Biotech Daily

Tuesday November 26, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 13%; 4D MEDICAL DOWN 9%**

*** FEDERAL $50m TO CURE TYPE 1 DIABETES**

*** AROA H1 REVENUE UP 25% TO $35m, LOSS DOWN 48% TO $3m**

*** PACIFIC EDGE H1 REVENUE DOWN 16% TO $10m, LOSS DOWN 5% TO $13m**

*** RENERVE DOWN 17.5% ON $7m NERVE REPAIR IPO**

*** GEORGE MEDICINES DEVELOPS GMRx2 FOR HYPERTENSION**

*** CLARITY: ST VINCENT'S DOSES FIRST CU-64 SAR-BIS-PSMA PATIENTS**

*** RESPIRI $14m SCRIP FOR ORB HEALTH**

*** HERAMED, METRONOMIC FOR US POSTPARTUM CARE**

*** FILAMON TO COMMERCIALIZE ALPHA-003 DEMENTIA TREATMENT**

*** BCAL RECEIVES $2.6m FEDERAL R&D TAX INCENTIVE**

*** CYNATA RECEIVES $1.9m FEDERAL R&D TAX INCENTIVE**

*** INOVIQ RECEIVES $1m FEDERAL R&D TAX INCENTIVE**

*** NEUROTECH WINS FDA NTI164 RETT ORPHAN STATUS**

*** GOODBYE LBT, HELLO CLEVER CULTURE SYSTEMS**

*** CLARIFICATION: OPYL**

*** RECCE: THIRD AUSTRALIAN ANTI-INFECTIVE PATENT FAMILY**

*** VAXXAS US VACCINE PATCH PATENT**

*** ANTEOTECH AGM 47% REM REPORT 1st STRIKE; DROPS PLACEMENT**

*** INVEX AGM 88% DEFEAT INCENTIVE PLAN**

*** PYC BEGINS POST-10-1 CONSOLIDATION TRADING**

*** RICHCAB, DALE-MCKENZIE BELOW 5% OF ARTRYA**

MARKET REPORT

The Australian stock market fell 0.69 percent on Tuesday November 26, 2024, with the ASX200 down 58.2 points to 8,359.4 points. Thirteen of the Biotech Daily Top 40 companies were up, 17 fell and 10 traded unchanged.

Paradigm was the best for the third trading day in a row (see yesterday's edition), up six cents or 13.0 percent to 52 cents, with 10.7 million shares traded. Amplia was up 5.75 percent; Opthea, SDI and Universal Biosensors climbed more than four percent; Aroa, Medadvisor, Nova Eye and Telix were up more than three percent; Resmed rose 2.1 percent; Clinuvel, Cochlear, Mesoblast, Polynovo and Pro Medicus were up one percent or more; with EBR up by 0.5 percent.

4D Medical led the falls, down 4.5 cents or 8.9 percent to 46 cents, with 886,232 shares traded, followed by Percheron, down 0.6 cents or 8.1 percent to 6.8 cents with 4.1 million shares traded. Immutep lost 6.1 percent; Avita and Resonance were down more than five percent; Syntara fell 4.55 percent; Alcidion, Compumedics, Dimerix and Micro-X were down three percent or more; Cynata, Emvision and Neuren shed more than two percent; Proteomics was down 1.5 percent; with Clarity, CSL, Cyclopharm and Genetic Signatures down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will invest $50.1 million for the "next phase of the search for a cure for type 1 diabetes".

A media release from the Minister for Health and Aged Care Mark Butler said the funding for the Australian Type 1 Diabetes Clinical Research Network was delivered through the Juvenile Diabetes Research Foundation Australia.

The Government said the Australian Type 1 Diabetes Clinical Research Network was opened 15 years ago and had funded 83 research projects, supported more than 450 researchers and "seen the number of [type 1 diabetes] clinical trials and studies double with over 10,000 people participating in clinical trials and studies".

The Federal Government said the five-year funding would "accelerate clinical research for prevention, treatment and a cure for type 1 diabetes, by extending and enhancing the specialized research the … Network pioneered".

The Government said the funds would support "a world-first study" to understand the role of environmental triggers on the onset of type 1 diabetes, from as early as pregnancy, as well as open a prevention screening pilot program testing children for early-stage type 1 diabetes, before symptoms begin, and develop therapies to prevent disease progress.

Mr Butler said he had been working with Juvenile Diabetes Research Foundation since he attended his first "Kids in the House event about 15 years ago, and the advances that we've made in those 15 years are just extraordinary".

