

Biotech Daily

Monday June 17, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: COMPUMEDICS, NEXT SCIENCE UP 10%; CYNATA DOWN 16%
- * NEUROTECH NTI164 MARIJUANA AUTISM REACHES 2-YEAR DOSING
- * FIREBRICK PHASE I NASODINE STUDY: 'SAFE, WELL-TOLERATED'
- * RHYTHM CLOSES RIGHTS OFFER; RAISES \$2.7m OF HOPED-FOR \$6.6m
- * PROTEOMICS APPOINTS GROWTH MEDICS FOR EURO PROMARKER D SALES
- * ENLITIC SIGNS THREE ENSIGHT SALES CONTRACTS
- * HERAMED HERACARE AT BROWARD HEALTH
- * ARCHER FABRICATES MEDICAL DIAGNOSTICS GFET 6" INCH WAFER
- * ALLEGRA: SHAREHOLDER DETAILS SOUGHT FOR TAKEOVER BID
- * CLEO TO RELEASE 7.5m ASX ESCROW SHARES
- * SELECTOR TAKES 5% OF NANOSONICS
- * FIL (FIDELITY) INCREASES, DILUTED TO 8.5% OF GENETIC SIGNATURES
- * REGAL FUNDS TAKES 8.5% OF IMMUTEP
- * MA (MOELIS) TAKES 6.7% OF TRAJAN
- * PHARMAUST APPOINTS DR KATIE MACFARLANE DIRECTOR
- * DEBORAH AMBROSINI REPLACES PERCHERON CFO, CO-SEC PHILLIP HAINS
- * COMPUMEDICS APPOINTS CRAIG GALLIVAN US SLEEP SALES HEAD

MARKET REPORT

The Australian stock market fell 0.31 percent on Monday June 17, 2024, with the ASX200 down 24.0 points to 7,700.3 points. Sixteen of the Biotech Daily Top 40 were up, 18 were down and six traded unchanged.

Compumedics and Next Science were equal best, both up 10 percent to 33 cents and 27.5 cents, respectively, with 112,716 shares and 161,276 shares traded, respectively. Atomo climbed 7.1 percent; Impedimed improved 5.8 percent; Emvision and Nova Eye were up more than four percent; Telix and Universal Biosensors were up more than three percent; Immutep and Nanosonics rose more than two percent; Cochlear, Neuren, Opthea and Pro Medicus were up more than one percent; with Mesoblast, Polynovo, Resmed and SDI up by less than one percent.

Cynata led the falls, down five cents or 16.1 percent to 26 cents, with 376,007 shares traded. Actinogen and Proteomics lost more than six percent; Dimerix, Percheron and Prescient fell more than four percent; Avita, Micro-X, Starpharma and Syntara were down more than three percent; Alcidion and Orthocell shed more than two percent; Clinuvel, Medadvisor, Medical Developments and Resonance were down more than one percent; with 4D Medical, CSL and Cyclopharm down by less than one percent.

NEUROTECH INTERNATIONAL

Neurotech says the 11 autism spectrum disorder patients from its phase I/II trial of marijuana-based NTI164 have reached two years of daily administration of the drug. Last year, Neurotech said it had ethics approval for 11 patients in its phase I/II trial of NTI164 for autism spectrum disorder to continue treatment under compassionate use via the special access scheme category B (BD: May 31, 2023).

Earlier this year, the company said the 11 patients had daily oral doses for 90 weeks and NTI164 had "an exceptional safety and tolerability profile" (BD: Feb 7, 2024).

Today, Neurotech said that at the two-year mark there were no serious adverse events and that no patients had dropped out due to safety or reversal in their clinical improvements that would warrant withdrawal from treatment.

The company said the results continued "to reinforce NTI164 as an attractive, long-term therapy for autism".

Neurotech director Dr Thomas Duthy said it was an "important milestone for Neurotech with our 11 level two or level three [autism spectrum disorder] patients who originally participated in the company's first clinical trial of NTI164 now having been on daily oral treatment with NTI164 for two years".

