Biotech Daily

Wednesday October 20, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ONCOSIL UP 15%; PATRYS, UNIVERSAL BIO DOWN 4.55%**

*** TELIX: 'TLX101 SAFE, LENGTHENS GLIOBLASTOMA SURVIVAL'**

*** ZELIRA: QUINCY STREET PLACEMENT RAISES $6.7m; 54% PREMIUM**

*** PHARMACARE PAYS $1.6m FOR MEDLAB FOOD ADDITIVE BUSINESS**

*** TRUSCREEN CLAIMS CERVICAL CANCER TEST SUCCESS; CHINA EXPANSION**

*** IMUGENE DOSES 1st CF33 CHECKVACC BREAST CANCER PATIENT**

*** OPTHEA TAKES OPT-302 WET AMD TRIALS TO ASIA-PACIFIC**

*** CONTROL BIONICS: 'RENT NEURONODE FOR IMMEDIATE USE'**

*** INCANNEX HIRES PROCAPS FOR IHL-42X MANUFACTURE**

*** ONCOSIL 50% DELIVER 2nd STRIKE; SPILL FAILS BY 2%; DR ROGER ASTON**

*** NEUROTECH 100% DIRECTOR FEE POOL HIKE AGM**

*** VECTUS PLEADS 'SCHULTZ, NEWS' TO ASX 24% QUERY**

*** ACORN TAKES 5.3% OF MICRO-X**

*** JASON CARROL TAKES 7% OF ISLAND**

*** PERENNIAL BELOW 5% IN HYDRIX**

MARKET REPORT

The Australian stock market was up 0.53 percent on Wednesday October 20, 2021, with the ASX200 up 38.8 points to 7,413.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell and seven traded unchanged. All three Big Caps were up.

Oncosil was the best, up 0.7 cents or 14.9 percent to 5.4 cents, with 5.7 million shares traded. Cyclopharm climbed 7.3 percent; Osprey improved 6.15 percent; Actinogen and Proteomics rose more than four percent; Antisense was up 3.6 percent; Compumedics and Paradigm climbed more than two percent; Mesoblast, Pro Medicus and Volpara were up more than one percent; with Avita, Cochlear, CSL, Polynovo and Resmed up by less than one percent.

Patrys and Universal Biosensors led the falls, both down 4.55 percent to 4.2 cents and 73.5 cents, respectively, with 4.5 million and 226,460 shares traded, respectively. Optiscan and Prescience fell more than four percent; Alterity and Uscom lost more than three percent; Amplia, Cynata, Kazia, Next Science, Pharmaxis and Starpharma shed more than two percent; Clinuvel, Genetic Signatures, Medical Developments, Nanosonics and Neuren were down more than one percent; with Immutep, Opthea and Telix down by less than one percent.

TELIX PHARMACEUTICALS

Telix says its 10-patient, phase I/II trial of TLX101 combined with external beam radiation therapy for glioblastoma met its primary objective of safety and tolerability.

Telix said that the Ipax-1 trial data showed overall survival of 15.97 months for the nine of 10 evaluable patients, with one patient dying from Covid-19.

The company said six of the 10 patients in the study were still alive and would be followed until one year after dosing for the final overall survival calculation expected in May 2022.

Telix chief medical officer Dr Colin Hayward said that "whilst a single arm study, the overall survival demonstrated in this initial patient population is encouraging".

"[Glioblastoma multiforme] has a median survival from initial diagnosis of 12 to 15 months, so the prospect of potentially improved [overall survival] in the second line setting warrants further investigation in a larger patient cohort, including earlier stage patients," Dr Hayward said.

The company said radiation exposure to key organs was within prescribed safety limits, the most frequent adverse event was fatigue in three patients, with diarrhoea, decreased lymphocyte count, headache and cerebral oedema, all of which occurred in two patients.

Telix said that with the exception of cerebral oedema, a common side-effect of radiotherapy to the brain, adverse events typically had an intensity of grade 1 or grade 2 and the therapy was generally well-tolerated by patients.

The company said the data was presented at the Congress of Neurological Surgeons meeting in Austin, Texas, from October 16 to 20, 2021.