"When I was a junior minister in the health portfolio [in 2010], we announced the first money into [the Australian Type 1 Diabetes Clinical Research Network] … and since then it's supported dozens of projects, hundreds of researchers and thousands of patients," Mr Butler said.

"We've got to continue to push the envelope, explore the frontiers of research, and find a cure for this thing so that type one becomes type none," Mr Butler said.

"This $50 million in funding will help us get there," Mr Butler said.

AROA BIOSURGERY

Aroa says revenue for the six months to September 30, 2024 was up 25.35 percent to $NZ39,092,000 ($A35,170,000) with net loss after tax down 47.8 percent to $NZ3,294,000 ($A2,963,500).

Aroa said increased revenue “was driven by robust growth” in sales of its sheep stomach-based Myriad products for soft tissue repair, with record sales for its Ovitex products for hernia and breast reconstruction.

The company said it was “focused on investment in growth and increased sales productivity to drive profitability and positive operating cashflows”.

Aroa chief executive officer Brian Ward said the company expected “total revenue of $NZ43 million to $NZ50 million in the second half of this year, and to be cash flow positive”.

Aroa said diluted loss per share fell 47.8 percent to 0.96 NZ cents, net tangible assets per share was down 9.5 percent to 19.0 NZ cents, and it had cash and equivalents of $NZ13,600,000 at September 30, 2024 compared to $NZ3,955,000 the prior year.

Aroa was up two cents or 3.1 percent to 67 cents with 1.3 million shares traded.

PACIFIC EDGE

Pacific Edge says unaudited revenue for the six months to September 30, 2024 fell 16.3 percent to $NZ10,959,000 ($A9,857,000), with net loss after tax down 4.9 percent to $NZ14,503,000 ($A13,044,000).

Pacific Edge said the revenue decrease reflected “the reduction in test volume in the wake of the ongoing [US] Medicare uncertainty” and the reduced reach of the sales team following the restructuring, with Cxbladder bladder cancer urine test volumes down 1.1 percent to 14,233 for the six months, and increased demand from Permanente Medical, rising Asia Pacific volumes and sales force efficiencies providing “some mitigation to the impact of Medicare uncertainty”.

The company said its net loss after tax of $14.5 million reflected “the benefits of the cash conservation initiatives”, with its underlying cash burn steady.

Pacific Edge said diluted loss per share fell 5.3 percent to 1.8 NZ cents, net tangible assets per share was down 41.0 percent to 4.9 NZ cents, and it had cash and equivalents of $NZ21,931,000 at September 30, 2024 compared to $NZ20,469,000 the prior year.

Pacific Edge was up 1.5 cents or 15.0 percent to 11.5 cents.

RENERVE

Renerve fell 17.5 percent to 16.5 cents following its $7 million initial public offer at 20 cents a share to list on the ASX to commercialize its nerve repair products.

Last month, Renerve said it hoped to raise up-to $7 million to list on the ASX under the code ‘RNV’ to commercialize its peripheral nerve repair product (BD: Oct 31, 2024).

The company said its chair was former Avexa (now Tali Digital) chair Stephen Cooper and its managing-director was former Avexa chief executive officer and Cann Group chair Dr Julian Chick, with directors including Dr Michael Panaccio and Dr David Rhodes.

Today, Renerve said the funds from the listing would be used to progress the company’s portfolio of peripheral nerve injury repair products to market and US commercial expansion.

The company said its existing Nervalign nerve cuff product already had US Food and Drug Administration approval and was currently in use in the US surgical market.

Renerve closed down one cent or 5.0 percent at 19 cents with 4.9 million shares traded.

GEORGE MEDICINES
THE GEORGE INSTITUTE FOR GLOBAL HEALTH, BRANDON CAPITAL

George Medicines says a 1,385-patient, phase III trial shows its GMRx2 triple-combination pill is more effective than dual combinations for hypertension.

A media release from George Medicines said it was a George Institute for Global Health spin-out and a member of Brandon Capital's Biocatalyst.

The company said GMRx2 was a combination of telmisartan, amlodipine and indapamide developed in quarter-dose, low-dose, and standard-dose options.

George Medicines said the trial and development programs were funded by Brandon Capital as well as the George Institute, Federation Private Equity and health insurer BUPA.

The company said phase III trial data showed that GMRx2 quarter and half doses "both delivered significant blood pressure reductions compared to placebo".

