Biotech Daily

Wednesday April 26, 2023

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: IMPEDIMED UP 19%; ONCOSIL DOWN 15%**

*** MESOBLAST RAISES $61m**

*** EXOPHARM RIGHTS RAISE $802k; $770k SHORTFALL**

*** 4D POSTS MAIDEN $1m QUARTERLY RECEIPTS**

*** FDA 510(k) APPROVAL FOR CARDIEX CONNEQT PULSE**

*** DORSAVI LAUNCHES VIMOVE 'RUN'**

*** PYC VP-001 RETINITIS PIGMENTOSA TYPE 11 STUDY APPROVED**

*** ALTERITY: WEARABLE SENSOR DATA ENDPOINT FOR ATH434 MSA TRIAL**

*** QBIOTICS STARTS PHASE II TIGILANOL TIGLATE SARCOMA TRIAL**

*** ANTISENSE: BULGARIA APPROVES ATL1102 DMD TRIAL**

*** CHIMERIC CHM1101 PHASE Ib TRIAL ETHICS APPROVAL**

*** STARPHARMA: 'DEP-SN-38 BEATS ENHERTU FOR CANCER, IN MICE'**

*** IMUGENE RECEIVES $12.6m FEDERAL R&D TAX INCENTIVE**

*** DR CHARLIE JANSEN REDUCES TO 8.9% OF VITURA**

*** IMMUTEP APPOINTS DR FLORIAN VOGL CMO; DR FRÉDÉRIC TRIEBEL CSO**

*** PROTEOMICS APPOINTS 4 ADVISERS**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Wednesday April 26, 2023, with the ASX200 down 5.7 points to 7,316.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and two were untraded.

Impedimed was the best, up three cents or 19.35 percent to 18.5 cents, with 26.9 million shares traded. Pharmaxis climbed 7.3 percent; Medical Developments and Starpharma improved more than four percent; Antisense, Immutep, Micro-X, Opthea, Resonance and Telix rose two percent or more; Emvision, Neuren and Next Science were up one percent or more; with CSL and Genetic Signatures up by less than one percent.

Monday's 30 percent best, Oncosil, led the falls, down 0.2 cents or 15.4 percent to 1.1 cents, with 6.5 million shares traded. Mesoblast lost 11.6 percent; Proteomics fell 8.3 percent; Actinogen, Kazia and Nova Eye were down more than seven percent; Avita and Paradigm shed more than six percent; Amplia and Cynata lost more than five percent; Dimerix fell four percent; Polynovo and Universal Biosensors were down more than three percent; Volpara shed two percent; Clinuvel, Orthocell and Pro Medicus were down more than one percent; with Cochlear, Nanosonics and Resmed down by less than one percent.

MESOBLAST

Mesoblast says it has raised about $US40 million ($A60.5 million) at 85 cents a share in a private placement to existing US, UK and Australian shareholders.
Mesoblast said the funds would be used to launch its remestemcel-L stem cell treatment for graft versus host disease in children, ongoing manufacturing costs and its phase III trial of rexlemestrocel-L for chronic low back pain.
Mesoblast fell 11.5 cents or 11.6 percent to 87.5 cents with 6.7 million shares traded.

EXOPHARM

Exopharm says it has raised $802,440 of a hoped $1,572,115 in a pro-rata, non-renounceable rights issue at one cent a share, leaving a shortfall of $769,675.
Last month, Exopharm said it hoped to raise $1.57 million in a rights issue, with funds used to support partnering activities, maintain its intellectual property, commercialization activities and for general working capital (BD: Mar 23, 2023).
Today, Exopharm said Alto Capital and Canary Capital were managers for the shortfall.
Exopharm was up 0.4 cents or 26.7 percent to 1.9 cents.

