

Biotech Daily

Thursday September 9, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: OSPREY UP 9%; NOVA EYE DOWN 10%
- * HAEMALOGIX RAISES 10m FOR MULTIPLE MYELOMA
- * ADHERIUM: FDA APPROVES 'NEXT GENERATION' HAILIE SENSOR
- * TELIX IMAGES LAST PATIENT IN JAPAN TLX591-CDX TRIAL
- * EPSILON, VALENS FACILITY DEAL: BUYS ALTERNAMED FOR \$4,3m SCRIP
- * AUSCANN APPOINTS KNOELL CPAT-01 ADVISOR
- * CLIME TAKES 10.5% OF MACH7
- * AUSTRALIAN ETHICAL TAKES 10.2% OF MACH7
- * DIRECTOR ANDREW KROGER DILUTED TO 41.5% IN CRYOSITE
- * STEVE PARKES REPLACES MACH7 CFO JENNI PILCHER

MARKET REPORT

The Australian stock market fell 1.9 percent on Thursday September 9, 2021, with the ASX200 down 142.5 points to 7,369.5 points. Nine of the Biotech Daily Top 40 stocks were up, 27 fell and four traded unchanged.

Osprey was the best, up 0.1 cents or 9.1 percent to 1.2 cents, with 1.1 million shares traded. Universal Biosensors climbed 4.2 percent; Medical Developments and Pharmaxis were up more than three percent; Dimerix, Kazia, Genetic Signatures, Proteomics and Resmed rose one percent or more; with Neuren up 0.9 percent.

Nova Eye led the falls, down four cents or 9.8 percent to 37 cents, with 270,817 shares traded, followed by Resonance down 9.1 percent to 10 cents with 746,059 shares traded. Actinogen, Imugene, Opthea and Starpharma lost six percent or more; Antisense was down 5.4 percent; Immutep, Mesoblast, Next Science, Polynovo, Prescient and Telix fell more than four percent; Alterity, Avita, Compumedics and LBT were down more than three percent; Amplia, Cyclopharm, Nanosonics, Oncosil, Paradigm, Patrys and Volpara shed more than two percent; Clinuvel, Cochlear and CSL were down more than one percent; with Cynata and Pro Medicus down by less than one percent.

HAEMALOGIX PTY LTD

Haemalogix says it has raised \$10 million at \$11.60 a share in a "fully subscribed" placement to develop its Kappamed monoclonal antibody for multiple myeloma.

Haemalogix said about 873,000 new shares would be issued under the placement and Platinum Asset Management had become a "core" institutional investor.

The company said that Kappamab targeted a cancer cell surface kappa myeloma antigen, which was believed to play a role in protecting the cancerous myeloma cell from the patient's own immune response.

Haemalogix said the funds raised would support manufacturing of the next batch of the antibody plus the conduct of a higher dose 30mg/kg monotherapy study and prepare for two further studies.

The company said that Haemalogix said WG Partners and Table Club Exchange Pty Ltd acted at advisors to the placement.

Haemalogix is a private company

ADHERIUM

Adherium says the US Food and Drug Administration has approved its next generation Hailie sensor with physiological measures for respiratory disease.

Adherium said it received FDA 510(k) clearance to market Hailie sensor for asthma and chronic obstructive pulmonary disease (COPD).

The company said the Hailie sensors (formerly known as Smartinhaler), attached to a patient's asthma or COPD medication inhaler to monitor use.

Adherium said the latest Hailie sensor, designed for use with AstraZeneca's Symbicort corticosteroid aerosol inhaler, was the first in a series of devices specifically designed to enhance patient care and clinical workflow by capturing clinical data and supporting patient management and treatment.

Adherium chief executive officer Rick Legleiter said the FDA's "first clearance of our next generation Hailie sensors with physiological measures is a significant regulatory step for the business".

"The stage is now set for physiological measures to be coupled with our existing adherence sensor capability," Mr Legleiter said.

"This FDA decision increases the number of 510(k)-cleared Adherium devices to 10 in the US and represents an unequalled and formidable track record of development and experience by the market leader in respiratory digital health," Mr Legleiter said.

Adherium was up 0.8 cents or 53.3 percent to 2.3 cents with 237.4 million shares traded.

TELIX PHARMACEUTICALS

Telix says that with Kanazawa University it has imaged the last of 10 Japanese patients in its phase I trial of TLX591-CDx, or Illuccix, for prostate cancer imaging.

Telix said the clinical evaluation of 68-gallium prostate specific membrane antigen-11 (68Ga-PSMA-11) was the first to obtain safety data in a representative Japanese patient population and confirm that the targeting and bio-distribution of TLX591-CDx in Japanese patients were consistent with international experience.

In May, the company said it had dosed the first patients in the trial (BD: May 25, 2021). Today, Telix said that, subject to positive outcomes, clinical data obtained would facilitate planning with Japan's Pharmaceuticals and Medical Devices Agency and potentially other Asian regulators.

Telix fell 27 cents or 4.1 percent to \$6.36 with 434,903 shares traded.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS CO)

Epsilon says it has a partnership with Valens Canada for the use of its Southport Queensland facility and will buy Alternamed from Cannvalate for \$4.3 million in shares. Epsilon said that the Kelowna, British Columbia-based Valens would pay "100 percent of the monthly operating costs of the Southport facility and have the right to use up to 85 percent of the production capacity".