George Medicines said a separate phase III trial of GMRx2 in 300 black, African participants with uncontrolled hypertension showed GMRx2 "outperformed a traditional treatment plan that begins with just one drug".

The Africa research, titled 'Low-Dose Triple-Pill vs Standard-Care Protocols for Hypertension Treatment in Nigeria: A Randomized Clinical Trial' was published in the Journal of the American Medical Association Network with an abstract available at: https://jamanetwork.com/journals/jama/article-abstract/2823291.

The company said both studies "showed excellent safety and tolerability profiles".

George Medicines said the phase III results were published in The Lancet, the Journal of the American Medical Association and the Journal of the American College of Cardiology.

Brandon Capital co-founding managing-partner Dr Stephen Thompson said George Medicine's success showed "the ability of Australian research to address critical global health issues when it receives the necessary timely investments and capability enhancements".

"GMRx2 is a home-grown innovation that has the potential to make a significant impact across the world, not just in the developed world, but in regions like sub-Saharan Africa, where hypertension is prevalent, but access to care is often limited," Dr Thompson said.

George Medicines is a private company.

CLARITY PHARMACEUTICALS

Clarity says the first two participants have been dosed in the St Vincent's Hospital-led phase II trial of its copper-64 Sar-Bis-PSMA for imaging prostate cancer.

Last week, Clarity said Sydney's St Vincent's Hospital would conduct an investigator-led, 50-patient, phase II trial of its copper-64 Sar-Bis-prostate specific membrane antigen [PSMA] for imaging prostate cancer compared to the standard-of-care gallium-68 PSMA-11 (BD: Nov 18, 2024).

The company said the primary endpoint of the trial was "to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between copper-64 Sar-Bis-PSMA and gallum-68-PSMA-11 positron emission tomography/computed tomography".

Clarity executive chair Dr Alan Taylor said patients had "already been dosed and had same-day and next-day imaging within a few days after [study] initiation".

Clarity fell one cent or 0.2 percent to $5.75 with 1.1 million shares traded.

RESPIRI

Respiri says it will pay $US9 million ($A13.9 million) in scrip to acquire the Dallas, Texas-based Orb Health and its chronic care management and patient services.

Respiri said Orb Health offered remote contact centres with administrative and clinical agents, patient information management and various health management services as well as its Enterprise Virtual Care for chronic care management.

The company said the acquisition of Orb Health was “a crucial milestone … to achieve full profitability [and would] … enable Respiri to expand its offerings, achieve economies of scale, add complementary expertise and realize synergies between the businesses”.

Respiri said it expected “significant synergies” to deliver cost savings of about $3.5 million on an annualized basis and was expected to deliver “monthly profitability for the US operations in early 2025”.

The company said it would pay an initial purchase price of $US9 million through the issue of shares, with Orb Health to invest $US700,000 in exchange for additional shares, with the funds to be used “as acquisition transition working capital”.

Respiri said an additional payment would be payable on Orb Health meeting financial targets by the end of 2024-’25, with the acquisition subject to shareholder approval for the issue of the shares and other customary conditions.

Respiri chief executive officer Marjan Mikel said the Orb Health business and team provided “an outstanding opportunity to continue to drive our capabilities to provide an even more comprehensive solution supporting our beyond-the-clinic promise”.

“They bring services that give us a broader solution that our clients want and need, whilst we bring a pedigree that can do the same for their existing clientele,” Mr Mikel said.

“All of this will deliver even better care to patients and drive our [per participant per month] revenues as a result,” Mr Mikel said.

“Realization of the near-term cost synergies of around $3.5 million should effectively make our US operations profitable,” Mr Mikel said.

“Further, this transaction will act as the model for likely future acquisitions, as we pursue the goal of becoming the preeminent market leader in the fragmented US connected care arena through organic and acquired growth,” Mr Mikel said.

Respiri was up 0.1 cents or 1.25 percent to 8.1 cents with 10.0 million shares traded.

HERAMED

Heramed says with the Washington DC-based Metronomic it will co-design post-partum care plans for Metronomic’s maternity care application Materno.

Heramed said Metronomic was “a digital health company building remote monitoring, tele-health and patient engagement platforms and services”.

The company said Metronomic’s Materno was an obstetrics-specific “platform that has focused on establishing a new digital care model for [obstetrician gynecologist] clinics in the US” and was available in 14 practices and managed service organizations in 10 states with an annual pregnancy panel of more than 10,000 pregnancies.

Heramed said the revenue model following the development of the software had not been determined, with a business plan to commercialize the product expected by April 2025.