4D MEDICAL

4D Medical says it has reported its first $1 million in receipts for its four-dimensional XV lung imaging technology for the three months to March 31, 2023.
4D said it received $1,234,000 for the three-month period, an increase of 67 percent on the previous three months to December 31, 2022.
A 4D executive told Biotech Daily the revenue was from commercial “software as a service” from customers in Australia and the US.
4D said it had a cash burn for the three months to March 31, 2023 of $8,471,000 with cash and equivalents of $36,816,000 at March 31.
4D was up 9.5 cents or 11.9 percent to 89.5 cents with 1.6 million shares traded.

CARDIEX (FORMERLY ATCOR MEDICAL)

Cardiex says it has US Food and Drug Administration 510(k) clearance for its Conneqt Pulse vascular biometric monitor for measuring brachial and central blood pressure.
Cardiex said the Conneqt Pulse was a remote patient monitoring device that incorporated subsidiary Atcor’s Sphygmocor technology but was a stand-alone medical device that was “easy to use and operate without requiring specialist training”.
The company said heart disease was the number one killer in the US, with one person dying every 34 seconds and nearly half of all American adults having high blood pressure.
Cardiex said that the FDA clearance of the Conneqt Pulse had “the potential to dramatically help stem this epidemic by improving access to, and reliability of, remote patient monitoring with advanced biometric insights”.
Cardiex managing-director Craig Cooper said the FDA clearance was “a major milestone in the field of cardiovascular health management”.
“At the time of launch, there is no other vital signs monitor that provides the level of features, personalization, or vascular health insights that will be available on the Pulse,” Mr Cooper said. “This technology has the potential to truly revolutionize the way hypertension and vascular disease is diagnosed and managed in the future.”
The company said Conneqt Pulse was expected to be availability by October 2023.
Cardiex was up 3.5 cents or 10.45 percent to 37 cents with 1.5 million shares traded.

DORSAVI

Dorsavi says it has upgraded its Vimove wearable patient monitoring and management bio-feedback sensors with a Run module for assessment while running.

Dorsavi said the upgrade allowed clinicians and physical therapists “greater autonomy to select their assessments of choice while providing real-time feedback and tailored corrective exercise”.

The company said that running data was analyzed by its artificial intelligence-based algorithms “to deliver advanced insights into key running metrics and identify potential inefficiencies in a patient’s movement”.

Dorsavi said the Run module would improve information for physical therapists, improve patient outcomes and address a larger market leading to increased sales growth.

Dorsavi chief executive officer Dr Andrew Ronchi said the upgrade would “capture meaningful real-time data, which provides clinicians with insights that the human eye cannot capture”.

“We listened to our customers and included a new offering that expands the product capability, allowing clinicians to improve their quality of care, and deliver better patient outcomes,” Dr Ronchi said. “We believe this has greatly enhanced the quality of our product as an all-purpose tool for physical therapy assessments, expanding our addressable market to new patient groups, and increasing our recurring revenue.”

Dorsavi was unchanged at 1.2 cents.

PYC THERAPEUTICS

PYC says it has approval for its 15 patient, phase I ‘Platypus’ study of intra-vitreally dosed VP-001 for adult patients with retinitis pigmentosa type 11, at six US sites.

In March, PYC said it had US Food and Drug Administration approval for the up-to 15-patient trial with dosing to begin by July 2023 (BD: Mar 6, 2023)

Today, the company said the open-label study would include a single-ascending dose starting from 3.0 micrograms of VP-001 in cohorts of three patients.

PYC said a safety review committee would assess each cohort four-weeks after the final cohort patient was dosed, with a 24-week safety follow-up assessment after the highest tolerated dose cohort was dosed.

PYC said final data would inform an application to the US Food and Drug Administration for a phase II multi-dose study and expected the first patient to be dosed by June 2023.

PYC was unchanged at 6.1 cents.

ALTERITY THERAPEUTICS

Alterity says wearable sensor data from the Biomuse multiple system atrophy (MSA) study has led to sensors being included as an endpoint for its phase II trial of ATH434.