Last year, Telix said the first eight patients in the study had progression-free survival of 4.33 months, compared to the average 2.5 months, and an overall survival rate of 15.97 months, with the therapy well tolerated and no limiting dosimetry (BD: Jan 17, 2021).

In June, Telix said it closed recruitment in the trial on positive data and would take the combination therapy to a first-line trial (BD Jun 21, 2021).

Telix said in June that having recruited 10 patients an interim analysis of safety and preliminary efficacy was "sufficiently encouraging to warrant study in front-line therapy, where radiation therapy is more extensively used".

Telix fell two cents or 0.3 percent to $5.78 with 372,701 shares traded.

ZELIRA THERAPEUTICS

Zelira says it has raised $US5 million ($A6.7 million) in a placement to Quincy Street Capital LLC at six cents, a 54 percent premium to its 3.9 cents last closing price.

Zelira said that Quincy Street Capital was a family office fund, which bought $US3.5 million in Zelira shares and invested $US1.5 million in an equity investment in Zelira's dermatology subsidiary, Ilera Derm LLC.

Biotech Daily understands that Quincy Street is a subsidiary of the Park City, Utah-based DeSola Capital, whose principal was real estate agent Gary C Grant.

The company said that Quincy Street would be issued one unlisted option for every two shares acquired, exercisable at nine cents each within two years.

Zelira said following the investments, Quincy Street became a substantial shareholder in Zelira with 6.3 percent and had three percent of Ilera Derm.

The company said the funds would accelerate its growth in clinical development and ongoing trials in Australia and the US, additional licencing for Zelira products and technologies, the commercialization of its Raf Five marijuana-based acne treatments and expand sales of its marijuana-derived Sprinjene products (BD: Sep 23, 2021)

Zelira was up 0.6 cents or 15.4 percent to 4.5 cents with 21.3 million shares traded.

MEDLAB CLINICAL

Medlab says it has sold its food additive business to Pharmacare due to reduce its costs and focus on its marijuana-based Nanabis and Nanocelle drug delivery system.
Medlab said Sydney's Pharmacare would pay $1.6 million on November 1, 2021, with a two-year earn out expected to be greater than $250,000 or five percent of net sales per year during the first and second year.
The company said it would focus on Nanabis and Nanocelle research and development and "emerging commercial partnering opportunities".
Medlab said that all food additive assets had been sold to Pharmacare, except for "certain … intellectual property assets that will be provided as an ongoing licence in perpetuity to Pharmacare for the Australian territory" and it reserved its rights for the rest of the world and was "actively pursuing significant opportunities".
Medlab was up half a cent or 3.2 percent to 16 cents.

TRUSCREEN GROUP

Truscreen says its 458-woman China market study concludes that its cervical cancer diagnostic is an effective alternative to cervical cytology and it has expanded to China.
Truscreen said the study, titled 'Clinical evaluation of a real-time optoelectronic device in cervical cancer screening' was published in the European Journal of Obstetrics & Gynecology and Reproductive Biology and an abstract was available at: https://www.ejog.org/article/S0301-2115(21)00482-6/fulltext#relatedArticles.
The company said the participants aged 25 to 65 years,received cervical cancer screening using Truscreen's device, the human papillomavirus (HPV) test and cytological testing using the Thinprep cytology test (TCT).
Truscreen said that for the detection of cervical intraepithelial neoplasia grade 2 or higher, the sensitivity and specificity of Truscreen were 83.78 percent and 78.86 percent, respectively, with the specificity of Truscreen significantly higher than those of HPV testing (50.59%, $p < 0.001$) and TCT (55.58%, $p < 0.001$).
The company said that in high-risk HPV-positive women, the specificity of HPV testing combined with Truscreen was significantly higher at 50.0 percent, compared to HPV testing combined with TCT which was 39.9 percent ($p = 0.004$).
Truscreen chief executive officer Juliet Hull said there was "an ever-increasing number of published studies coming through that highlight the effectiveness of the Truscreen screening device in detecting cervical cancer".
"It adds to the body of evidence already available, with a substantial amount of the publishes studies undertaken in China, our major offshore market," Ms Hull said.
"But the full set of advantages the Truscreen screening device provides to both patients and clinics do not get reflected in these studies," Ms Hull said.
"When measured against other screening options, our device is non-invasive, affordable, quick, easy to learn and independent from laboratory infrastructure, making it a cost-effective alternative to expensive cytology methods," Ms Hull said.
Separately, the company said it was expanding in China with the launch of the Truscreen Made in China device.
The company said its China distributor Beijing Siweixiangtai was marketing the device to the private health check sector and expected the "first major project" to begin this year, and it was increasing access in Central Europe with a focus on Serbia and Poland.
The company said it had completed verification and validation of a firmware update that was progressively being released to Truscreen devices already in the market.
Truscreen was up 1.2 cents or 19.05 percent to 7.5 cents with 45.95 million shares traded.

