Australian and New Zealand” where the product was currently sold.
The company said beginning sales early next year in another region would “further compliment the excellent revenue growth being delivered in these existing markets”.
Orthocell said it was in discussions with a distributor ahead of the market launch, which would fast-track first sales in Singapore, and it was “on-track to receive US [Food and Drug Administration] regulatory clearance” by March 30, 2025.
Orthocell managing-director Paul Anderson said the company was “delighted to receive Singaporean regulatory approval for Remplir in this important regional gateway market”.
“This approval is further validation of Orthocell’s, high quality product, manufacturing processes and expanding global footprint… and strengthens our position to increase revenue and builds further confidence in our US FDA clearance anticipated in … 2025,” Mr Anderson said.
Orthocell was up 3.5 cents or 7.3 percent to 51.5 cents with 3.2 million shares traded.

ECHO IQ

Echo IQ says it has US Food and Drug Administration 510(k) clearance to market and sell the artificial intelligence-based Echosolv for detecting aortic stenosis (AS).

Earlier this year, Echo IQ said it had submitted its FDA 510(k) application for market clearance of its Echosolv algorithm for detecting aortic stenosis (BD: May 7, 2024).

Today, Echo IQ said the FDA review had determined that the company showed "substantial equivalence to the predicate device cited in this submission and has cleared it for marketing and use in the US".

The company said prior to FDA clearance it had been in discussions "with a number of parties including large hospital groups, device manufacturers and pharmaceutical companies, on the commercial and clinical benefits of Echosolv [aortic stenosis] … [and was] well placed to convert these negotiations into material agreements".

Echo IQ said it would work with its US consultancy to obtain insurance reimbursement codes for users of Echosolv aortic stenosis, which would develop financial incentives for more widespread use of Echosolv in US hospital settings on a fee-per-use basis.

The company said the first step of commercialization was the "appointment of a suitably credentialed chief executive officer based in the US who can lead the team".

Echo IQ executive chair Andrew Grover said the FDA clearance was a "major milestone … and provides the foundation to deliver a material value uplift for our shareholders".

"The company now has the ability to commercialize its technology in the world's largest and most well-regulated market, for a condition which is widespread and chronically underdiagnosed," Mr Grover said.

"Echosolv AS shows significant improvements in the detection of severe aortic stenosis when compared to current clinical practice," Mr Grover said.

"Prior to the FDA's decision, we have undertaken extensive discussions with a number of hospital groups in the US, as well as potential licencing opportunities with device manufacturers and pharmaceutical companies," Mr Grover said.

Echo IQ was untraded at 24 cents.

IMPEDIMED

Impedimed says the US National Accreditation Program for Breast Centers (NABPC) has included bio-impedance spectroscopy (BIS) as a standard for breast cancer.

Impedimed said the NABPC was a quality program of the American College of Surgeons and that bio-impedance spectroscopy had been included on its updated 'Optimal Resources for Breast Care Standards' for the first time.

The company said its Sozo digital health platform was the only US Food Drug Administration-cleared bio-impedance spectroscopy technology for the clinical assessment of lymphoedema.

Impedimed said that NAPBC-accredited centres must implement and comply with standards outlined in NAPBC Optimal Resources for Breast Care.

The company said examples of evidence-based guidelines included referral to outpatient rehabilitation for evaluation and treatment of lymphoedema and the use of a lymphoedema prevention program, including regular symptom assessment and evaluation using objective measurements of lymphoedema, such as bio-impedance spectroscopy.

Impedimed managing-director Dr Parmjot Bains said that "coinciding with the start of breast cancer awareness month, the inclusion of BIS as an example of high-quality care in the NABPC accreditation standards continues to support the use of our technology as a standard-of-care to support survivorship for breast cancer patients".

Impedimed was up 0.1 cents or 1.7 percent to 5.9 cents.

CLARITY PHARMACEUTICALS

Clarity says Spectronrx will manufacture both copper-64 (Cu-64) isotope and copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) for its phase III trial.