The company said the use of its Australian Therapeutic Goods Administration-approved and EU good manufacturing practice (GMP) Southport facility would provide Valens direct access to Australia and New Zealand, as well as Europe the UK and the Asia-Pacific. Epsilon said the contract was for five years with options to extend for a further six years and Valens would provide operational and management consultancy to bring its intellectual property, technology and team to Southport to take advantage of the GMP capability.

The company said that Valens would use Southport "for all production of medicinal cannabis products for sale in Australian or New Zealand, including through its distribution relationship with Cannvalate".

Epsilon chief executive officer Jarrod White told Biotech Daily that the company would issue about 28 million shares valued at \$4.3 million at 15 cents a share to Melbourne's Cannvalate for the acquisition of Alternamed Pty Ltd.

Mr White said the share issue was subject to shareholder approval and conditions precedent which he expected to conclude "by the end of the year" and the shares would be held in escrow for a further 12 months following the issue.

The company said that Cannvalate would be entitled to have a director on the board of Epsilon which was currently Dr Rob Jenny.

Cannvalate executive chair Dr Sud Agerwal is a director and chief medical officer of Incannex and Cannvalate is a 19.2 percent shareholder of the ASX-listed marijuana company Lifespot Health.

In its announcement, Epsilon said that the Alternamed acquisition included "its portfolio of provisional patent applications for three novel cannabinoid therapeutic clinical assets with potential for schedule 3 medicine development and access to a Sigma Pharmaceuticals storage facility controlled by Cannvalate".

The company said the three assets targeted irritable bowel syndrome, menstrual pain, and smoking cessation which were "highly prospective in terms of their potential as schedule 3 medicines".

Epsilon said that the Southport facility was "the largest cannabis extraction facility in the Southern Hemisphere with TGA and EU GMP capability".

The company said that Cannvalate would provide advice "on matters including the launch of the Medimar platform, development of clinical trial drug manufacturing capabilities, and business development support services".

Epsilon said that Cannvalate held 2,000,000 of its shares through a related entity and completion of the Alternamed acquisition was subject to the execution of the definitive agreements with Valens.

Epsilon chair Steven Xu said the two agreements were "a critical next step for Epsilon as we look to expand our global footprint with established partners, and increase our production throughput as a contract pharmaceutical manufacturer of scale".

"The execution of these agreements is the culmination of many months of negotiations and due diligence between the parties, led on our side by our chief executive officer Jarrod White and our chief operating officer, Sonny Didugu and clearly sets out a path for the future of Epsilon's production assets".

Epsilon was up 1.5 cents or 10 percent to 16.5 cents with 1.9 million shares traded.

AUSCANN GROUP (ACQUIRED CANNPAL ANIMAL THERAPEUTICS)

Auscann says it has appointed Knoell Animal Health to advise on the marijuana-based CPAT-01 clinical and US regulatory program for dog osteo-arthritis.

Auscann said it appointed the Mannheim, Germany-based Knoell ahead of its presubmission conference meeting with the US Food and Drug Administration, Center for Veterinary Medicine (FDA-CVM) to approve CPAT-01.

The company said CPAT-01 was a veterinary drug candidate with tetrahydrocannabinol and cannabidiol extracts for pain and inflammation in dogs.

Last year, Auscann said it acquired Cannpal (BD: Nov 16, 2020).

Auscann fell 0.1 cents or 1.1 percent to nine cents.

MACH7 TECHNOLOGIES

Clime Investment Management says it has increased its substantial share-holding in Mach7 from 21,791,222 shares (9.22%) to 24,712,209 shares (10.45%).

The Sydney-based Clime said that between June 17 and September 7, 2021, it bought 2,920,987 shares on market at prices ranging from 91 cents to \$1.07 a share. Mach7 fell 3.5 cents or 3.5 percent to 97 cents.

MACH7 TECHNOLOGIES

Australian Ethical said it increased its substantial shareholding in Mach7 from 20,647,645 shares (8.73%) to 24,003,622 shares (10.15%).

The Sydney-based Australian Ethical said that on September 7, 2021, it bought 3,355,977 shares in 3 batches for \$3,259,263 or an average of 97.1 cents a share.

CRYOSITE

Director Andrew Kroger and associates, say their 20,266,964 share-holding in Cryosite has been diluted from 43.25 percent to 41.52 percent.

Mr Kroger said the shares were held directly and by Process Wastewater Technologies, Austen Bay Pty Ltd and SHR Pty Ltd.

Cryosite said the dilution followed the exercise of 1,300,000 options by chair Bryan Dulhunty and 650,000 options by chief executive officer John Hogg.

Cryosite was untraded at 42 cents.

MACH7 TECHNOLOGIES

Mach 7 says Steve Parkes will replace chief financial officer Jenni Pilcher, who was departing "to pursue other opportunities", effective from September 27, 2021 Mach 7 said that Mr Parkes was based in New York and had financial, commercial and strategic experience and previously held roles in information technology, high-tech, healthcare and media and advertising.

Mach7 said Ms Pilcher would leave the company on October 18, 2021.

The company said that Ms Pilcher was also its company secretary and told Biotech Daily that the process of appointing a company secretary.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: editor@biotechdaily.com.au; www.biotechdaily.com.au; www.biotechdaily.co