

Biotech Daily

Thursday November 3, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 15%; IMUGENE DOWN 7%
- * CSL 2022 R&D BRIEFING: SPENDING UP, VIFOR EXPANDS PIPELINE
- * NEW ZEALAND APPROVES RHYTHM'S COLOSTAT
- * ANTEO CLOSES EUROPE SARS-COV-2 RAPID ANTIGEN TEST TRIAL
- * ALTHEA 'COMMITMENTS' FOR \$1.5m; PLAN FOR \$2.5m MORE
- * ACRUX RECEIVES FURTHER \$92k FEDERAL R&D TAX INCENTIVE
- * PHARMAUST: DNDI EXTENDS EPICHEM CONTRACT \$32k
- * OVENTUS (IN ADMINISTRATION) SIGNS CANADA DISTRIBUTION DEAL
- * KAZIA WITHDRAWS 3.5m CEO DR JAMES GARNER OPTIONS
- * HEALTH CANADA AMENDS CRESO MERNOVA MARIJUANA LICENCE
- * HEALTHCARE 2030, BERGEN, EUGENE TABLIS REDUCE TO 11% IN NUHEARA
- * PHILLIP, BIOSCIENCE MANAGERS TAKE 23% OF ADHERIUM
- * TRUDELL MEDICAL TAKES 19.9% OF ADHERIUM
- * EPSILON DIRECTORS CEASE SUBSTANTIAL WITH BOARD CHANGES
- * AUSBIOTECH APPOINTS DR MARTHE D'OMBRAIN; DIRECTOR CHANGES
- * MTP CONNECT TO LOSE CHAIR SUE MACLEMAN; NEW CHAIR WANTED

MARKET REPORT

The Australian stock market fell 1.84 percent on Thursday November 3, with the ASX200 down 128.8 points to 6,857.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded. All three Big Caps fell.

Genetic Signatures was the best, up 10 cents or 15.15 percent to 76 cents, with 27,297 shares traded. Cynata climbed 10.3 percent; Immutep and Kazia improved eight percent or more; Emvision, Impedimed, Oncosil, Resonance and Volpara rose more than two percent; Medical Developments, Nanosonics and Proteomics were up more than one percent; with Clinuvel up by 0.4 percent.

Imugene led the falls, down 1.5 cents or 7.3 percent to 19 cents, with 26.7 million shares traded. Cochlear, Polynovo, Prescient, Starpharma and Telix lost three percent or more; Avita and Next Science shed more than two percent; Atomo, CSL, Opthea, Orthocell, Paradigm, Pharmaxis and Resmed were down more than one percent; with Mesoblast, Neuren and Pro Medicus down by less than one percent.

CSL

CSL says research and development spending for the year to June 30, 2022 was up 15.4 percent to \$US1,156 million (\$A1,821 million) compared to the prior period.

CSL said research and development accounted for 10.9 percent of total revenue for the same period compared to 9.7 percent in 2021 (BD: Oct 19, 2021; Aug 17, 2022). In its 2022 research and development briefing, the company said it had made progress in the development of its drug candidate pipeline, progressing its eblasakimab for atopic dermatitis, or eczema, and introducing its clazakizumab monoclonal antibodies for transplants to phase II trials, and the progression of etranacogene dezaparvovec for haemophilia B to registration or post-registration.

CSL said its acquisition of Switzerland's Vifor Pharma added 13 drugs to its portfolio, six of which were at the registration or post-registration stage (BD: Dec 14, 2022).

The company said that the Vifor acquisition had added five drugs to its phase III program and one each to its phase I and phase II programs.

CSL said that

The company said yesterday's agreement with San Francisco's Arcturus Therapeutics was subject to "customary regulatory clearances" and it was therefore unclear how this would affect its pipeline (BD: Nov 2, 2022).

CSL said that as part of the agreement with Arcturus, CSL Seqirus would target selfamplifying mRNA vaccine capability, allowing the entrainment of multiple pathogens in the one vaccine, and lower required dosage for comparable antigen levels.

The company said its new Melbourne headquarters was on track for completion by early 2023, and would house 800 employees, as well as a joint venture between CSL, the Walter and Eliza Hall Institute, and the University of Melbourne.

CSL said its Marburg and Boston facilities were both on track to open in 2022, with the capacity to house about 500 CSL Behring employees and 300 CSL Seqirus employees, respectively.

CSL fell \$4.37 or 1.55 percent to \$278.34 with 500,231 shares traded.