Alterity said that a poster from the ‘Biomarkers of progression in multiple system atrophy’ (Biomuse) study, titled ‘Wearable Sensors for Quantitative Motor Assessments in Multiple System Atrophy’ was presented at the American Academy of Neurology meeting, with the study showing sensors might be useful in assessing neurological disease progression.

The company said the ‘Timed Up and Go’ test quantified functional mobility suggesting the clinical relevance of the outcomes was important in assessing MSA outpatients.

Alterity chief executive officer Dr David Stamler said that as a result of the study the company had incorporated wearable sensor data as a secondary endpoints “to determine the effect of our agent on gait stability”.

Alterity was unchanged at 0.8 cents.

QBIOTICS

Qbiotics says it has opened recruitment for 10-patient, phase II trial of intra-tumoral tigilanol tiglate, or EBC-46, for soft tissue sarcoma.

Last year, Qbiotics said it had received its first US Food and Drug Administration investigational new drug application approval for the trial (BD: Jul 25, 2023).

At that time, the company said the open-label trial would evaluate the efficacy and dose-ranging in patients with advanced or metastatic soft tissue sarcoma, receiving up-to five intra-tumoral treatments of tigilanol tiglate, administered four weeks apart.

Today, Qbiotics said the trial's primary objective was to evaluate the degree of tumor ablation defined as the proportion of patients achieving 30 percent or more reduction in tumor volume assessed by ultrasound compared to baseline, with secondary and exploratory objectives to assess safety and tolerability of tigilanol tiglate, incidence of adverse events and serious adverse events, and pharmacokinetics, as well as local rate of recurrence at the injection site at six months post initial injection and assessment of tumor response in biopsy samples.

The company said that tigilanol tiglate was a plant-derived small molecule, administered by injection directly into a solid tumor.

Qbiotics said the QB46C-H07 trial would be conducted at New York's Memorial Sloan Kettering Cancer Centre with Dr Edmund Bartlett as principal investigator.

Qbiotics managing-director Dr Victoria Gordon said the opening of the trial "ahead of schedule, marks a significant milestone for Qbiotics that brings the company a step closer to addressing a major unmet need for patients with soft tissue sarcoma which currently has limited effective treatment options".

Qbiotics is a public unlisted company.

ANTISENSE THERAPEUTICS

Antisense says Bulgaria has approved its 45-patient double-blind, placebo-controlled, phase IIb trial of ATL1102 in non-ambulant boys with Duchenne muscular dystrophy.

Earlier this year, Antisense said the Turkish Medicines and Medical Device Agency was the first regulator to approve the trial (BD: Feb 14, 2023).

Today, the company said it had submitted clinical trial applications for the study in the UK, Bulgaria and Turkey and approvals would come through in a "staggered manner".

Antisense said the UK Medicines and Healthcare Products Regulatory Agency had evaluated its application and it had received review questions, and expected to submit an application to the Australian Therapeutic Goods Administration.

Antisense was up 0.2 cents or 2.7 percent to 7.7 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has ethics approval for its up-to 32-patient, multi-site, two-part, phase Ib clinical trial of CHM1101 for progressive glioblastoma multiforme brain cancer.

Chimeric said that part A would treat three to six patients to complete the phase I dose escalation confirmation trial at the Duarte, California City of Hope Cancer Centre.

The company said that by the end of 2023 a clinical safety and efficacy assessment of the initial patients would inform the part B dose expansion cohort of 12 to 26 patients.

Chimeric said that in line with regulatory feedback, a registration trial would follow when the dose expansion cohort had been completed.

Chimeric was up 0.4 cents or six percent to 7.1 cents.

