Biotech Daily

Wednesday August 28, 2024

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: AROA UP 10%; NOVA EYE DOWN 7%**

*** SOMNOMED REVENUE UP 10% TO $92m; LOSS UP 53% TO $12m**

*** MACH7 REVENUE DOWN 3% TO $29m; LOSS UP 660% TO $8m**

*** CONTROL BIONICS REVENUE DOWN 5% TO $5m; LOSS DOWN 5% TO $5.9m**

*** ENA DOSES 2 OF 5 COHORTS IN PHASE Ib INNA-051 TRIAL**

*** MONASH DEVELOPS FINGER-PRICK ALZHEIMER'S BLOOD TEST**

*** GRIFFITH UNI INTRA-NASAL COVID-19 VACCINE**

*** TELIX FILES US TLX101-CDX (PIXCLARA) BRAIN CANCER IMAGING NDA**

*** CURVEBEAM RETAIL RIGHTS RAISE $1.6m; TOTAL $11.54m OF $13.6m**

*** BCAL TO OPEN US OPERATIONS IN NORTH CAROLINA**

*** CHIMERIC DOSES 1st PHASE I/II CHM-CDH17 CANCER PATIENT**

*** RHYTHM RECEIVES 1st COLORECTAL CANCER TEST PROTOTYPES**

*** IMPEDIMED EGM 26% OPPOSE DIRECTOR RIGHTS, OPTIONS**

*** FISHER & PAYKEL AGM 19% OPPOSE DIRECTOR GRAHAM MCLEAN**

*** ARGENT (MGC) ASX DELISTING, 4m M-D SHARES, 600k CHAIR RIGHTS EGM**

*** ACORN TAKES 6.5% OF AROA**

*** ANACACIA TAKES 8% OF COGSTATE**

*** ALLAN GRAY REDUCES TO 5.7% OF STARPHARMA**

MARKET REPORT

The Australian stock market was even on Wednesday August 28, 2024, with the ASX200 up 0.2 points to 8,071.4 points. Eight of the Biotech Daily Top 40 companies were up, 20 fell, 11 traded unchanged and one was untraded.

Aroa was the best, up 4.5 cents or 9.6 percent to 51.5 cents, with 325,048 shares traded. Emvision climbed 8.1 percent; Resmed was up 5.6 percent; Universal Biosensors improved 3.6 percent; Immutep and SDI rose more than two percent; Starpharma was up 1.05 percent; with Clinuvel and Mesoblast up by less than one percent.

Nova Eye led the falls, down 1.5 cents or 6.7 percent to 21 cents, with 635,509 shares traded. Telix lost 5.9 percent; Amplia, Atomo and Medical Developments fell four percent or more; Alcidion, Medadvisor, Proteomics and Resonance were down more than three percent; Avita, Nanosonics, Neuren and Paradigm shed two percent or more; Clarity, Micro-X and Opthea were down more than one percent; with Cochlear, CSL, Cyclopharm, Genetic Signatures, Polynovo and Pro Medicus down by less than one percent.

SOMNOMED

Somnomed says revenue for the year to June 30, 2024 was up 9.6 percent to $91,651,069, with net loss after tax up 53.0 percent to $12,241,726.
Somnomed said revenue was from sales of its Somnodent range for obstructive sleep apnoea, snoring, bruxism and other sleep-related breathing disorders.
The company said sales rose 11.0 percent in Europe to $52.5 million, North America was up 8.9 percent to $32.9 million, with the Asia Pacific up 3.3 percent to $6.3 million.
Somnomed said revenue was up about 20 percent in July and August due to “the reduction of backlog” and strong sales, but expected revenue to slow as the backlog was cleared; and it expected revenue of about $100 million in the coming year, with earnings before interest, taxation, depreciation and amortization (Ebitda) of more than $5 million.
The company said diluted loss per share slipped 0.4 percent to 10.14 cents, and net tangible asset backing per share was 10.0 cents compared to 0.2 cents in the previous corresponding period.
Last year, Somnomed said its net tangible asset backing per share was negative 7.6 cents in the year to June 30, 2023 (BD: Aug 31, 2023).
In 2023-’24, Somnomed raised $38.1 million and today said it had cash and equivalents of $16,178,843 at June 30, 2024 compared to $11,956,406 the prior year (BD: Sep 26, 2023; May 6, 2024).
Somnomed was up one cent or 2.7 percent to 38.5 cents.