RHYTHM BIOSCIENCES

Rhythm says New Zealand's Medsafe has registered its Colostat bowel cancer blood test on the New Zealand database of medical devices, allowing it to be marketed and sold. Rhythm managing-director Glenn Gilbert said the company was "pleased to expand its international regulatory approval footprint into New Zealand which enables the company to commence marketing and sales activities for Colostat".

"Bowel cancer is the second highest cause of cancer death in New Zealand and a growing issue with one in 10 now diagnosed under the age of 50," Mr Gilbert said.

"Colostat is a simple blood test which has the potential to make a material impact on health outcomes through mass screening for higher participation to achieve early diagnosis," Mr Gilbert said.

"We look forward to working with the Ministry of Health's National Screening Unit to enhance New Zealand's National Bowel Screening Program," Mr Gilbert said. Rhythm

In May, Rhythm said it had filed the final Australian Therapeutic Goods Administration filing for Colostat and expected a decision this year (BD: May 12, 2022).

Last year, Rhythm said that it had received Conformité Européenne (CE) mark approval (BD: Nov 30, 2021).

Rhythm was up 12.5 cents or 11.0 percent to \$1.265.

ANTEOTECH

Anteo says it has halted the European trial of its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test to free \$700,000 for other diagnostics. Anteo said it would focus on its Covid-19 influenza A and influenza B and other point-of-care tests.

In May, the company said it had registered an updated, multiple sampling method Eugeni Covid-19 rapid antigen test in Europe under the in-vitro diagnostic directive, for the same core Sars-Cov-2 Ag Rapid Diagnostic Test, but covered multiple sampling method use claims, including combined nose and throat sampling and nasal mid-turbinate sampling (BD: May 18, 2022).

Today, Anteo said that "a small number of outliers ... [had] adversely affected the performance of the Eugeni Sars-Cov-2 Ag [rapid diagnostic test] ... [which were] inconsistent with our previously reported performance and these outliers are concentrated in one geographic region".

The company said it did not intend to pursue further regulatory approval for the single Sars-Cov-2 rapid antigen test.

Anteo fell 0.3 cents or 5.3 percent to 5.4 cents with 1.8 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it has "firm commitments" to raise \$1.5 million in a placement at 6.7 cents a share, and hopes to raise \$2.5 million in a share plan.

Althea said the offer price was a 19.1 percent discount to the 5-day volume-weighted average price to October 28, 2022.

The company said funds raised would be used to support the launch of additional marijuana products and support it to reach cash flow break even and operating profitability by April 2023.

Althea said the record date was November 1, 2022 the option to purchase up to \$30,000 worth of its shares, but did not specify the opening or closing dates.

The company said Canaccord Genuity (Australia) was the placement lead manager. Althea fell 1.4 cents or 16.9 percent to 6.9 cents with 2.8 million shares traded.

ACRUX

Acrux says it has received \$92,704 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Acrux said the rebate related to an overseas finding claim by a subsidiary company for research and development expenditure for the year to June 30, 2022.

The company said it had received a total of \$3,731,741.

Acrux was unchanged at 7.3 cents.

PHARMAUST

Pharmaust says its subsidiary Epichem will receive up to \$32,000 for provision of medicinal chemistry services to Geneva's Drugs for Neglected Diseases Initiative. Pharmaust said the partnership would cease in March 2023 due to development of monepantel reaching a new phase and changes in the Drugs for Neglected Diseases Initiative's program funding.

Pharmaust was unchanged at 7.6 cents.

OVENTUS MEDICAL (IN ADMINISTRATION)

Oventus administrators Grant Thornton says the Toronto Ontario-based Open Airways Dental Solutions will distribute its sleep apnoea products in Canada.

In June, Osprey entered voluntary administration to restructure (Jun 14, 2022).

Today, Grant Thornton said that under the five-year agreement, Open Airways Dental Solutions would distribute Oventus' O2vent Optima, Optima Mini, Exvent Multipack, Exvent Annual Resupply Packs, Connector Bands and Bite Fork at its own cost, in all Canadian provinces.

Oventus was in a suspension and last traded at two cents.

KAZIA THERAPEUTICS

Kazia says it has withdrawn a resolution proposing to issue Dr James Garner with 3,500,000 options from its annual general meeting (BD: Oct 14, 2022).

Kazia said that "in light of recent market turbulence, the directors have determined that this grant is not appropriate".

Kazia was up one cent or eight percent to 13.5 cents.

