



Biotech Daily

Thursday November 23, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: OPTHEA UP 12%; NOVA EYE DOWN 7%**
- * **PACIFIC EDGE H1 REVENUE UP 50% TO \$12m, LOSS UP 44% TO \$14m**
- * **PARADIGM RETAIL RIGHTS RAISE \$2.8m, \$6.2m SHORTFALL; TOTAL \$30m**
- * **LBT MARKETS APAS FOR ENVIRONMENTAL MONITORING IN EUROPE**
- * **CHIMERIC: CHM1301 KILLS OVARIAN, PANCREATIC CANCER, IN-VITRO**
- * **QUEENSLAND UNI CLAMP 2 'FUNCTIONALLY EQUIVALENT' TO NOVAVAX**
- * **CENTENARY: INVASION-BLOCK HALTS MELANOMA, IN MICE**
- * **ALGORAE, MONASH START MARIJUANA PRE-CLINICAL HEART STUDY**
- * **RECCE WINS R327, R529 CANADA PATENT**
- * **EPSILON CHALLENGES DIRECTOR ALAN BEASLEY EGM REQUISITION**
- * **VITURA REBUTS AGM DISSIDENT LETTER**
- * **GENETIC TECHNOLOGIES 29% DEFEAT PLACEMENT CAPACITY**
- * **MEDLAB SUBSIDIARY SALE EGM**
- * **INCANNEX APPOINTS COMPUTERSHARE FOR US REGISTRY**
- * **AEGROS APPOINTS DR ERIN EVANS, DAVE SHARMA, JAN BULT ADVISORS**
- * **BOTANIX REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.62 percent on Thursday November 23, 2023, with the ASX200 down 44.2 points to 7,029.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, 13 traded unchanged and one was untraded. All three Big Caps fell.

Opthea was the best, up 4.5 cents or 12.2 percent to 41.5 cents, with 313,192 shares traded. Genetic Signatures climbed 10 percent; Alcidion was up 9.5 percent; Avita improved 6.4 percent; Antisense and Next Science were up more than five percent; Clinuvel, Immutep and Orthocell improved more than three percent; Atomo and Medical Developments rose more than two percent; Proteomics and Volpara were up more than one percent; with Polynovo, Pro Medicus and Telix up by less than one percent.

Nova Eye led the falls, down one cent or 7.14 percent to 13 cents, with 289,466 shares traded. Emvision lost five percent; Impedimed fell four percent; 4D Medical, Dimerix and Pharmaxis were down more than three percent; Imugene shed 2.4 percent; Neuren, Paradigm and Prescient were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

PACIFIC EDGE

Pacific Edge says revenue for the six months to September 30, 2023, was up 50.4 percent to \$NZ13,095,000 (\$A12,086,139), with net loss after tax up 44.3 percent to \$NZ15,252,000 (\$A14,076,960).

Pacific Edge said it had \$NZ11,403,000 in sales revenue from its Cxbladder urine test from the US and \$630,000 from the rest of the world.

The company said that restricting and cost-saving initiatives implemented late into the financial period were not yet evident in its operating expenditure and that it had incurred extra costs defending its Medicare coverage.

Pacific Edge expenses increased to \$NZ31.8 million from \$NZ24.2 million, driven by “increased headcount as investments made for revenue growth in the six months to September 30, 2023 and increased expenses relating to volume growth”.

The company said diluted loss per share was up 46.15 percent to 1.9 NZ cents, while net tangible assets per share fell 31.4 percent from 12.1 NZ cents to 8.3 NZ cents.

The company said that it had cash and cash equivalents of \$NZ20,469,000 at September 30, 2023 compared to \$NZ37,989,000 at September 30, 2022.

Pacific Edge fell 0.3 cents or 3.1 percent to 9.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its retail offer raised \$2,787,952 of a hoped-for about \$9.1 million, taking the total raised to about \$23.9 million, with an underwritten shortfall of \$6.21 million.

Last month, Paradigm said it hoped to raise \$30 million through an \$18 million institutional placement and a \$12.1 million institutional and retail entitlement offer (BD: Oct 30, 2023).

The following day the company said that the placement had raised \$18 million and the institutional offer raised \$3.1 million (BD: Oct 31, 2023).