MACH7 TECHNOLOGIES

Mach7 says its revenue for the year to June 30, 2024 was down 3.1 percent to $29,112,863, with net loss after tax up 660.4 percent to $7,970,324.
Mach7 said revenue from subscriptions, maintenance and support, and licencing its Enterprise imaging software, diagnostic viewing and workflow applications and data management systems in North America fell 3.1 percent to $24,249,369, Asia Pacific was down 12.6 percent to $3,320,017, with the Middle East up 3.4 percent to $857,017 and Europe and other regions up 73.9 percent to $686,460.
Mach7 said operating expenditure increased 13 percent “due to the increased cost of operations mainly driven by company growth” inflation and increased labor costs.
The company said diluted loss per share rose 725.0 percent to 3.3 cents, with net tangible assets per share unchanged at 10.0 cents, and it had cash and equivalents of $26,175,405 at June 30, 2024 compared to $23,394,568 at June 30, 2023.
Mach7 fell three cents or 5.1 percent to 56 cents with 1.2 million shares traded.

CONTROL BIONICS

Control Bionics says revenue for the year to June 30, 2024 was down 5.17 percent to $5,350,774, with net loss after tax up 5.02 percent to $5,913,779.
Control Bionics said revenue was from sales of its disability communications technology including Neuronode Trilogy, Neuronode Duo and Eye-gaze Duo devices, despite “significant issues with the [National Disability Insurance Scheme] approval process”.
The company said it had reduced operating costs, while increasing research and development spend.
The company said its diluted loss per share fell 40.5 percent to 3.71 cents, net tangible assets per share was down 71.1 percent to 0.93 cents, and it had cash and equivalents of $980,760 at June 30, 2024 compared to $935,503 at June 30, 2023.
Control Bionics was up half a cent or 5.6 percent to 9.5 cents.

ENA RESPIRATORY

Ena says it has dosed the first 16 of up-to 40-participants in its phase Ib study of INNA-051 intra-nasal, dry powder, immuno-modulator for respiratory viral infections.

Earlier this year, Ena said the US Food and Drug Administration had approved an investigational new drug application for the study (BD: Apr 30, 2024).

Today, the company said the study was designed to test the safety, pharmaco-dynamics and pharmaco-kinetics of INNA-051 administered intra-nasally as a drug powder formulation to individuals above the age of 60 years old.

Ena chief executive officer Christophe Demaison told Biotech Daily the study would recruit five cohorts of eight healthy participants, and the first two cohorts had been dosed.

The company said the study was being conducted at Sydney's Scientia Clinical Research facility, with the first two cohorts dosed with single ascending doses "in line with expectations for INNA-051's mode-of-action and the multiple ascending dose phase of weekly dosing is underway", with results expected by the end of 2024.

The company said it was preparing for an international phase IIb study to assess the safety and potential efficacy of INNA-051 in decreasing the duration and severity of illness related to community-acquired respiratory viral infections in older adults in assisted living facilities at risk due to comorbidities.

Prof Demaison said "despite advances in vaccines and anti-viral treatments, serious viral respiratory infections remain a major cause of hospitalization and mortality for older adults with comorbidities, a population of over 34 million people in the US alone".

"INNA-051 is designed to boost the body's innate immune response, the natural first line of defence, directly at the site of infection and prevent complications relating to viral infections whether caused by a common respiratory virus or an emerging new strain," Prof Demaison said.

"This phase Ib is a further important step in our clinical development plan as we aim to bring this potentially impactful new approach to patients at risk of significant harm from respiratory viral infections," Prof Demaison said.

ENA is a private company.

MONASH UNIVERSITY

Monash University says it has developed a proof-of-concept, finger-prick, blood test to detect the hallmark protein biomarkers in early Alzheimer's disease.