CRESO PHARMA

Creso says Health Canada has approved an amended licence for subsidiary Mernova to sell marijuana "extracts, electric vaporizers, edibles and topical products".

Creso said it would leverage its amended licence to enter new provincial markets.

Creso was up fell 0.1 cents or 3.6 percent to 2.9 cents with 5.6 million shares traded.

NUHEARA

Healthcare 2030, Bergen and Eugene Tablis say they have reduced their substantial holding in Nuheara from 18,060,672 shares (13.16%) to 15,260,648 shares (11.12%). The Boca Raton, Florida based Healthcare 2030, Bergen Global Opportunity Fund, Bergen Asset Management and Eugene Tablis said that between October 12, and November 1, 2022, they sold 2,800,024 shares for \$603,448, or 21.5 cents a share. Nuheara fell five cents or 16.4 percent to 25.5 cents with 3.4 million shares traded.

ADHERIUM

Phillip Asset Management for Bioscience Managers says they have increased their Adherium holding from 500,000,000 shares (19.52%) to 1,106,007,400 shares (23.16%). Melbourne's Phillip Asset Management, as trustee for Bioscience Managers Translation Fund I, said that on October 28, 2022, it bought 606,007,400 shares for \$3,030,037, or 0.5 cents a share.

Adherium was up 0.1 cents or 25 percent to 0.5 cents with 2.35 million shares traded.

ADHERIUM

Trudell Medical says it has increased it substantial holding in Adherium from 423,080,272 shares (16.51%) to 950,580,272 shares (19.91%).

The London, Ontario-based Trudell said that on October 28, 2022, it bought 527,500,000 shares for \$2,637,500, or 0.5 cents a share.

EPSILON HEALTHCARE

Lawyers Baker McKenzie say Epsilon chair Xiao (Josh) Cui, deputy chair Alan Beasley, Stuart Cameron and the Karantzias Superfund have ceased their substantial holding. In October, Biotech Daily incorrectly reported that former chair Alan Beasley had become a 9.01 percent substantial shareholder in Epsilon (BD: Oct 11, 2022).

While the substantial holder notice referred to Watercress Asset Management, Watercress Capital, Stuart Cameron and the Karantzias Superfund, the sub-editor did not notice the explanation that they were "acting, or proposing to act, in concert in relation to effecting corporate governance changes, including to the composition of the board of directors". Earlier this week, Epsilon said that chair Steven Xu had resigned with Xiao Josh Cui appointed chair and Mr Beasley appointed deputy chair with Mr Cameron and Simon Rowe continuing as non-executive directors (BD: Nov 1, 2022).

Today, Baker McKenzie said Mr Cui was associated with JK Esther Holdings, Watercress Asset Management and Watercress Capital, the corporate governance changes had been implemented and the group had ceased to be associates of each other. Epsilon was up 0.1 cents or 3.1 percent to 3.3 cents.

AUSBIOTECH

Ausbiotech says it has appointed CSL head of research innovation Dr Marthe D'Ombrain as a director, replacing Dr Jan Tennent and Dr Serge Scrofani.

Ausbiotech said Dr D'Ombrain had experience in research, commercialization, licencing, strategy, business development, project management, partnerships, and fundraising. The industry organization said Dr D'Ombrain had been involved in establishing the biomedical incubator at CSL's new headquarters to "support Australian and international start-up companies to translate promising medical research into commercial outcomes". Ausbiotech said its board comprised Alterity director Geoffrey Kempler as its chair, with directors including Opthea chief executive officer Dr Megan Baldwin, Ausbiotech chief executive officer Lorraine Chiroiu, Esfam Biotech's Serg Duchini, Uniquest chief executive officer Dr Dean Moss, Biocurate chief operating officer and company secretary Linda Peterson, Patrys chief executive officer Dr James Campbell and Dr D'Ombrain.

MTP CONNECT

MTP Connect says that six-year former chief executive officer and current chair Sue MacLeman will retire following a search for a replacement chair.

MTP Connect said that Ms MacLeman was the inaugural chief executive officer from 2016 and chair from 2018.

"All organisations need innovation and new thinking to stay impactful, relevant and agile," Ms MacLeman said.

"As the Growth Centre for the medical technology, biotechnology and pharmaceutical sector, MTP Connect has delivered impressive impacts, contributing to \$1.3 billion flowing into Australia's medical products sector," Ms MacLeman said.

"We have a high performing, national team of which I am very proud and have also secured an extension to our operating timeframe from the Australian Government," Ms MacLeman said.