Today, Paradigm said the shortfall would be placed by the lead manager and underwriter Bell Potter Securities.

Paradigm fell half a cent or 1.3 percent to 39 cents.

LBT INNOVATIONS

LBT says it has begun marketing its Apas Pharma QC technology in Europe and hopes the technology will be used in environmental monitoring.

In 2022, LBT said it was developing an automated plate assessment system (Apas) for pharmaceutical companies, Apas Pharma, for microbial quality control, along with other products (BD: Aug 10, 2022).

In August, the company said data from an Astrazeneca study showed its Apas Pharma QC to have 100 percent sensitivity for detecting microbes from 1,515 monitoring plates (BD: Aug 10, 2023).

Today, LBT said marketing and building awareness of the Apas technology within pharmaceutical microbiology was important to “establish the brand and technology for potential pharmaceutical customers that perform manual routine environmental monitoring practices”.

LBT managing-director Brent Barnes said that Pharmalab was “our first demonstration of Apas Pharma QC to a European audience”.

“The presentation by Astrazeneca provides an important users-perspective on the benefits Apas Pharma QC can have for customers looking to implement a best practice environmental monitoring process,” Mr Barnes said.

LBT traded unchanged at half a cent with 2.6 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says CHM1301 is up-to four times more effective at killing ovarian and pancreatic cancer than first generation natural killer cell treatments, in vitro.

Chimeric said CHM1301 was the latest generation of its chlorotoxin chimeric antigen receptor natural killer (CLTX CAR NK) cell therapies.

The company said CHM1301 killed ovarian cancer cells up-to 260 percent more than CHM0201 cells, while pancreatic cancer cell killing was up by 300 percent.

Chimeric said it would advance CHM1301 to the next stage of pre-clinical development using its recently developed armored NK cell platform CHM0301.

Chimeric chief executive officer Jennifer Chow said the work was “highly impactful as it demonstrates the synergy of the assets that currently exist in Chimeric’s portfolio, the ability for Chimeric to expand into new disease areas and the potential for enhanced efficacy with an off-the-shelf version of our CHM1101 CAR”.

“Being able to achieve this success through our cost effective, academic collaboration with Dr David Wald at Case Western Reserve University also enables Chimeric to continue to build out a promising next generation pipeline while focusing resources on our current clinical stage assets”.

Chimeric was up 0.2 cents or 6.9 percent to 3.1 cents with 103.0 million shares traded.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says proof-of-concept testing of its Clamp 2 Covid-19 vaccine shows it is “functionally equivalent” to the Nuvaxovid (Novavax) vaccine.

The University said its re-engineered, second-generation clamp platform produced a vaccine “equally safe and virus-neutralizing” as the Australian-approved Novavax.

In 2020, CSL said the phase I trial of the UQ-CSL V451 Covid-19 vaccine was “not going ahead as planned” due to false positive HIV results, caused by the generation of antibodies directed towards fragments of the gp41 protein, a component used to stabilize the vaccine, and it was “unexpected that the levels induced would interfere with certain HIV tests” (BD: Dec 11, 2020).

Today, the University of Queensland’s Prof Keith Chappell said “the Clamp 2 trial group showed a 2.5-fold boost in neutralizing titres and it was 2.1 [fold] in the Novavax group”.

“The two vaccines produced highly comparable results, however while there were no new Covid infections among the Clamp2 volunteers, there have been three Covid cases detected amongst Nuvaxovid recipients so far,” Prof Chappell said.

The University said a company had been founded to develop the patented molecular clamp and that a six-month, proof-of-concept human trial was supported by the Queensland and Federal Governments and “philanthropic partners”.

“[The University’s] commercialization company Uniquet has licenced the technology to Vicebio, which is progressing its use against respiratory pathogens such as respiratory syncytial virus, human metapneumovirus and parainfluenza viruses,” Prof Chappell said.

The University said the Coalition for Epidemic Preparedness Innovation had supported its vaccine research for five years and in 2022 committed up-to \$8.5 million for the development of treatments for future diseases.

The Coalition for Epidemic Preparedness Innovation (CEPI) director of programs and innovative technology Dr In-Kyu Yoon said “advancing vaccine platforms [like the University of Queensland’s molecular clamp technology] would be crucial for developing vaccines against new emerging infectious threats”.