"The initial positive results of this trial have been the catalyst for further research and development investment by Neurotech which has now delivered strong clinical benefits in a further phase II/III [autism spectrum disorder] study and additional clinical benefits in phase I/II trials in [paediatric neuropsychiatric syndrome] and Rett syndrome without compromising patient safety," Dr Duthy said.

"All three of these neurological disorders lack safe and effective therapies and accordingly represent a significant commercial opportunity for Neurotech as we develop our core NTI164 asset," Dr Duthy said.

Neurotech was up 0.2 cents or 3.3 percent to 6.3 cents with 1.9 million shares traded.

FIREBRICK

Firebrick says a 2018 phase I Nasodine safety trial has been published in the International Forum of Allergy and Rhinology, showing it is "safe and well-tolerated".

Firebrick said the article, titled 'Phase 1 Study of the Iodine Absorption, Safety, and Tolerability of a 0.5 percent Povidone-Iodine Nasal Spray (Nasodine)' was available at: https://onlinelibrary.wiley.com/doi/10.1002/alr.23389.

The company said the study concluded that a commercial dose of 0.5 percent Nasodine povidone-iodine was "safe and well-tolerated and did not cause clinically significant elevation of serum iodine in euthyroid adults, when applied four times daily for five days, at a dose of 1.12ml".

Firebrick chair Dr Peter Molloy told Biotech Daily that the study was completed in 2018 and referred to in the prospectus as supporting safety and tolerability, and therefore subsequent clinical efficacy trials.

Dr Molloy said the publication was the full details of the trial, with a focus on the iodine absorption results.

"Given that the labelling of the commercial product states that anyone with thyroid disease should contact their physician before use, the full published iodine absorption data are likely to be useful," Dr Molloy said.

"This published paper is the first clinical safety assessment of a [povidone-iodine] nasal spray that addresses systemic iodine absorption by the nasal route," Dr Molloy said. "Its publication in IFAR is an important endorsement of the importance of this data." Firebrick fell half a cent or 7.5 percent to 6.2 cents.

RHYTHM BIOSCIENCES

Rhythm says it has closed the shortfall offer for its pro-rata, non-renounceable rights offer, raising a total of \$2,745,416 of a hoped-for \$6,634,278.

Earlier this year, Rhythm said it had raised \$2,483,947 of a hoped-for \$6.6 million in its three-for-10 rights offer at 10 cents a share and it hoped to place the \$4,150,331 shortfall (BD: Feb 9, Mar 21, 2024).

Today, the company said it had raised \$2,122,289 in the rights offer, \$361,658 from underwriters in the shortfall offer and \$261,469 from the shortfall placement. Rhythm was unchanged at 6.6 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says medical device sales agency Growth Medics BV will help it sell its Promarker D diabetic kidney test to partners and customers in the European Union. Proteomics said the Almelo, Netherlands-based Growth Medics had a "track record assisting medical device and diagnostic companies achieve market penetration, and the digital marketing experience required for Proteomics' global go-to market strategy". The company said Growth Medics would help "in the identification, recruitment and management of new partners and customers in Europe", as well as providing business development and marketing support, including attending trade shows.

Proteomics said the initial two-year Growth Medics partnership was on "market standard fee-for-service terms" and that Growth Medics would receive commissions for successful revenue generating partnerships.

The company said it had agreed not to appoint any similar sales agency for the Netherlands, Belgium, Italy and Spain.

Proteomics managing-director Dr Richard Lipscombe said the company believed Growth Medics was "an ideal partner to drive the commercialization of Promarker D through Europe due to their extensive market knowledge, proven track record, regulatory expertise, and strong relationships with key stakeholders".

"Their multilingual and multicultural capabilities ensure targeted sales and marketing strategies," Dr Lipscombe said.

Proteomics fell six cents or 6.9 percent to 81 cents.

ENLITIC INC

Enlitic says Esaote SpA, Clairvo Technologies and Datafirst Corp will distribute and sell its Ensight 2.0 and other x-ray-related technologies.

Enlitic said it had a three-year distribution agreement with Genoa, Italy's Esaote to sell its Ensight 2.0 radiology and medical imaging management software in Europe.

The company said the Tokyo-based Clairvo Technologies, a subsidiary of Marubeni, would exclusively commercialize its chest x-ray technologies in Japan for one year, and that the agreement would automatically renew annually for up-to 10 years.