STARPHARMA

Starpharma says its dendrimer enhanced product (DEP) SN-38 antibody-drug conjugate, (ADC) outperforms Enhertu anti-tumor activity for ovarian cancer, in mice.
Starpharma said that Enhertu was an approved drug for human epidermal growth factor receptor 2 (HER2) positive breast cancer.
The company said that antibody-drug conjugates (ADCs) were “an innovative and growing area of cancer treatment, with encouraging clinical advances and product approvals in recent years”.
Starpharma said that currently marketed HER2-targeted ADCs included the Roche-Genentech Kadcyla and the Astrazeneca- Daiichi-Sankyo Enhertu.
The company said its HER2-targeted DEP-SN-38 ADC comprised a HER2-directed antibody, trastuzumab, linked to DEP-dendrimers loaded with the topoisomerase I inhibitor, SN-38, which was the active metabolite of irinotecan.
According to the US National Library of Medicine, irinotecan is used to treat solid tumors.
Starpharma said its DEP-SN-38 was designed “with a higher drug-to-antibody ratio, or drug loading, than currently marketed ADCs” and in a mouse model of an ovarian cancer cell line that overexpressed HER2, intravenous DEP-SN-38-ADC and Enhertu “significantly inhibited tumor growth compared with saline control”.
Starpharma said the anti-tumor effect of DEP-SN-38 ADC “was statistically significantly greater than … Enhertu over the duration of the study ($p < 0.0001$)” and all animals in the DEP-SN-38 ADC group survived to the end of the study, with survival significantly greater for DEP-SN-38 ADC-treated animals compared with Enhertu and controls ($p < 0.0002$).
Starpharma said that its DEP-SN-38 ADC “achieved superior tumor growth inhibition and survival compared with Enhertu”.
The company said its DEP achieved a higher drug payload, than conventional ADCs it had greater flexibility to control drug release profiles and it had the ability to widen the therapeutic index of toxic drug payloads”.
Starpharma chief executive officer Dr Jackie Fairley said that the company’s DEP technology delivered “a number of advantages in the design of innovative [antibody-drug conjugates], including the ability to load more drug payload molecules per construct and having greater flexibility in linker strategies”.
Starpharma was up two cents or 4.2 percent to 50 cents.

IMUGENE

Imugene says it has received $12.6 million from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.
Imugene said the incentive related to research and development expenditure for the year to June 30, 2022.
Imugene was unchanged at 13 cents with 17.35 million shares traded.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Dr Matua Hasyo Charlie Jansen says he has reduced his substantial holding in Vitura from 55,413,425 shares (10.1%) to 48,837,899 shares (8.9%).
On Monday, Vitura said Dr Jansen as trustee for the Whanau Family Trust sold 5,000,000 shares at 28 cents a share in a block trade to institutions (BD: Apr 24, 2023).
Dr Jansen said between April 28, 2022 and April 21, 2023 he sold shares at prices ranging from 28 cents per share to 62 cents per share.
Vitura fell half a cent or 1.7 percent to 29.5 cents with 6.7 million shares traded.

IMMUTEP

Immutep says it has appointed Prof Florian Vogl as chief medical officer, effective from May 1, 2023, replacing Prof Frédéric Triebel who continues as chief scientific officer, Immutep said Prof Vogl was formerly Cellestia Biotech's chief medical officer and Rainier Therapeutics' European head of clinical development and previously worked for Novartis and Amgen.

The company said Prof Vogl held a Doctor of Medicine and Doctor of Philosophy from the University of Munich.

Immutep was up half a cent or two percent to 26 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has appointed four US-based endocrinology and nephrology key opinion leaders to its advisory board for clinical and commercial rollout strategies.

The company said the appointments were: Detroit's Henry Ford Health nurse practitioner in diabetes Davida Kruger; Washington State University's Prof Josh Neumiller; Thomas Jefferson University's Prof Neil Skolnik; and dietitian Hope Warshaw.

Proteomics international managing director Dr Richard Lipscombe said the appointees brought "a wealth of knowledge in treating diabetes patients and they [would] be important advocates for the use of the Promarkerd test".

Proteomics fell 7.5 cents or 8.3 percent to 83 cents.