“CEPI is striving towards vaccines being developed within 100 days of a new virus emerging,” Dr Yoon said.

CENTENARY INSTITUTE

The Centenary says its 'Invasion-Block' screening technology helps researchers identify enzymes that make melanoma cells less able to invade tissue, in mice.

The Institute said the technology was combined with an image analysis program called S-Marvel to study "thousands of compounds" including drugs already approved for use in humans.

The Centenary Institute said Invasion-Block showed the enzyme classes Abl/src, PKC (protein kinase C), PI3K (phosphatidylinositol 3-kinases) and ATM (Ataxia-telangiectasia mutated) kinases to curb melanoma cells invasion of tissue.

The Institute said researchers used clustered regularly interspaced short palindromic repeats (Crisp) technology to "turn off the gene responsible" for expressing ATM kinase in melanoma cells, after which melanoma cells became invasive in laboratory tests and didn't spread as much to the lymph nodes when tested in mice.

The Centenary said the study with the Medical University of Vienna was titled 'Invasion-Block and S-MARVEL: A high-content screening and image analysis platform identifies ATM kinase as a modulator of melanoma invasion and metastasis', was published in The Proceedings of the National Academy of Sciences with an abstract available at:

<https://www.pnas.org/doi/10.1073/pnas.2303978120#data-availability>.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it will conduct pre-clinical studies of its marijuana-based combination drug AI-168 for cardio-vascular diseases with Melbourne's Monash University.

Algorae said its AI-168 drug candidate was "a cannabinoid with another pharmaceutical drug" but did not disclose the other drug.

The company said the studies in cardio-vascular disease laboratory models were expected to give "an understanding of the mechanism of action of AI-168 across a range of cardio-vascular diseases".

Algorae said the pre-clinical efficacy of AI-168 would be compared to existing classes of drugs used to treat cardio-vascular diseases.

The company said results were expected intermittently during the next 12 months and would "guide the next steps in the [research and development] program for AI-168 and potentially serve to underpin further patent applications".

Algorae said had filed a provisional patent application for AI-168 and that applying for further patents was part of its "broader strategy to identify new opportunities to develop intellectual property assets that align with the company's commercial interests".

Algorae traded unchanged at 1.3 cents.

RECCE PHARMACEUTICALS

Recce says the Canadian Patent Office has granted a family of patents for its R327 and R529 anti-infective treatments.

Recce said the patent was titled 'Process for Preparation of Biologically Active Copolymer' and would protect its intellectual property until 2041.

The company said the family of patents protected the process of preparation of R327 and R529 as well as their use to treat bacterial and viral infections and multiple methods of administration.

Recce said this was the first wholly-owned patent it had been granted in Canada, with further Patent Cooperation Treaty country submissions in various stages of review.

Recce fell one cent or 2.2 percent to 44 cents.

EPSILON HEALTHCARE

Epsilon says the extraordinary general meeting requisitioned by deputy chair Alan Beasley to remove the other two directors has not followed “due processes”.

On Tuesday, Epsilon (then The Hydroponics Co) founder Mr Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing “the governance of the board” (BD: Nov 21, 2023).

Yesterday, Epsilon responded to a detailed ASX query relating to the company’s finances and noting a number of discrepancies (BD: Nov 22, 2023).

Today, the company said that Mr Beasley had called a meeting under section 249CA of the Corporations Act 2001 and noted that a director “cannot be removed unless the procedures required by [section] 203D are followed.

Epsilon said “that the due procedures have not been followed”.

Section 203D of the Act stipulates a number of conditions required including a minimum of two months’ notice, writing to the director(s) concerned and other conditions.

In its announcement to the ASX “approved for release by the majority of the board of directors” the company said that “the resolutions to remove directors of the Company that are proposed to be moved at the meeting of December 22, 2023, even if the notice of meeting constitutes the notice of intention to move the resolution, will be invalid because the required procedure has not been followed”.

“Those resolutions must not be put to the meeting because the meeting called by the director is not at least two months after the notice of intention to move has been given,” Epsilon said.

Epsilon was up 0.3 cents or 11.1 percent to three cents.

VITURA HEALTH

Vitura says that a letter supporting the appointment of directors, opposed by the existing board, contains “false and misleading information”.