Enlitic said it had a three-year marketing and technology agreement with Raleigh, North Carolina's Datafirst Corp to jointly market and distribute both parties' products and services to their existing customers.

Enlitic managing-director Michael Sistenich said the partnerships were "significant milestones in the commercialization of our products as they unlock the door to even more of our estimated total serviceable market" having accelerated the development roadmap with the release of Ensight 2.0 to expand the capability of the suite of uses.

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

HERAMED

Heramed says its Heracare software has begun operation at the Fort Lauderdale, Florida-based Broward Health, with 20 mothers using it in a "controlled rollout".

Earlier this year, Heramed said it had a two-year agreement with Broward Health for its Heracare platform and Herabeat foetal heart monitoring devices (BD Feb 28, 2024). Heramed said the maternity monitoring software would "scale to support at least 700 pregnancies, beginning with 700 Heracare licences and 200 bundles of hardware including 200 Herabeat devices".

Heramed was up 0.3 cents or 17.65 percent to two cents with 2.2 million shares traded.

ARCHER MATERIALS

Archer says it has fabricated one of its Biochip graphene field effect transistor (GFET) designs for medical diagnostics through a six-inch whole wafer.

Earlier this year, Archer Materials said it had developed a computer chip to detect the electronic signals from genetic sequence reactions, enabling the potential detection of multiple diseases (BD: Jan 23, 2024).

At that time, the company said in December 2023 it had sent its graphene field effect transistor (GFET) design to an ISO 13485 certified foundry in Spain for fabrication, and the graphene field effect transistors were "designed to be fabricated with structures suitable for liquid multiplexing".

Today, the company said the fabrication had been completed by Graphenea, its foundry partner in Spain.

Archer said the graphene field effect transistors were "designed with structures suitable for liquid multiplexing, with advances in chip design features, including in gating design and materials, to address technological challenges in maintaining graphene device stability from chip-to-chip".

The company said it had previously completed a multi-project wafer run at its foundry in Germany and a four-inch wafer run at its foundry in the Netherlands.

Archer chief executive officer Dr Mohammad Choucair said the company had shown "its specialized GFET designs can be fabricated through a whole six-inch wafer run". "By performing these types of wafer runs, including in Graphenea's commercial graphene foundry, Archer aims to optimize its GFET designs, performance, and readiness for compatibility with the advanced fabrication processes and equipment needed to potentially produce GFET chips at scale," Dr Choucair said.

Archer fell half a cent or 1.4 percent to 36 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra Innovations Pty Ltd says it requires its Allegra Medical shareholders' details in relation to its off-market takeover bid by 7pm (AEST) on June 17, 2024.

Last month, Allegra said Allegra Innovations Pty Ltd, a related party of Allegra director Dr Nicholas Hartnell, would pay 0.4 cents a share in a cash take-over bid, valuing it at \$478,444 (BD: May 27, 2024).

Today, the company said Allegra Innovations had appointed Automic Group as its share registry and that it would appoint "a printer and mail-house to arrange the printing and mailing of the bidder's statement and associated documents".

Allegra was in a suspension and last traded at 2.9 cents.

CLEO DIAGNOSTICS

Cleo says it will release 7,500,000 shares from ASX escrow on June 23, 2024. According to its most recent filing, Cleo had 74,100,001 shares on offer, meaning that following the release of the shares from ASX escrow it would have 81,600,001 shares available for trading, with a further 46,900,000 shares remaining in ASX escrow. Cleo fell one cent or 2.6 percent to 38 cents.

NANOSONICS

Sydney's Selector Funds Management says it has become a substantial shareholder in Nanosonics with 15,187,962 shares, or 5.01 percent.

Selector said it acquired the shares between March 1, 2018 and June 13, 2024, but did not disclose the consideration, as required under the Corporations Act 2001.

Earlier this year, Selector said it had ceased its substantial shareholding in Nanosonics, with the disposal of 13,939,898 shares (BD: Mar 15, 2024).

Nanosonics was up eight cents or 2.8 percent to \$2.97 with 826,593 shares traded.