The company did not disclose any other commercial terms of the agreement.

Heramed managing-director Anoushka Gungadin said the commercial opportunity in post-partum care was “evolving incredibly quickly and by combining Heracare with the care management solution, billing and reimbursement capability of Materno into one integrated solution we will have an opportunity provide a market leading offering”.

Heramed was unchanged at 2.2 cents with 1.2 million shares traded.

FILAMON LIMITED

Melbourne's Filamon says it is developing the tau and neuro-filament protectant Alpha-003 for diseases including two forms of dementia and Parkinson's disease.

A media release from Filamon said Alpha-003 was co-discovered by the Western Sydney University's Prof Kieran Scott and it was designed "to bind to and prevent both tau and neuro-filaments from being disrupted by inflammatory forces, giving it an important first-in-class mechanism-of-action".

According to the company's website, Alpha-003 was co-discovered by its co-founder Prof Paul De Souza, who was a former Western Sydney University professor and currently worked at the University of Sydney.

The website said Filamon's co-founding managing-director was Prof Graham Kelly, founder of Novogen (now Kazia), MEI Pharma (formerly Marshall Edwards), Noxopharm and Nyrada.

Filamon said the drug was able to cross the mammalian blood-brain barrier and it aimed to have the compound "in the clinic in 2026".

Filamon said Alpha-003 was being developed to treat tauo-pathies which included two forms of dementia, Alzheimer's disease and fronto-temporal dementia as well as progressive supranuclear palsy and chronic traumatic encephalopathy.

Prof Scott said the underlying problem with most forms of dementia was "the destruction of a key structural component of brain cells known as micro- tubules".

"These long, hollow tubes are vital to healthy brain function," Prof Scott said.

"In dementia, these micro-tubules degrade, resulting in the death of brain cells," Prof Scott said. "To date, no-one has found a way of preventing micro-tubular destruction."

"We believe Alpha-003 has the potential to be that first drug by stabilizing the two main brain cell components whose job is to protect micro-tubules from damage, tau and neuro-filaments," Prof Scott said.

Filamon is a public unlisted company.

BCAL DIAGNOSTICS

Bcal says it has received $2,628,000 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Bcal said the incentive related to research and development expenditure for its Breastest breast cancer diagnostic for the year to June 30, 2024.

Bcal was up half a cent or five percent to 10.5 cents.

CYNATA THERAPEUTICS

Cynata says it has received $1,885,140 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Cynata said the incentive related to research and development for the year to June 30, 2024.

Cynata fell half a cent or 2.3 percent to 21.5 cents.

INOVIQ

Inoviq says it has received $1,018,000 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Inoviq said the incentive related to expenditure for the year to June 30, 2024.

Inoviq fell 1.5 cents or 3.4 percent to 42.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has US Food and Drug Administration orphan drug designation for the use of NTI164 marijuana in children and adults with Rett syndrome.

Neurotech said the FDA granted orphan drug status to a drug or biological product to prevent, diagnose or treat a rare disease or condition affecting fewer than 200,000 people in the US, and qualified it "for incentives including tax credits for qualified clinical trials, exemption from user fees and potential seven years of market exclusivity after approval".

Neurotech executive director Dr Thomas Duthy said the company was "very pleased to have secured this orphan designation from the FDA".

"Rett syndrome remains a difficult to treat rare neurological disorder where safe and effective treatments are needed," Dr Duthy said. "Our phase I/II clinical trial demonstrated significant clinical effects in these patients with an excellent safety profile extending beyond the initial 12 weeks of the trial."

Dr Duthy said the European orphan drug request outcome was expected by April 2025.

Neurotech was up 0.3 cents or 4.55 percent to 6.9 cents with six million shares traded.

CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture Systems says it has formally changed its name from LBT Innovations and changed its ASX ticker code to 'CC5', effective from tomorrow.

Earlier this month, LBT said its annual general meeting approved its change of company name with 99.85 percent in favor (BD: Nov 14, 2024).

LBT fell 0.1 cents or 5.6 percent to 1.7 cents with 1.1 million shares traded.

CLARIFICATION: OPYL

Opyl says its artificial intelligence (A.I.) Trialkey platform will provide Melbourne's Southern Clinical Development Consulting with projects "starting from $5,000".

Last week, Opyl said it would provide its Trialkey platform for planning clinical trials to Southern Clinical Development Consulting (BD: Nov 21, 2024).

Today, the company said there was no minimum number of reports under the agreement and no other material information relevant to assessing the impact of the agreement.