In September and October, Elizabeth Sarah Jansen, as trustee for the Stanford Investment Trust, proposed under section 249N of the Corporations Act 2001, to appoint Shane Francis Tanner, Nathan James Hight and Benjamin David Ngahua Jansen as Vitura directors at its next annual general meeting (BD: Oct 6, 2023).

Later in October, the company said its board “unanimously recommends” shareholders vote against the resolutions to elect Mr Tanner, Mr Hight and Benjamin Jansen as directors (BD: Oct 27, 2023).

Today, Vitura said it had attached the letter relating to the annual general meeting planned for November 28, 2023 at 10am (AEDT).

The company said that on November 15, 2023, it wrote to shareholders “regarding false and misleading information being published in the public domain by a small group of shareholders”.

Vitura said that the attached statement contained “numerous inaccurate, false and misleading statements and representations” and said that Ms Elizabeth Sarah Jansen had requested that the statement be distributed Vitura shareholders.

The company responded to several allegations and said it did not “wish to respond to each and every statement and representation made in the E Jansen statement ... [but] notes that shareholders should exercise caution in reading the E Jansen Statement”.

Vitura then gave several examples of what it said were “incomplete, inaccurate, false and/or misleading statements”.

Vitura fell half a cent or 1.6 percent to 31.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says 28.5 percent of its annual meeting faced defeated the increased placement capacity special resolution.

Genetic Technologies said the resolution required 75 percent of the vote to pass, but was opposed by 563,447,638 votes (28.52%) with 1,412,162,500 votes (71.48%) in favor.

The company said 242,779,122 votes (22.21%) opposed the approval of its remuneration report, with 850,151,607 votes (77.79%) in favor, while the resolution to approve its 100-to-one share consolidation had the largest number of votes against, with 594,940,715 votes (29.92%) opposed and 1,393,289,137 votes (70.08%) in favor.

The company said the issue of warrants to HC Wainwright and the ratification of the prior issue shares were opposed by more than 18.75 percent of the vote, with the election of directors Peter Rubinstein and Dr Lindsay Wakefield passed by a wider margin.

According to its most recent filing, Genetic Technologies had 11,541,658,143 shares on offer, meaning the 594,940,715 votes against the 100-to-one share consolidation amounted to 5.15 percent of the company, sufficient to requisition extraordinary general meetings.

Genetic Technologies was unchanged at 0.2 cents with 12 million shares traded.

MEDLAB CLINICAL

Medlab says its extraordinary general meeting will vote to approve the sale of its subsidiary Medlab Pty Ltd and intellectual property to executive director Dr Sean Hall.

Earlier this month, Medlab said Dr Hall would buy Medlab Pty Ltd and licence its products to T2 Pharma Pty Ltd, raise capital and make board changes (BD: Nov 10, 2023).

The meeting will be held online and in person at Hall Chadwick, Level 14/440 Collins Street, Melbourne, on December 22, 2023, at 1pm (AEDT).

Medlab was in a suspension and last traded at a post-consolidation \$6.60.

INCANNEX HEALTHCARE

Incannex says it has appointed Computershare as its US shareholder registry to delist from the ASX and list on the Nasdaq, effective on November 28, 2023.

Last week, Incannex said it would be suspended from the ASX that day, delist from the ASX and list on the Nasdaq on November 28, 2023 (BD: Nov 17, 2023).

Today, the company said shareholders were required to open an online account with Computershare to access their US shareholdings, and expected holding statements to be issued on December 4, 2023.

Incannex last traded at 4.1 cents.

AEGROS

Aegros says it has appointed Dr Erin Evans, Dave Sharma and Jan Bult to its strategic advisory board to advise the board for its proposed initial public offering.

Aegros said Mr Sharma was previously the Australian ambassador to Israel and Federal Member for Wentworth and would chair the board.

The company said Dr Erin Evans was Life Sciences Queensland chief executive officer and would advise on engagement with the Queensland Government.

Aegros said Mr Bult was the president of the Plasma Protein Therapeutics Association and would provide advice on the therapeutic plasma industry.

Aegros is a public unlisted company.

BOTANIX PHARMACEUTICALS

Botanix says it has requested a trading halt “pending release of an announcement regarding a proposed capital raising”.

Trading will resume November 27, 2023, or on an earlier announcement.

Botanix last traded at 15.5 cents.