Biotech Daily

Wednesday April 17, 2024

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: RESONANCE UP 12%; MICRO-X DOWN 13%**

*** AUSTCO 9-MONTH REVENUE UP 28% TO $37m; PROFIT UP 367% TO $2.8m**

*** LITTLE GREEN RECEIPTS UP 28% TO RECORD $27m**

*** NEUROTECH 'COMMITMENTS' FOR $10m PLACEMENT**

*** MICRO-X PLACEMENT RAISES $4m; $1m SHARE PLAN TO GO**

*** NEUROTECH PHASE II/III NTI164 MARIJUANA TRIAL MEETS ENDPOINTS**

*** NEUROTECH PHASE I/II NTI164 RETT TRIAL MEETS ENDPOINTS**

*** NEXT SCIENCE: 'XPERIENCE LEADS TO 0% KNEE SURGERY INFECTION'**

*** OSTEOPORE REINSTATED TO ASX**

*** FIREBRICK MARKETS NASODINE 'NASAL HYGIENE' IN US**

*** IMMUTEP: SPAIN 'POSITIVE FEEDBACK' FOR PHASE III EFTI NSCLC TRIAL**

*** GENETIC TECHNOLOGIES TO DEVELOP GENETYPE CANCER TEST**

*** PETERS TAKES 25.7% OF OPTISCAN**

*** IMPEDIMED APPOINTS HEAD OF PRODUCT, SALES; SCRAPS CSO, COO**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Wednesday April 17, 2024, with the ASX200 down 6.9 points to 7,605.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded.

Resonance was the best, up 0.9 cents or 12 percent to 8.4 cents, with 374,825 shares traded. Next Science climbed 10.5 percent; Paradigm was up 7.1 percent; Emvision and Proteomics were up more than four percent; Avita and Prescient were up more than three percent; Cochlear, Polynovo and SDI rose more than one percent; with Cyclopharm, Neuren and Resmed up by less than one percent.

Micro-X led the falls, down 1.5 cents or 13.04 percent to 10 cents, with 1.97 million shares traded; followed by Amplia down 12.86 percent to 6.1 cents, with 611,279 shares traded. Cynata lost 9.5 percent; Starpharma shed 7.4 percent; Curvebeam, Immutep, Mesoblast, Nanosonics, Nova Eye, Opthea, Orthocell and Universal Biosensors were down two percent or more; Dimerix, Percheron, Pro Medicus and Telix were down more than one percent; with Clarity and CSL down by less than one percent.

AUSTCO HEALTHCARE

Austco says that revenue for the nine months to March 31, 2024 was up 28.1 percent to $36.9 million, with net profit after tax up 366.7 percent to $2.8 million.
Austco said that the revenue came from contracts for its Tacera clinical communications, patient management and workflow systems, and included a $2.2 million contract with the Beeton, Ontario-based Simcoe Village, as well as a $1.2 million contract for systems at Melbourne's Whittlesea Community Hospital
(BD: Dec 27, 2023, Apr 15, 2024).
The company said the nine-month revenue included $4.6 million of revenue and a $600,000 net profit after tax for the four months after acquiring Teknocorp.
Last year, Austco said that it had completed its acquisition of Melbourne's Teknocorp, which was a reseller of its nurse health call software, for $1,900,000 upfront in cash and the issue of 3,888,889 shares at 18.0 cents a share, or worth $700,000
(BD: May 29, Nov 28, 2023).
Today, the company said it would "continue to focus on expanding its product portfolio, strengthening customer relationships and pursuing strategic initiatives to drive long-term value creation for shareholders.
Austco fell half a cent or 2.6 percent to 19 cents with 1.2 million shares traded.