IMUGENE

Imugene says the Los Angeles-based City of Hope has dosed the first of up to 12 patients in its phase I trial of CF33, now Checkvacc, for triple negative breast cancer.

In July, Imugene said the US Food and Drug Administration had approved its investigational new drug application for a phase I trial of CF33 for triple-negative breast cancer (BD: Jul 2, 2021).

The company said the study would evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33 combined with a humanized sodium-iodide symporter (hNIS) and an anti-programmed death-ligand 1 (CF33-hNIS-anti PDL1) antibody, or Checkvacc, for metastatic triple-negative breast cancer.

Today, Imugene said the dose escalation would be followed by an expansion to 12 patients at the final dose, which would be the recommended phase II dose.

Imugene managing-director Leslie Chong said it was “timely that we see our first patient joining the trial during breast cancer awareness month, an issue that is particularly critical right now as mammograms and breast screening are down sharply due to Covid-19 restrictions”.

Imugene was unchanged at 45 cents with 18.0 million shares traded.

OPTHEA

Opthea says it has begun Asia-Pacific enrolment in its phase III trials of OPT-302 with ranibizumab and aflibercept for wet age-related macular degeneration (AMD).

Earlier this month, Opthea said it had begun European enrolment into the two phase III trials of OPT-302 (BD: Oct 5, 2021).

In March, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blinded, controlled trials, evaluating the efficacy and safety of OPT-302 in combination with ranibizumab (Lucentis) or OPT-302 with aflibercept (Eylea), compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).

Opthea managing-director Dr Megan Baldwin said over the following weeks, “we anticipate opening sites in additional countries in the Asia Pacific region including South Korea and the Philippines”.

Opthea fell one cent or 0.8 percent to $1.27.

CONTROL BIONICS

Control Bionics says it has introduced a rental facility for Australian customers to rent its Neuronode products for people with communication disabilities.

Control Bionics said the products for rent were the Neuronode Trilogy including the Eye Gaze and Neuronode for touch and eye control of computer systems.

The company said the rental model was introduced because of the delay in access to the products as well as the time taken to obtain funding from the Australian National Disability Insurance Scheme (NDIS) and other external funders.

Control Bionics said the rental model allowed customers to use of the products immediately and once third-party funding was obtained, the rented units could be purchased.

The company said its equipment was classified as an augmentative and alternative communication product which helped “people with a range of conditions to find their voice”.

Control Bionics fell half a cent or 0.85 percent to 58 cents.

INCANNEX HEALTHCARE

Incannex says it has a development and manufacturing agreement with Procaps SA for its IHL-42X soft gel capsules for obstructive sleep apnoea.
Incannex said its IHL-42X was a combination of dronabinol and acetazolamide and the soft gel capsules would be used in phase II, phase III and open label clinical trials.
Last year, the company said it had ethics approval for a 48-patient, phase IIb, randomized, double-blind, placebo-controlled, dose-ranging trial of the marijuana-derived IHL-42X for obstructive sleep apnoea at Melbourne's Alfred Hospital, assessing the therapeutic benefit of IHL-42X at three dose levels (BD: Sep 24, 2020).
Today, Incannex said the Barranquilla, Colombia-based Procaps manufacturing plant had US, Canada, Australia and UK regulatory approvals.
The company said the agreement would remain in place for "as long as supply of IHL-42X soft gel capsules are required for clinical trial purposes".
Incannex said it was "undertaking a proof-of-concept phase II clinical trial to assess IHL-42X" with the primary endpoint a reduction in apnoea hypopnoea index, with said secondary endpoints the reduction in oxygen desaturation index, reduction in daytime somnolence measured by the Epworth sleepiness scale and improvement in mood.
The company said patient dosing was expected to be completed this year with results by April 2022.
Incannex said these results would be used to support an investigational new drug application to the FDA and to inform the design of subsequent clinical trials.
Incannex was unchanged at 36 cents with 3.35 million shares traded.

