Biotech Daily

Thursday August 17, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN, ORTHOCELL UP 4%; ATOMO DOWN 16%**

*** QBIOTICS: TIGILANOL TIGLATE 'SAFE, TOLERATED FOR HNSCC'**

*** HUDSON INSTITUTE: 'INTERFERON EPSILON FOR OVARIAN CANCER'**

*** BRANDON CAPITAL $50m CUREATOR PLUS OPENS**

*** MTP CONNECT: 2 RESEARCHERS WIN $250k REDI FELLOWSHIPS**

*** ZELIRA: $1.7m OF $5.1m NOTE FOR HOPE MARIJUANA AUTISM TRIAL**

*** CORRECTION: IMUGENE**

*** VISIONEERING H1 REVENUE UP 26% To $7.2m, LOSS DOWN 43% TO $2.8m**

*** USCOM REVENUE DOWN 5% TO $2.7m; LOSS UP 31% TO $2.6m**

*** ALLEGRA: FDA WANTS MORE SR–HT–GAHNITE SPINAL CAGE DATA**

*** VOLPARA AGM 42% OPPOSE BOUW OPTIONS, 10% PLACEMENT LOSS**

*** RESONANCE REQUESTS 'MATERIAL CONTRACT' TRADING HALT**

*** PYC COMPLETES 1st VP-001 RP11 COHORT**

MARKET REPORT

The Australian stock market fell 0.68 percent on Thursday August 17, 2023, with the ASX200 down 49.2 points to 7,146.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and five were untraded.

Actinogen and Orthocell were the equal best, both up 3.85 percent to 2.7 cents and 40.5 cents, respectively, with 373,025 shares and 222,000 shares traded, respectively. Proteomics and Volpara climbed more than three percent; Emvision rose 2.6 percent; Clinuvel, Cochlear, Cyclopharm, Neuren and Pro Medicus were up more than one percent; with Medical Developments and Paradigm up by less than one percent.

Yesterday's 15.6 best, Atomo, led the falls, down 0.6 cents or 16.2 percent to 3.1 cents, with 11.3 million shares traded. Pharmaxis fell 8.3 percent; Polynovo lost 7.1 percent; Mesoblast was down 6.3 percent; Dimerix, Opthea and Resmed were down more than five percent; Micro-X fell 4.35 percent; Avita, Cynata and Immutep were down more than three percent; 4D Medical, Impedimed and Nanosonics shed more than two percent; Universal Biosensors was down 1.85 percent; with CSL and Telix down by less than one percent.

QBIOTICS GROUP

Qbiotics says its 19-patient, phase I/IIa trial of tigilanol tiglate for head and neck squamous cell carcinoma (HNSCC) has met safety and tolerability primary endpoints.

Qbiotics said tigilanol tiglate treatment was well tolerated at all dose levels, with the drug successfully escalated to a dose of 2.4mg/m2 without any serious adverse events, except for an extension of an overnight stay for one patient.

The company said adverse effects reported were local, expected and associated with the mode of action of the drug.

Qbiotics said rapid induction of haemorrhagic necrosis was evident within hours in all injected tumors at all dose levels, with no necrosis in the surrounding normal tissue.

Qbiotics chief executive officer Dr Victoria Gordon said the company was "very pleased with the results of this trial in patients with HNSCC which provides increased confidence in the safety and tolerability of tigilanol tiglate and expands our understanding of the immune-stimulating mode of action of the drug".

"Surgery and radiotherapy are currently the mainstay for patients with [head and neck squamous cell carcinoma], however these treatment approaches are frequently anatomically difficult and often result in significant disfigurement," Dr Gordon said.

"We see potential for tigilanol tiglate, alone or in combination with other modalities, to offer an effective future treatment option for HNSCC tumors with good clinical and cosmetic outcome for patients," Dr Gordon said.

Qbiotics is a public unlisted company.

HUDSON INSTITUTE OF MEDICAL RESEARCH

Hudson Institute says the protein interferon epsilon, produced in the female reproductive tract, could be used to fight ovarian cancer.

The Institute said interferon epsilon was a signaling protein made in the epithelium lining organs, including the female reproductive tract.

The researchers said that they had characterized interferon epsilon's anti-tumor activity in several preclinical models: ovarian cancer patient-derived xenografts, orthotopic and disseminated syngeneic models and tumor cell lines, with or without mutations in TRP53 and BRCA genes.

The researchers said that they had demonstrated that interferon epsilon was "an intrinsic tumor suppressor in the female reproductive tract whose activities in models of established and advanced ovarian cancer, distinct from other type I [interferons] are compelling indications of potential new therapeutic approaches for ovarian cancer".

The research article, titled 'Interferon-ε is a novel tumour suppressor and restricts ovarian cancer' was published in the journal Nature, and an abstract is available at: https://www.nature.com/articles/s41586-023-06421-w.

The Hudson Institute's Dr Nicole Campbell said that "in high grade serous ovarian cancers, the commonest form of ovarian cancer, tumor cells recruit and activate immune-suppressive cells which prevent anti-tumor immune cells from killing tumor cells, so we're aiming to develop new therapeutics which can reverse that process and improve survival".