LITTLE GREEN PHARMA

Little Green says receipts from customers for the year to March 31, 2024 were up 28.1 percent to a record $26,878,000 compared to the previous corresponding period.
Little Green said the increased sales were due to the collection of overdue receivables from December 31, 2023 and a significant increase in sales, with marijuana flower sales up 57 percent, marijuana oil sales up two percent and marijuana vaporizer sales up seven percent.
The company did not state its net profit or loss after taxation.
Little Green said that it had a cash burn of $2,843,000 for the year, with cash and cash equivalents of $4,974,000 at March 31, 2024, compared to cash and cash equivalents of $12,400,000 at March 31, 2023.
The company said that it had used $3,335,000 of its available loans and had $49,000 of unused financing facilities at March 31, 2024.
Little Green was unchanged at 13.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has "binding commitments" to raise $10.0 million at 10.0 cents a share in an institutional placement, with one attaching option for every two shares issued.
Neurotech said the issue price was a 4.6 percent discount to the 15-day volume weighted average price, a 3.5 percent discount to the five-day volume weighted average price and a 4.8 percent discount to the last closing price of 10.5 cents.
The company said the attaching options would be exercisable at 16.0 cents each within two years of the issue date.
Neurotech said the funds would be used to further its clinical trial activities, regulatory development work, investigational new drug enabling toxicology initiatives, product manufacturing and expansion, costs associated with the raise and general working capital.
Neurotech fell half a cent or 4.8 percent to 10 cents with 13.85 million shares traded.

MICRO-X

Micro-X says it has raised $4 million at 9.5 cents a share in an institutional placement and hopes to raise a further $1 million in a share purchase plan at the same price.
Micro-X said the issue price was a 21 percent discount to the 15-day volume weighted average price, or a 17 percent discount to the last closing price.
The company said participants in the capital raising would receive one attaching option for every two shares issued, exercisable at 13.5 cents each within two years of the issue date, subject to shareholder approval.
Micro-X said all four of its substantial shareholders had participated in the placement, and that it had received $100,000 in commitments from its directors.
The company said the funds would be used to commercialize its Argus remote x-ray camera, partnerships for its stroke imaging products, development of its prototype stroke imaging unit, costs associated with the capital raise and working capital.
Micro-X said Morgans Corporate and Hawkesbury Partners were joint lead managers of the placement.
The company said the share purchase plan had a record date of April 16, would open on April 24 and close on May 17, 2024.
Micro-X fell 1.5 cents or 13 percent to 10 cents with 1.97 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says its 54-patient, phase II/III trial of its NTI164 marijuana for autism led to “a statistically significant improvement in severity of illness at eight weeks ($p < 0.001$)”.
In 2022, Neurotech said it had treated the first patient in its randomized, controlled, double-blind trial of NTI164 for children with autism spectrum disorder (BD Dec 19, 2022).
Today, the company said the trial met its primary endpoint of an improvement in clinical global impression severity of illness score, with the NTI164 treatment group reporting an eight-week score of 3.77 out of seven compared to a 5.54 baseline, or a 32 percent improvement, compared to a 28 percent improvement in the placebo cohort ($p < 0.001$); and said there was a “significant down-staging of a patient’s illness severity noted with 88 percent of patients classified as markedly or severely ill at baseline in the NTI164 arm”.
Neurotech said the study met its secondary endpoints with a “significant, clinically meaningful treatment effect or benefit” in adaptive behaviors of 3.23, or 95 percent in the NTI164 group compared to placebo at eight weeks ($p = 0.024$).
The company said the results showed a significant improvement in social responsive scale and clinical global impression improvement scores for patients treated with NTI164 compared to placebo ($p = 0.028$ and $p < 0.001$, respectively).
Neurotech said there were no serious adverse events reported in the eight-week trial in either group and 11 adverse events across seven patients in both arms were recorded, including nausea and, or vomiting in two NTI164 treated patients.
The company concluded that its NTI164 marijuana treatment led to “a statistically significant and clinically meaningful improvement in [autism spectrum disorder] across multiple measures of assessments” and that all patients were able to receive NTI164 for an additional 52-week period.
Neurotech said it intended to accelerate registration-related regulatory discussions with the Australian Therapeutic Goods Administration.
Neurotech executive director Dr Thomas Duthy said the results “absolutely and unequivocally confirm our earlier clinical findings for NTI164 in [autism spectrum disorder] and again demonstrate substantial clinical benefits in these children across multiple measures”.