GENETIC SIGNATURES

FIL Ltd (Fidelity Investment Management) says it has increased and been diluted in Genetic Signatures from 16,475,459 shares (9.99%) to 18,341,646 shares (8.52%). The Hong Kong-based FIL said that on January 18, 2024 it exercised 1,866,187 rights for 37.00 cents a share.

Earlier this month, Genetic Signatures said that it had raised \$21.5 million at 75.0 cents a share in a \$6.0 million placement and \$15.5 million, in a one-for-5.82, fully-underwritten institutional rights offer, with an \$8.5 million retail rights offer to follow (BD: Jun 4, 6, 2024). Genetic Signatures was unchanged at 67.5 cents.

IMMUTEP

Regal Funds says it has increased its substantial shareholding in Immutep from 88,013,280 shares (7.40%) to 121,230,690 shares (8.51%).

The Sydney-based Regal Funds said that between February 19 and June 12, 2024 it bought and sold shares in various transactions, with the single largest purchase 28,947,368 shares on June 12 for \$11,000,000, or 38.0 cents a share.

Earlier this month, Immutep said it expected to raise \$100.2 million at 38 cents a share in a fully-underwritten placement and rights offer (BD: Jun 3, 2024).

Immutep was up one cent or 2.4 percent to 42 cents with 2.6 million shares traded.

TRAJAN GROUP HOLDINGS

MA (Moelis Australia) Financial Group says it has increased its substantial holding in Trajan from 8,332,632 shares (5.47%) to 10,210,146 shares (6.71%).

New York's MA said that between May 14 and June 13, 2024 it bought shares, with the single largest purchase 721,714 shares for \$631,500, or 87.5 cents a share.

Trajan fell half a cent or 0.5 percent to 93 cents.

PHARMAUST

Pharmaust says it has appointed Dr Katie MacFarlane as a non-executive director, effective from today.

Pharmaust said Dr MacFarlane was the founder of commercial and strategic consulting firm Smartpharma, the head of commercial for Arkayli Biopharma, and had been chief commercial officer at Agile Therapeutics, head of marketing at Warner Chilcott and at Parke-Davis and a director of Respirerx.

The company said Dr MacFarlane held a Bachelor of Science and a Doctor of Pharmacy from West Lafayette, Indiana's Purdue University.

Pharmaust chair Sergio Duchini said the US-based Dr MacFarlane would "be invaluable in establishing Pharmaust as a global leader in neurodegenerative diseases".

Earlier this month, the company said chair Dr Roger Aston, directors Robert Bishop, Dr Thomas Duthy had resigned from the company, followed by the resignation of interim chair and 16-year director Sam Wright (BD: May 9, 17, 2024).

Pharmaust was up two cents or 8.9 percent to 24.5 cents.

PERCHERON THERAPEUTICS

Percheron says it has appointed Deborah Ambrosini to replace Phillip Hains as its chief financial officer and company secretary, effective immediately.

Percheron said Ms Ambrosini had worked for Cortical Dynamics, Acrux and Cann Group, as well as Price Waterhouse Coopers (PWC).

According to her Linkedin profile, Ms Ambrosini held a Bachelor of Accounting and Business Law from Perth's Curtin University.

The company said Mr Hains was a partner at Acclime Group, and previously the CFO Solutions, and that the company would "continue to work closely with the Acclime Group team on its accounting and statutory compliance obligations".

Percheron fell 0.4 cents or 4.35 percent to 8.8 cents with 1.2 million shares traded.

COMPUMEDICS

Compumedics says it has appointed Craig Gallivan as head of US sales for its home sleep testing products, including Somfit.

Last year, Compumedics said it had US Food and Drug Administration approval to market its Somfit device for at-home sleep testing

Compumedics said the Dallas, Texas-based Mr Gallivan had previously worked at Zoll Itamar, as well as Abbott and Merck.

According to his Linkedin page, Mr Gallivan held a Bachelor of Business Administration from the Antigonish, Canada-based St Francis Xavier University and a Master of Business Administration from the College Station-based Texas A&M (agricultural and Mechanical) University.

Compumedics was up three cents or 10 percent to 33 cents.