ONCOSIL MEDICAL

Oncosil says its annual general meeting delivered a remuneration report second strike, with the contingent board spill motion failing narrowly with 51.87 percent against.
Oncosil said that 67,974,921 votes (50.41%) opposed the remuneration report with 66,863,201 votes (49.59% in favor.
The company said the board spill motion failed with 68,737,455 votes (51.87%) opposing the spill of directors, while 63,771,055 votes (48.13%) voting for the spill.
Last year, Oncosil said that 38.4 percent of votes at the annual general meeting opposed the remuneration report, earning a "first strike" (BD: Oct 21, 2020).
The Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a board spill vote, and if passed by more than 50 percent of votes the directors must stand for re-election within 90 days.
Prior to the results being published, Oncosil announced the resignation of founder, former chair and co-inventor of the Brachysil radiation technology Dr Roger Aston.
The company later said the re-election resolution was withdrawn prior to the meeting, but 94,878,670 proxy votes (49.69%) opposed Dr Aston's re-election with 82,422,849 votes (43.15%) in favor and 13,695,511 votes (7.17%) at the "proxy's discretion".
Oncosil said that 21.25 percent of votes opposed the omnibus incentive plan, 13.09 percent of votes opposed the issue of performance rights to chief executive officer Nigel Lange, with director Otto Buttula re-elected overwhelmingly.
According to the company's most recent filing, it had 792,343,294 shares on offer, meaning the proxy votes against Dr Aston amounted to 11.97 percent, sufficient to requisition extraordinary general meetings.
Oncosil was up 0.7 cents or 14.9 percent to 5.4 cents with 5.7 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says its annual general meeting will vote to increase the fee pool for non-executive directors by 100 percent, from $300,000 to $600,000 a year.
Neurotech said the increase would provide “the ability to appoint additional directors with the requisite skills and experience as appropriate” and pay market rates.
The company said shareholders would vote to issue 500,000 options each to directors Krista Bates and Prof Allan Cripps, exercisable at nine cents each by May 12, 2023.
Neurotech said the meeting would vote on the remuneration report, the election of directors Ms Bates, Prof Cripps and Mark Davies and the 10 percent placement capacity.
The meeting will be held at Double Tree by Hilton Perth Waterfront, 1 Barrack Square, Perth, Western Australia on November 18, 2021, at 3:30pm (AWST).
Neurotech fell 0.3 cents or 6.1 percent to 4.6 cents with 1.5 million shares traded.

VECTUS BIOSYSTEMS

Vectus says it is not aware of any information concerning it that has not been previously announced to the market which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 24.3 percent from $1.77 to $2.20 yesterday, October 19, 2021, and noted a “significant increase” in the trading volume.
Vectus said previous announcements had generated “significant interest”.
Vectus was unchanged at $2.00.

MICRO-X

Melbourne’s Acorn Capital says it has become a substantial shareholder in Micro-X with 24,324,957 shares or 5.29 percent.
Acorn said it bought shares between June 24 and October 18, 2021, with its most recent and single largest purchase 1,925,000 shares for $589,063 or 30.6 cents a share.
Micro-X was up half a cent or 1.6 percent to 31 cents.

ISLAND PHARMACEUTICALS

Jason Alan Carroll says he has increased his shareholding in Island Pharmaceuticals from 4,875,000 shares (6.0%) to 5,675,000 (7.0 %).
The Melbourne-based Mr Carrol said between October 14 and October 19, 2021, he bought 800,000 shares for $254,432 or an average of 31.8 cents a share.
Island fell one cent or 3.1 percent to 31.5 cents.

HYDRIX

Sydney’s Perennial Value Management says it has reduced its shareholding in Hydrix below the five percent substantial shareholder level.
Perennial said that on October 14 and 15, 2021 it sold 616,300 shares for $83,018 or an average of 13.47 cents a share.
Biotech Daily calculates that Perennial retains 7,847,021 shares (4.78%).
Hydrix was unchanged at 12.5 cents.