NEUROTECH INTERNATIONAL

Neurotech says results from its phase I/II trial of its NTI164 marijuana shows a "statistically significant clinical improvement in Rett syndrome patients" (p = 0.04).
Last year, Neurotech said it had approval for a 14-patient, phase I/II trial of its NTI164 marijuana treatment for Rett syndrome in females (BD: Jul 10, 2023).
Today, Neurotech said the primary endpoint of a clinical global impression improvement at 12 weeks compared to baseline was met, with a mean improvement of 0.3 (p = 0.04).
Neurotech said the result "compares favorably" to Neuren's US Food and Drug Administration approved treatment for Rett syndrome trofenitide, marketed by Acadia as Daybue, which showed a 0.3 or eight percent clinical global impression improvement (p = 0.003) (BD: Mar 13, 2023).
The company said all 14 patients completed the 12-week daily oral NTI164 treatment and all extended to 52 weeks of treatment.
In 2021, Neuren said its 187-patient, phase III trial of trofinetide showed statistically significant benefit for Rett syndrome compared to placebo, for both co-primary endpoints, with improvement over placebo in the Rett syndrome behavior questionnaire (p = 0.0175) and the clinical global impression of improvement (p = 0.0030) (BD: Dec 7, 2021).
Today, Neurotech said the data collection was ongoing, with additional analysis on the primary endpoint, secondary endpoint and safety data expected in the "next two to four weeks".
Neurotech executive director Dr Thomas Duthy said there remained "an urgent need for more safe and effective therapies in Rett syndrome".
"Data analysis and interpretation continues, and we are very much looking forward to finalizing and reporting further detailed clinical findings over the next two to four weeks and thereafter presenting this data at a major scientific meeting," Dr Duthy said.

NEXT SCIENCE

Next Science says two retrospective studies of show its Xperience wound treatment led to zero percent surgical site infections in 1,471 patients following knee and hip arthroplasties.
In 2022, Next Science said a study by the Chicago, Illinois-based Dr Ravi Bashyal showed its Xperience no-rinse, post-surgical anti-microbial was effective against both free-floating and biofilm bacteria, in-vitro (BD: May 11, 2022).
Today, the company said the 2022 data compared the use of Xperience in 471 consecutive knee and hip arthroplasties compared to a control group of 824 knee and hip surgery patients between 2020 and 2021 and would be published "in the coming months".
Next Science said the 2023 results compared the use of Xperience in 1,000 knee and hip arthroplasties compared to the same control group, and that the publication of the data was expected "later in the year".
Next Science managing-director Harry Hall said the "studies add to the growing body of clinical evidence that increasingly challenge the standard-of-care in surgical irrigation".
"We will continue to work closely with surgeons to conduct clinical research that demonstrates the effectiveness of our products," Mr Hall said.
Next Science was up four cents or 10.5 percent to 42 cents.

OSTEOPORE

Osteopore says it has been reinstated on the ASX, following the filing of its annual report for the year to December 31, 2023.
Osteopore fell 18 cents or 60 percent to 12 cents.

FIREBRICK

Firebrick says it has begun marketing its Nasodine nasal spray online in the US for $US24.99 ($A38.94) a unit, for "'nasal hygiene' without any therapeutic claims".

Firebrick said the commercialized Nasodine used the same formulation and packaging that it had tested in its previous clinical trials, and that it would be marketed "as a nasal cleanser with the power of povidone-iodine … [to] help maintain nasal hygiene by eliminating germs, allergens and other airborne threats that disrupt nasal hygiene".

In 2022, Firebrick opened on the ASX up 125 percent having raised $7 million at 20 cents a share to commercialize its anti-viral Nasodine, based on Betadine, for the common cold and Covid-19 (BD: Feb 1, 2022).

Last year, the company said that its 39-patient, phase II trial showed that Nasodine reduced Covid-19 viral load 100 percent compared to 48 percent for placebo ($p = 0.028$), but said it was not planning further Covid-19 studies or intending to pursue regulatory approval (BD: Aug 7, 2023).

Later, Firebrick said that its phase III trial of Nasodine for the common cold did not meet its primary endpoint, with sterile water placebo better at impacting cold severity (BD: Sep 13, 2023).

Today, the company said based on legal advice it had marketed Nasodine without any therapeutic claims, which allowed it to commercialize the nasal spray without US Food and Drug Administration approval.

Firebrick said "since 2020, multiple [povidone-iodine] nasal sprays have been introduced in the US and continue to be marketed" as non-therapeutic products.