Monash University said the device was the size of a credit card and used a "world-first, patented sensor technology which can detect ultra-low concentrations of disease markers in blood in minutes".

The University said the number of Australians diagnosed with dementia was expected to double by 2054 and the blood test could become a tool to streamline diagnoses by giving general practitioners access to non-invasive diagnostics.

Monash University said the point-of-care testing sensor was developed by Prof Sudha Mokkapati and removed the need for laboratory-based pathology tests.

"It's simple to use, low-cost and portable so it could be made widely accessible to [general practitioners] to screen patients right at the point-of-care," Prof Mokkapati said. "Detecting very early disease in large populations could dramatically change the trajectory of this burdening disease for many patients, and shave millions off associated healthcare costs."

"We've completed testing that shows the technology is highly advanced by design and capable of detecting ultra-low levels of several disease biomarkers in blood," Prof Mokkapati said. The next stage is to undertake the clinical validation needed to bring this a step closer to reality, and we're reliant on further funding to progress this."

GRIFFITH UNIVERSITY

The Gold Coast, Queensland-based Griffith University says it has developed a needle-free, intra-nasal Covid-19 vaccine which shows “promise in early tests”.
Griffith University said the Covid-19 mucosal vaccine was “set to be a game-changer not only when delivering the vaccine itself, but also for people who are needle-phobic”.
The University said researchers had been testing the efficacy of delivering a Covid-19 vaccine in the nasal passages and had developed a live-attenuated, intra-nasal vaccine called CDO-7N-1 which was designed to induce potential mucosal immunity as well as systemic immunity with a single dose.
Griffith University said live-attenuated vaccines offered induced “potent and long-lived humoral and cellular immunity, often with just a single dose …. [and] comprise the entire virus thereby providing broad immunity, in contrast to a single antigen which is used in many other vaccine platforms”.
The University said the vaccine had been licensed to Hyderabad’s Indian Immunologicals Ltd, a major vaccine manufacturer.
Griffith University said the research, titled ‘A single-dose intranasal live-attenuated codon deoptimized vaccine provides broad protection against Sars-Cov-2 and its variants’ was published in the peer reviewed journal Nature Communication, with the full article available at: https://www.nature.com/articles/s41467-024-51535-y.
Study lead author Dr Xiang Liu said the vaccine provided cross-protection against all variants of concern and had neutralizing capacity against Sars-Cov-1.
“The vaccine offers potent protection against transmission, prevents reinfection and the spread of the virus, while also reducing the generation of new variants,” Dr Liu said.
“Unlike the mRNA vaccine which targets only the spike protein, CDO-7N-1 induces immunity to all major Sars-Cov-2 proteins and is highly effective against all major variants to date,” Dr Liu said. “Importantly, the vaccine remains stable at 4.0 degrees Celsius for seven months, making it ideal for low-and-middle-income countries.”

TELIX PHARMACEUTICALS

Telix says it has filed a new drug application for its TLX101-CDx, or Pixclara, imaging agent for brain cancer with the US Food and Drug Administration.
Telix said Pixclara was an investigational positron emission tomography agent for the characterization of progressive or recurrent glioma, or brain cancer, from treatment-related changes in both adult and pediatric patients.
The company said the diagnostic had been granted orphan drug and fast track designation by the FDA which gave it “expedited review and closer consultation with the agency during the review process”.
Telix said Pixclara was already included in international clinical practice guidelines for the imaging of gliomas, but that there was “currently no FDA-approved targeted amino acid [positron emission tomography] agent for adult and pediatric brain cancer imaging commercially available in the US”.
The company said Pixclara was being developed as the companion diagnostic and therapeutic imaging agent for TLX101, its neuro-oncology drug candidate, which targeted the same amino acid transported mechanism with therapeutic targeted radiation.
Telix precision medicine chief executive officer Kevin Richardson said filing the new drug application for Pixclara was “an important milestone, reflecting our commitment to improved and accessible neuro-oncology imaging in the US, and taking us one step closer to commercial availability in 2025, subject to FDA approval”.
Telix fell $1.18 or 5.9 percent to $18.79 with 1.7 million shares traded.