Dublin's Trinity College researcher Dr Nollaig Bourke said that "we knew that interferon epsilon was part of a family of proteins known for their anti-tumor activities and we wondered what would happen if we could try restore this lost expression".

"We tried giving interferon epsilon back to help block the growth of ovarian cancer cells and therefore prevent the growth of primary and secondary tumors … the results were very striking, confirming that interferon epsilon was a very effective tumor suppressor in ovarian cancer," Dr Bourke said.

BRANDON CAPITAL, AND HEALTH

Brandon Capital says expressions of interest are open for its new, $50 million Cureator Plus program, in collaboration with AND Health.

Last year, Brandon Capital said its Cureator program awarded $17.4 million to 23 projects delivered by Brandon Biocatalyst, formerly the Medical Research Commercialisation Fund (BD: Jul 6, 20, 2022).

Today, the company said Cureator Plus would provide successful applicants up-to $5 million in non-dilutive funding, delivered in tranches on meeting commercial milestones.

Brandon Capital said its program aimed to reverse a decline in Australian innovation, granting applicants access to research teams, commercial capability coaching, intellectual property development, professional governance, management and finance support.

For more information go to: https://cureatorplus.grantplatform.com/.

MTP CONNECT

MTP Connect says Dr Destiny Dalseno and Dr Shayanti Mukherjee have won $250,000 Researcher Exchange and Development within Industry (REDI) fellowships.

MTP Connect said Walter and Eliza Hall Institute research fellow Dr Dalseno would undertake a three-month project at the Seoul, South Korea-based Yuhan Corp to study drug development for solid tumors.

The Federally-funded industry organization said the Hudson Institute of Medical Research's Dr Mukherjee would undertake a six-month project with Melbourne's Moderna's Regional Research Centre for Respiratory Medicines & Tropical Diseases.

MTP Connect said the REDI fellowships were a Federal Medical Research Future Fund initiative providing up-to $250,000 for each fellow to collaborate on research projects involving discovery, translation and commercialization.

ZELIRA THERAPEUTICS

Zelira says it has received the first tranche of $US1,069,000 ($A1,674,000) from the Forman Trust and Mr Malik Majeed for its trial of Hope marijuana for autism.

Earlier this year, Zelira said the Dallas, Texas-based Cantheon Capital LLC would provide $US8.6 million ($A12.4 million) for phase II and III trials of Hope under a special purpose vehicle (SPV), or joint venture subsidiary (BD: Feb 15, 2023).

In May, the company said it had received $US3 million from the Philadelphia, Pennsylvania-based Forman Family Foundation and a further $US250,000 from Philadelphia-based chief executive officer of PRWT Services Companies Malik Majeed to fund clinical trials for its Hope marijuana product for autism (BD: May 22, 2023).

Today, Zelira said the Foman Trust Mr Majeed $US1,069,000 was the first tranche from its $US3,250,000 ($A5,091,000) Xelira-Hope1 special purpose vehicle convertible note which had an interest rate of 10 percent per annum and a term of 12 months.

The company said it expected to receive subsequent rounds of closing this quarter from its continuing fund-raising efforts to support the trial.

Zelira managing director Dr Oludare Odumosu said the funding would allow the company to begin its formal US Food and Drug Administration trial process for the Hope 1 autism spectrum disorder program.

"Looking ahead, Zelira anticipates continued success in our funding efforts for the SPV, facilitating subsequent closures on the balance of the circa $US35 million capital raise to fund Hope 1 trials," Dr Odumosu said.

Zelira fell 13 cents or 8.7 percent to $1.36.

CORRECTION: IMUGENE

Last night's edition incorrectly reported that Imugene would pay Precision Biosciences up to $US227 million for its autologous "azer-cell" CD19 Car T-cell therapy for blood cancers.
In fact, the therapy is allogeneic and intended for blood cancer patients who had relapsed following autologous Car-T treatment.
The mistake was made by the new Wednesday sub-editor who confused his own chimeric antigen receptor T-cells with those bought off-the-shelf.
He has been sent to Durham, North Carolina for a refresher course in T-cell nomenclature but Biotech Daily will not be charging him the introduction fee.
Imugene was in a trading halt "pending an announcement in relation to a proposed capital raising" and last traded at 9.4 cents.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the six months to June 30, 2023 was up 25.6 percent to $US4,671,000 ($A7,318,000) with net loss after tax down 43.1 percent to $US1,795,000 ($A2,812,000).
Visioneering said revenue increased due to growth in its operating segments, with higher demand from existing customers for its multifocal contact lenses and due to the previous period being negatively impacted by a product launch at the end of 2021, during the Covid-19 pandemic.
The company said the reduced loss was due to nine percent lower marketing costs, 27 percent decrease in clinical and manufacturing expenses due to lower personnel costs and a 13 percent reduction in general and administrative expenses.
Visioneering said diluted loss per share was down 53.8 percent to 6.0 US cents, net tangible asset backing per share fell 53.6 percent to 13 US cents, and that it had cash of $US3,267,000 at June 30, 2023 compared to $US6,856,000 at June 30, 2022.
Visioneering was untraded at 22 cents.