The company said a contract manufacturer had completed a first commercial batch of finished product, with 30,000 units available for sale, and that it had engaged a US-based online marketing agency for a social media advertising campaign.

Firebrick said it had "several other products in development and expects some of these to become available in the future".

The company said it would not market Nasodine in Australia, but that Australians could order from the US and import the product for personal use.

In 2022, Firebrick said it would appeal against the Australian Therapeutic Goods Administration initial decision not to approve Nasodine, based on the existing data; and later, withdrew its appeal (BD: Mar 1, 2022, Jan 21, 2024).

Today, the company said it intended "to continue its discussions with the Therapeutic Goods Administration about potential pathways to Nasodine's approval in Australia".

Firebrick managing-director Dr Peter Molloy said Nasodine would "be the only [povidone-iodine] nasal spray in the US that is supported by demonstrated safety in clinical trials and a growing list of peer-reviewed publications."

"We plan to build a portfolio of products under the Nasodine brand and launch them in the US and other markets," Dr Molloy said.

"Launching Nasodine into the world's premier pharmaceutical market is a momentous event for our company, culminating more than 10 years of [research and development] and heralding our transition to a commercial pharmaceutical business," Dr Molloy said.

"Our position has always been that if we can make Nasodine available, people will use it," Dr Molloy said.

"In a post-Covid-19 world, where everyone is concerned about nasal hygiene, we believe Nasodine is the answer," Dr Molloy said.

Firebrick was up 2.7 cents or 51.9 percent to 7.9 cents with 11.3 million shares traded.

IMMUTEP

Immutep says it has “positive feedback” from Spanish regulatory authorities to conduct a phase III trial of its eftilagimod alpha, or ‘efti’ for non-small cell lung cancer (NSCLC)
Immutep said the Spanish Agency for Medicines and Health Products was “supportive” of its registrational trial in metastatic non-small cell lung cancer and evaluating efti with anti-programmed cell death-1 (PD-1) therapy and with or without chemotherapy.
The company said the meeting discussed “general aspects of the trial design, including selection of the control arm and statistics, and the specificities of the patient population”, but did not disclose the number of patients expected.
Immutep fell one cent or 2.8 percent to 35 cents.

GENETIC TECHNOLOGIES

Genetic Tehcnologies says it will develop Genetype genomic tests using methylation, mutation and liquid biopsy for diagnosing various types of cancers.
Genetic Technologies said the tests would help “determine which therapies will have the most efficacious impact in treating a range of cancers including melanoma, lung, pancreatic, colorectal, breast, ovarian and brain cancers”.
Genetic Technologies was up half a cent or three percent to 17 cents.

OPTISCAN IMAGING

Peters Investments says it has increased its shareholding in Optiscan from 206,296,445 shares (24.705%) to 214,750,000 shares (25.708%).
The Perth-based Peters Investments said that between Aug 4, 2023 and Apr 16, 2024 it 13,033,555 shares for $1,094,673 or 8.4 cents a share and sold 4,580,000 shares for $365,603 or 8.0 cents a share.
Optiscan fell 0.9 cents or 8.6 percent to 9.6 cents.

IMPEDIMED

Impedimed says it has appointed Tim Benkovic head of sales and customer success and director Andrew Grant interim head of product development and customer affairs.
Impedimed said the organizational changes were part of its measures to increase sales and “more tightly manage cashflow and establish greater cost discipline”, which resulted in the roles of chief strategy officer and chief operating officer becoming redundant.
The company said chair McGregor Grant would “assume responsibility for operations, including [information technology] infrastructure as chief financial and operating officer”.
Impedimed said Mr Benkovic had more than 30 years of experience, having worked for Nanosonics, Fresenius and Hill-Rom Welch Allyn.
The company said Mr Andrew Grant was expected be the head of product development and customer affairs for up-to six months on a fixed yearly salary of $313,000, and he would continue as a director and receive an additional $112,000 a year in director fees.
Impedimed said as a result of the changes it expected annualized operating costs for the year to June 30, 2025 to be reduced by 10 to 15 percent compared to the prior period.
The company said it was in discussions to appoint an additional director.
Impedimed was unchanged at 9.4 cents with 5.7 million shares traded.