Opyl was untraded at 2.7 cents.

RECCE PHARMACEUTICALS

Recce says the Australian Patent Office has granted the final patent under its Patent Family 3 relating to its anti-infectives, including R327 and R529.

Recce said the patent family, titled 'Anti-Virus Agent and Method for Treatment of Viral Infection' protected its intellectual property until 2037.

Recce managing-director James Graham told Biotech Daily that although the family patent title specified anti-virus agents and viral infections, the final patent granted today related to the broader process of manufacture for all of the company's anti-infectives.

The company said the final patent protected the manufacture of its anti-infectives and a copolymer made by the claimed process, the use of R327 or R529 for the treatment of infections and the methods of administration of R327 or R529 by oral, injection, inhalation as well as transdermal dose applications; and following the grant it was patent protected in "all major pharmaceutical markets", including Australia, China, US, Europe, Germany, France, Spain, the UK, Italy, Sweden, Japan and Hong Kong.

Recce fell half a cent or 1.1 percent to 46.5 cents.

VAXXAS PTY LTD

Vaxxas says the US Patent and Trademark Office has granted it a patent for the design and use of its high-density micro-array patches to administer vaccines via the skin.
A spokesperson for Vaxxas said the patent, titled 'Microprojection arrays with enhanced skin penetrating properties and methods thereof' protected its intellectual property until October 31, 2036.
Vaxxas said the additional patent meant its 42 patents covered "all significant proprietary aspects of the company's vaccine delivery platform and products, including the manufacture and use of the … technology and novel applicator device, vaccine formulations, and methods for formulating, loading and coating vaccines".
The company said its patent portfolio included patents in the US, Europe, Asia and Australia.
Vaxxas is a private company.

ANTEOTECH

Anteotech says its annual general meeting voted a 46.92 percent remuneration report first strike and withdrew the resolution on the 10 percent placement facility.
Last month, Anteotech said shareholders would vote to issue managing-director David Radford 5,400,000 performance rights and 10,800,000 options (BD: Oct 24, 2024).
Today, the company said the remuneration report was opposed by 476,971,089 votes (46.92%) with 539,522,555 votes (53.08%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive annual meetings must to vote on a board spill.
Anteotech said Mr Radford's options were opposed by 515,105,628 votes (46.90%) and his performance rights were opposed by 505,437,568 votes (46.01%).
The company said the equity incentive plan faced 23.47 percent opposition with the re-election of directors Ewan Crouch and Dr Geoff Cumming opposed by 19.76 percent and 17.78 percent of the meeting, respectively.
According to its most recent filing, Anteotech had 2,664,770,015 shares on issue, meaning that the 515,105,628 votes against Mr Radford's options amounted to 19.3 percent of the company, sufficient to requisition extraordinary general meetings.
Anteotech was unchanged at two cents with 7.7 million shares traded.

INVEX THERAPEUTICS

Invex says its annual general meeting has defeated the issue of securities to unrelated parties under an incentive plan, with all other resolutions passed easily.
In its notice of annual general meeting, Invex said the meeting would vote to issue a maximum of 3,750,000 securities over three years under the employee incentive scheme.
The company said the incentive plan was opposed by 17,834,660 votes (88.06%) with 2,418,133 votes (11.94%) in favor.
Invex said the remaining resolutions were passed with more than 99.1 percent of the meeting in support.
According to its annual report, Invex had 75,153,848 shares on issue, meaning that the 17,834,660 votes against the incentive plan amounted to 23.7 percent of the company, sufficient to requisition extraordinary general meetings.
Invex fell 0.3 cents or 4.3 percent to 6.7 cents.

PYC THERAPEUTICS

PYC says it has begun trading following its 10-to-one consolidation.
Earlier this month, PYC said it expected to begin post-consolidation trading on November 28, 2024 (BD: Oct 15, Nov 12, 2024).
PYC closed up a post-consolidation two cents or 1.1 percent to a post-consolidation $1.87 with 97,912 shares traded.

ARTRYA

Richcab Pty Ltd says as trustee for the Dale-McKenzie Superannuation Fund its shareholding in Artrya has been diluted to 4.45 percent of the company.
The Perth-based Richcab said that on April 2, 2024 it bought 10,000 shares for $2,830, or 28.3 cents a share.
Earlier this month, Artrya said it had “binding commitments” to raise $5 million at 42.0 cents a share in a placement (BD: Nov 12, 2024).
Artrya fell one cent or 2.4 percent to 41 cents.