CURVEBEAM AI

Curvebeam says it raised $1.64 million at 18 cents a share in its one-for-six, retail rights offer, taking the total raised to $11.54 million, with a shortfall of about $2 million.
Earlier this month, Curvebeam said it hoped to raise up-to $13.6 million; and later, said it had raised $7.9 million at 18 cents a share through a $2.0 million first tranche of its placement and $5.9 million one-for-six, institutional rights offer, with a $2 million second tranche and up-to $3.6 million retail offer to follow (BD: Aug 2, 14, 2024).
Today, the company said it could issue shortfall shares within three months.
Curvebeam was unchanged at 18 cents.

BCAL DIAGNOSTICS

Bcal says it has established a North Carolina-based subsidiary, called Bcal Diagnostics Inc, to expand its operations in the US from September 2, 2024.
Bcal said the US subsidiary gave the company an “opportunity to accelerate and validate new products on US patient centric data and gain an in-county understanding of the US diagnostics market”.
The company said opening US operations had followed an internal restructure by its US research partner Precion Inc, and that purchasing equipment from Precion was “required for the function of a US laboratory”.
In 2022, Bcal said it had an agreement with the Morrisville, North Carolina-based Precion Inc to develop its blood-based test for breast cancer (BD: Jun 28, 2022).
Today, the company said chief executive officer Shane Ryan was appointed head of the subsidiary with chair Jayne Shaw and directors Dr John Hurrell and Johnathan Trollip appointed to the subsidiary’s board.
Bcal said Precion’s former chief technology officer, Dr Klaus-Peter Adam, would oversee US operations as the subsidiary’s director of research and product development.
The company said it had appointed Cory Dunn as the head of business development and marketing and said she had “a wealth of US and Australian marketing experience and comprehensive knowledge of the US breast cancer network”.
Bcal said that “while the specific financial terms on which Bcal has been able to establish its US operations are commercially confidential, the Bcal board considers the opportunistic establishment of Bcal US as being extremely cost-effective”.
The company said following its recent $10.5 million capital raise its US operations could operating in “the short-term without needing to raise any further capital”.
Bcal fell half a cent or four percent to 12 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first patient in its 15-patient, phase I/II trial of CHM CDH17, formerly CHM2101, chimeric antigen receptor T-cells for various cancer types.
Last month, Chimeric said it had enrolled the first patient in the trial of CDH17 cell therapy for colorectal and gastric cancer and intestinal neuroendocrine tumors (BD: Jul 22, 2024).
Today, the company said the first patient was dosed at Nashville, Tennessee’s Sarah Cannon Research Institute, with phase I expected to enrol 15 patients, lead to dose selection and expansion for indication-specific phase II cohorts, and that the trial would evaluate the safety and objective response rate of CHM CDH17 in the three cancer types.
Chimeric chair Paul Hopper said the milestone was “a great moment for patients and the culmination of years of hard work by the Chimeric team”.
Chimeric was unchanged at 1.6 cents with 4.6 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has received the first batch of functional prototypes of its colorectal cancer blood test from its contract manufacturer Quansys Biosciences.
Rhythm said receipt of the prototype test-kits from the Logan, Utah-based Quansys was “a major step forward for the company; and paves the way for further in-house assay testing in advance of final design iteration and clinical validation of this next generation colorectal cancer diagnostic prior to its planned commercial launch”.
The company said the kits combined five separate antibody-based assays that previously constituted the Colostat assay into a single reaction for each patient blood sample and that the format was designed “to further increase the assay’s reliability”.
Rhythm said it would “continue to focus on colonoscopy triage in which its multiplex assay will be used to prioritize those individuals scheduled for colonoscopy”.
Rhythm was up half a cent or 8.1 percent to 6.7 cents.