USCOM

Uscom says revenue for the year to June 30, 2023, was down 4.9 percent to $2,727,153, with net loss after tax up 31.4 percent to $2,590,888.
Last year, Uscom revenue for the year to June 30, 2022 was reported as $2,600,227, calculated to include interest received and sundry income but excluding research and development tax incentives, grants and foreign exchange gains.
Uscom said product and services revenue was up 6.2 percent to $2,664,166, primarily from sales of its Uscom1A ultra-sonic cardiac output monitor, Uscom BP+ blood pressure monitor and Spirosonic pulmonary function tests.
Uscom executive chair Prof Rob Phillips said sales increased compared to the prior corresponding period, particularly in the three months to June 30, 2023, "reflecting a first wave of recovery".
"The anticipated rebound from Covid has been slower than anticipated and further complicated by the Russian war, inflation and high interest rates all creating unexpected challenges and dampening the rebound of medical markets," Prof Phillips said.
The company said that diluted loss per share was up 36.4 percent to 1.5 cents, net tangible asset backing per share fell 53.1 percent to 0.015 cents, and it had cash and equivalents of $2,178,740 at June 30, 2022 compared to $4,704,185 at June 30, 2021.
Uscom was untraded at 5.2 cents.

ALLEGRA ORTHOPAEDICS

Allegra says the US Food and Drug Administration has requested “more information” regarding its Sr–Ht–Gahnite spinal cage application.
In March, Allegra said it submitted a 510(k) application to the FDA for its Sr-Ht-Gahnite spinal cage device for bone healing (BD: Mar 31, 2023)
Allegra previously said Sr-Ht-gahnite was composed of strontium, hardystonite (a calciumzinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, 2016).
In February, the company said the spinal cage showed a bone healing response “indicative of a fused spinal level” as well as biocompatibility, in sheep (BD: Feb 22, 2023).
In March, Allegra said it expected feedback from the FDA within 90-days and said “the submission was a milestone in the innovation of its 3D-printed bio-ceramic spinal fusion cage which began in 2014”.
Yesterday afternoon, the company said the FDA was “reviewing the device under the 510(k) pathway and [had] requested additional information”.
Allegra said it would submit the information and expected a response “within two to three months”.
The company said that it was “the sole proprietor of the Sr-Ht-Gahnite material and following FDA clearance … will aim to apply the technology to fulfilling unmet needs across a broad range of applications, including spine, hip and knee, and extremities”.
Allegra was untraded at six cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says 42.3 percent of investors opposed the issue of options to director Mark Bouw. with 36.8 percent defeating the 10 percent placement capacity.
Last month, Volpara said its annual general meeting would vote to re-elect director Mark Bouw and issue him 450,000 options, exercisable at $1.30 each by January 1, 2030, in addition to his $70,000 salary (BD: Jul 24, 2023).
Today, the company said there were 42,680,535 votes (42.27%) against the resolution to approve Mr Bouw’s options, with 58,287,560 votes (57.73%) in favor.
Volpara said that 37,146,922 votes (36.84%) opposed the special resolution to approve an additional 10 percent placement capacity, with 63,674,222 votes (63.16%) in favor.
Special resolutions require a 75 percent majority to pass.
Volpara said the resolutions to re-elect director Roger Allen, approve the long-term incentive plan, to ratify the prior issue of shares and issue restricted stock units to chief executive officer Teri Thomas were opposed by 5.51 percent to 8.21 percent of the votes at the meeting.
The company said the resolutions to elect directors Karen Lindgren and Mr Bouw, amend its constitution and to fix the auditor fees passed with less than one percent dissent.
According to the company’s most recent notice, it had 254,358,308 shares on issue, meaning that the votes against Mr Bouw’s options amounted to 16.8 percent of all shares on issue, sufficient to call extraordinary general meetings.
Volpara was up 2.5 cents or 3.3 percent to 78.5 cents.

RESONANCE HEALTH

Resonance says it has requested a trading halt for an announcement regarding a contract for service provision for “a clinical trial … by a major pharmaceutical company”.
Trading will resume August 21, 2023, or on an earlier announcement.
Resonance last traded at 6.5 cents.

PYC THERAPEUTICS

PYC says it has completed the first cohort of patients in its phase I, single ascending dose study of VP-001 for the blinding eye disease retinitis pigmentosa type-11 (RP11).

In June, PYC said it had dosed the first of nine patients in the trial (BD: Jun 30, 2023).

Today, the company said a safety review committee would meet in September to review the initial data generated for patients in cohort one and would consider approval to escalate to dosing cohort two.

PYC said it remained on track to complete cohorts two and three by the end of 2023, and the study was expected to accelerate as it opened more clinical trial sites.

PYC said it expected to transition to a phase II multi-dose study of VP-001 by July 2024, after completing the ongoing phase I study.

PYC fell 0.2 cents or 3.5 percent to 5.5 cents with 1.4 million shares traded.