Last year, Clarity said it had opened the first clinical site for its 'Clarify' 383-patient, registrational, phase III trial of copper-64 Sar-Bis-PSMA as a diagnostic for prostate cancer (BD: Nov 30, 2023).

Earlier this year, the company said the Indianapolis, Indiana-based Spectronrx would manufacture and supply the copper-64 isotope for the trial (BD: May 30, 2024).

Today, Clarity said the agreement was an extension of its previous master service and supply agreements with Spectronrx, which meant Spectronrx would produce both the isotope and final product at the same facility in the US.

The company said it was progressing two registrational phase III trials with copper-64 Sar-Bis-PSMA, and the agreement ensured "abundant and seamless supply with central distribution of the product from Spectronrx facility in Indiana to all 50 [US] states on demand, providing universal access to this agent for the pivotal trials".

Clarity executive chair Dr Alan Taylor said the company was "excited to continue strengthening our supply network, ensuring vulnerable patients in need of novel diagnostic options can get access to what we believe is a best-in-class product, on time and at any treatment centre with a positron emission tomography camera".

"Current-generation radio-pharmaceutical diagnostic products rely on isotopes with very short half-lives, specifically gallium-68 with a half-life of [about] one hour and fluorine-18 with a half-life of [about] two hours, which translate into short shelf-lives of the diagnostic products," Dr Taylor said.

"This limits the use of these products to large treatment centres and hospitals with radio-pharmacy facilities nearby that can produce fluorine-18 and, or gallium-68," Dr Taylor said.

"Copper-64 has an ideal 12.7-hour half-life and can overcome the overwhelming supply restraints of other diagnostic isotopes through central manufacture and distribution across the US from a single facility," Dr Taylor said. "We believe that this approach has the potential to reduce disparities in prostate cancer care, providing patients with access to next-generation imaging products, regardless of their geographic location."

Clarity fell 22 cents or 2.8 percent to $7.67 with 1.3 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has enrolled 36 patients of 60-to-100 patients in stage two of its phase II trial of gastrointestinal reprogramming, or Garp, for irritable bowel syndrome (IBS).

Last year, Anatara said it had dosed all 70 patients in the first stage of its phase I/II trial of Garp, and that the treatment was a "multi-component, coated complementary medicine" that included its pineapple stem-based bromelain (BD: Aug 31, 2023).

Earlier this year, the company said it had opened five sites for the 60-to-100-patient, second stage of its up-to 140-patient phase II trial of Garp (BD: Apr 9, 2024).

In August, Anatara said it had enrolled 30 patients of up-to 100 patients in stage two of its phase II trial of Garp for IBS (BD: Aug 30, 2024).

Today, the company said a further about 20 patients were currently in final screening to determine suitability to enter the trial and a "much larger group of potential patients, identified as potentially eligible from the initial questionnaires, are being followed up".

Anatara said it had opened two trial sites at Adelaide's South Australian Health & Medical Research Institute (SAHMRI) and Maroochydore, Queensland's Coastal Digestive Health Research Institute (CDHRI), with headline results expected by April 2025.

Anatara was up 0.1 cents or two percent to 5.2 cents.

PERCHERON THERAPEUTICS

Percheron says it has received $2.35 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Percheron said the rebate related to research and development expenditure for the year to June 30, 2024, with the funds to be used for its phase IIb clinical trial of avicursen [formerly ATL1102] in Duchenne muscular dystrophy.
Percheron fell 0.6 cents or 5.7 percent to 9.9 cents.

IMAGION BIOSYSTEMS

Imagion has requested a trading halt "pending an announcement to be made by the company to the market in relation to a proposed capital raising".
Trading will resume on October 10, 2024, or on an earlier announcement.
Imagion last traded at 3.7 cents.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS COMPANY)

Epsilon says it has completed its deed of company arrangement (DOCA) for its wholly-owned subsidiaries Pharma Pty Ltd and Epsilon Clincs Pty Ltd.
Earlier this year, Epsilon administrator SV Partners' Ian Purchas said the final creditors meeting resolved to adopt a deed of company arrangement (DOCA) proposed by founder Alan Beasely (BD: Jun 5, 2024).
Epsilon was in a suspension and last traded at 2.4 cents a share.