IMPEDIMED

Impedimed says investors passed all resolutions with up-to 26.26 percent opposed to executive director McGregor Grant’s 6,500,000 rights and 6,500,000 options.
Last month, Impedimed said its extraordinary general meeting would vote to issue 15,000,000 rights and 15,000,000 options to managing-director Dr Parmjot Bains and Mr Grant (BD: Jul 29, 2024).
Today, the company said the issue of Mr Grant’s incentive options and rights was opposed by 245,004,078 votes (26.26%), with 687,989,338 votes (73.74%) against.
Impedimed said the resolutions to approve Mr Grant and Dr Bain’s termination benefits were opposed by 22.78 percent and 21.28 percent of the meeting, respectively, with Dr Bains’ rights and options facing 21.06 percent dissent.
According to its most recent notice, Impedimed had 2,023,093,918 shares on offer, meaning that the votes against Mr Grant’s incentive securities amounted to about 12.1 percent of the company, sufficient to requisition extraordinary general meetings.
Impedimed was unchanged at 5.4 cents with 1.45 million shares traded.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says its annual general meeting has passed all resolutions but with up-to 18.78 percent of votes opposing the election of director Graham McLean.
Last month, Fisher & Paykel said investors would vote to issue managing-director Lewis Gradon 100,000 performance rights and 190,000 options (BD: Jul 10, 2024).
Today, the company said the election of Mr McLean was opposed by 84,241,690 votes (18.78%), with 364,226,483 votes (81.22%) in favor.
Fisher & Paykel said the election of Michael Daniell as a director was opposed by 5.64 percent of the vote, with the approval of the auditor fees and issue of performance rights and options to managing-director Lewis Gradon passed by more than 97.78 percent of the vote.
According to its most recent notice, Fisher & Paykel had 585,712,745 shares on offer, meaning that the votes against Mr McLean’s election amounted to about 14.4 percent of the company, sufficient to call an extraordinary general meeting.
Fisher & Paykel was up 66 cents or two percent to $33.05 with 422,202 shares traded.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says investors will vote to delist from the ASX, issue 4,000,000 shares to managing-director Roby Zomer and 600,000 rights to chair Brett Mitchell.
Earlier this month, Argent said it would delist from the ASX on September 23, 2024 due to a lack of liquidity, fundraising difficulties and costs, and would remain on the London Stock Exchange (BD: Aug 15, 2024).
Today, the company said its extraordinary general meeting would vote to approve its delisting from the ASX, effective on October 4, 2024.
Argent said shareholders would vote to issue Mr Zomer 4,000,000 shares in four tranches as a "financial benefit", with the first tranche freely tradable from the issue date and the remaining tranches to be in escrow pending performance hurdles.
The company said it would issue Mr Mitchell 600,000 performance rights in three tranches, subject to milestones and expiring five years from issue.
Argent said the meeting would vote to ratify the prior issue of shares and warrants under two placements.
Last year the then MGC approved a 1,000-to-one consolidation (BD: Oct 26, 2023).
The meeting will be held at Suite 1, 295 Rokeby Road, Subiaco, Western Australia on October 1, 2024 at 4pm (AWST).
Argent fell 2.5 cents or 7.25 percent to 32 cents.

AROA BIOSURGERY

Melbourne's Acorn Capital Ltd says it has increased its substantial shareholding in Aroa from 17,278,636 shares (5.02%) to 22,491,106 shares (6.52%).
Acorn said it bought the shares between May 8 and August 23, 2024, with the single largest purchase 3,441,949 shares on August 23 for $1,552,285, or 45.1 cents a share.
Aroa was up 4.5 cents or 9.6 percent to 51.5 cents with 325,048 shares traded.

COGSTATE

Sydney's Anacacia Pty Ltd says it has increased its substantial shareholding in Cogstate from 12,134,747 shares (7.1%) to 14,023,266 shares (8.2%).
Anacacia portfolio manager Tom Granger said that between June 25 and August 23, 2024 the company bought 1,888,519 shares for $2,048,187, or $1.08 a share.
Cogstate was up one cent or 0.9 percent to $1.075.

STARPHARMA HOLDINGS

Allan Gray Australia Pty Ltd says it has decreased its substantial shareholding in Starpharma from 27,938,497 shares (6.78%) to 23,690,480 shares (5.74%).
The Sydney-based Allan Gray said that between August 1 and 23, 2024 it sold 4,248,017 shares for $390,381, or 9.2 cents a share.
Starpharma was up 0.1 cents or 1.05 percent to 9.6 cents.