RECCE PHARMACEUTICALS

Recce says investors will vote on its remuneration report and a potential second-strike board spill and the issue of 11,500,000 options to its board and management.
Last year, Recce said its annual general meeting defeated its remuneration report with 21,772,862 votes (58.36%) opposed (BD: Nov 8, 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 and if passed by more than 50 percent the directors must stand for re-election.
Today, the company said the annual general meeting would vote to issue chair Dr John Prendergast 2,650,000 options, managing-director James Graham 3,000,000 options, director Dr Alan Dunton 2,250,000 options, director Michele Diliza 1,600,000 options and directors Dr Justin Ward and Alistair McKeough 1,000,000 options, each; all exercisable at 80 cents each within five years and were in addition to the recipients' yearly pay.
The company said the meeting would vote to elect directors Dr Dunton and Mr McKeough, approve the future and prior issue of shares, adopt the new constitution, renew the proportional takeover provisions and approve a capital reduction.
Recce said a special general meeting would be held if the resolution for a selective capital reduction was approved, which would result in the cancellation of all of its 8,754,423 class B performance shares.
The annual general meeting will be held online and in person at Automic, Level 5, 126 Phillip Street, Sydney on November 6, 2024 at 1:30pm (AEDT).
The special general meeting will be held online at the conclusion of the annual general meeting, or about 3pm (AEDT).
Recce was up 1.5 cents or 2.9 percent to 53.5 cents.

HERAMED

Heramed says more than 3,800 “accumulated” expectant mothers at September 30, 2024, had been included in the Heracare foetal monitoring platform.
Heramed said the increase continued to showed “the growing adoption of our digital maternity care solution”.
The company said the number of active users continued “to reach new records also with in excess of 710 mothers currently having their pregnancies managed through the Heracare platform”.
Heramed said the increase in user growth was continuing to build its evidence base and value proposition that Heracare was “improving the existing standard-of-care in pregnancy”.
The company said the primary driver behind the current increase was the launch of Heracare at Miami, Florida’s Broward Health, with more than 207 pregnant mothers successfully onboarded in the first 100 days.
Heramed was unchanged at 2.1 cents with 2.2 million shares traded.

OPTHEA

Opthea says it has appointed Dr Parisa Zamiri as its chief medical officer, Tom Reilly as its chief financial officer and Anand Sundaram as head of marketing.
Opthea said Dr Zamiri’s appointment was effective from yesterday and that she would oversee clinical development and operations, regulatory and medical affairs as well as bio-metrics.
The company said Dr Zamiri had been chief medical officer at Complement Therapeutics and Graybug Vision as well as head of clinical development for ophthalmology at Novartis.
Opthea said Dr Zamiri held a Doctor of Medicine from Kings College Hospital, London and a Doctor of Philosophy from Boston’s Harvard Medical School.
The company said Mr Reilly would replace interim chief financial officer Daniel Geffken from October 28, 2024.
Last month, Opthea said Mr Geffken replaced Peter Lang as interim chief financial officer (BD: Sep 5, 2024).
Today, the company said Mr Reilly had more than 25 years of experience including as chief financial officer and head of human resources at Amarin Corp as well as chief financial officer of Cara Therapeutics, head of finance at Allergan General Medicines and financial controller for Novartis Pharmaceuticals US.
Opthea said Mr Reilly held a bachelor’s degree from New York’s Manhattan College and a Master of Business Administration from South Orange, New Jersey’s Seton Hall University.
The company said Mr Sundaram’s appointment was effective on October 14, 2024, and that he had worked for Astellas, formerly Iveric Bio, Novartis and Genentech.
Opthea said Mr Sundaram held two Bachelor degrees from the Durham, North Carolina-based Duke University.
Opthea fell 1.5 cents or 1.7 percent to 88 cents with 4.1 million shares traded.