

Biotech Daily

Thursday July 6, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: CYNATA UP 22%; ATOMO DOWN 8.5%
- * VICTORIA \$14.8m FOR MEDICAL IMAGING, RESEARCH
- * DRAGONFLY \$5m MARIJUANA IPO
- * COMPUMEDICS UNAUDITED REVENUE \$41m; CPAP SOMFIT DEAL
- * IMRICOR, GEM GLOBAL \$30m DRAW-DOWN EQUITY FACILITY
- * PACIFIC EDGE: NOVITAS CONTINUES US CXBLADDER INSURANCE
- * DORSAVI ADDS VIDEO TRACKING TO WEARABLE VIMOVE RUN MODULE
- * INOVIQ, PROMEGA TO SELL EXO-NET, NUCLEIC ACID PURIFIERS
- * REGENEUS PLEADS SCHULTZ TO ASX 89% QUERY
- * PHARMAUST: LYMPHOMA DOG SURVIVES 365 DAYS
- * INCANNEX: PHASE I MARIJUANA IHL-42X ETHICS APPROVAL
- * LUMOS REQUESTS 'CAPITAL RAISING' TRADING HALT
- * GZ REDUCES TO 7% OF LUMOS
- * DARREN COLLINS REPLACES SOMNOMED CFO HERVE FIEVET

MARKET REPORT

The Australian stock market fell 1.24 percent on Thursday July 6, 2023, with the ASX200 down 89.8 points to 7,163.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell and nine traded unchanged. All three Big Caps fell.

Cynata was the best on no news, up 2.5 cents or 21.7 percent to 14 cents, with 904,548 shares traded. Medical Developments was up 15.8 percent; Cyclopharm climbed five percent; Micro-X was up 4.2 percent; Compumedics was up 3.1 percent; Alcidion, Amplia, Dimerix and Pharmaxis rose two percent or more; Antisense and Volpara were up by more than one percent.

Atomo led the falls for the second day in a row, down 0.5 cents or 8.5 percent to 5.4 cents, with 7.3 million shares traded. Impedimed lost 7.5 percent; Opthea was down 6.5 percent; 4D Medical and Polynovo were down more than five percent; Nanosonics, Starpharma and Universal Biosensors fell more than four percent; Avita, Imugene, Neuren, Next Science and Prescient shed more than two percent; Clinuvel, Emvision, Mesoblast and Nova Eye were down more than one percent; with Cochlear, CSL, Paradigm, Pro Medicus, Resmed and Telix down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it has provided \$14.8 million for medical imaging at several sites through the Higher Education State Investment Fund.

The State Government said that researchers would share the equipment and expertise through the Victorian Biomedical Imaging Capability project "ensuring Victoria remains at the forefront of drug discovery and new medical treatment".

A media release from the Victoria Minister for Higher Education Gayle Tierney said the project was a partnership with the National Imaging Facility, a network of imaging research institutes including Monash University, University of Melbourne, La Trobe University and Swinburne University.

The Government said the investment would upgrade imaging capabilities at the University of Melbourne, Swinburne University, Monash Health and Olivia Newton-John Cancer Research Institute, as well as radiochemistry facilities at Austin Health and Peter MacCallum Cancer Centre.

The media release said the \$350 million Victorian Higher Education State Investment Fund supported universities with financial assistance for capital works, applied research and research infrastructure.

DRAGONFLY BIOSCIENCES

Dragonfly hopes to raise up to \$5,000,000 in an initial public offer at 20 cents a share to list on the ASX under the code DRF on August 1, to commercialize its marijuana products. A Dragonfly term sheet said that for every two shares acquired investors would receive one attaching option, exercisable at 35 cents each by December 31, 2024.

The offer is currently open and closes on July 13, 2023.

Dragonfly says its 'seed-to-shelf' cannabidiol (CBD) business trades under the Dragonfly CBD brand and it "owns the entire value chain from their certified organic farms, extraction facilities and state of the art laboratories used for producing premium CBD products". The company says it offers cannabidiol in oral dropper formats ranging in strength from 500mg to 3.000mg.

In 2020, the Australian Therapeutic Goods Administration said it had down-scheduled "certain low dose cannabidiol preparations" up to a maximum of 150mg/day, from schedule 4 (prescription medicine) to schedule 3 (pharmacist only medicine) or over-the-counter, but said there were no products available at that time (BD: Dec 15, 2020). Dragonfly said that in July 2021, two of its "biggest selling CBD products received official approval from the Therapeutic Goods Administration for use in Australia when they down-scheduled low-dose CBD from a prescription medicine to a pharmacist-only medicine" with both products "available to the public via medical practitioners".

The company said its products had been voted "Best CBD product" in 2020 by Boots UK, it distributed to national grocery and specialty chains including Tesco, Sainsbury's, Harrods and Amazon UK and had the UK's "widest distribution base for CBD products". The company said that it would issue up to 25,000,000 shares in the initial public offer, currently had 105,333,435 on issue and would have 162,246,120 shares on issue if it raised the maximum in the offer, implying a market capitalization of \$32.4 million. Dragonfly said its chair was the Sofia, Bulgaria-based Radost Draganova, with chief executive officer Regan Saveall and directors including Chris Wronski, Dale Klynhout and Warren Goward.

The company said the joint lead managers to the offer were RM Corporate Finance Pty Ltd and Finexia Securities.

The prospectus is available at: https://dragonflybiosciences.com/prospectus-disclaimer.

COMPUMEDICS

Compumedics says unaudited revenue for the year was up 11 percent from \$37 million to \$41 million and CPAP Direct will sell its Somfit sleep tests in Queensland.

Compumedics said that sales orders for its diagnostics excluding magneto-

encephalography (MEG) was up 3.6 percent to \$43.0 million for the year to June 30, 2023, from \$41.5 million last year.

The company said earnings before interest, taxes, depreciation and amortization (Ebitda) would be up-to \$2 million before a MEG write-down of \$6.9 million and it had \$3.6 million in cash at June 30, and unused banking facilities of \$1.4 million.

Separately, Compumedics said it had signed a distribution deal with CPAP Direct to sell its Somfit and Somfit home sleep testing services in Queensland for \$500,000 in the first year, including \$200,000 of recurring service revenue.

The company said it expected service revenue for the deal to increase more than three times in the first 24 to 36 months as Somfit was made available.

Compumedics said this was the first of several expected state-based distribution contracts that would eventually cover Australia.

Compumedics was up half a cent or 3.1 percent to 16.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says Luxembourg's Gem Global Yield LLC will provide a \$30 million, three-year draw-down equity facility, but did not disclose the terms of the draw-downs.

Imricor said it could use the facility at its discretion to draw down funds in tranches in exchange for issuing CHESS depositary interests CDIs).

The company said it would issue Gem Global Yield 5.7 million three-year call options at an exercise price of 61 cents, as well as paying Gem Global \$600,000.

Imricor chief executive officer Steve Wedan said the agreement meant the company would have the "required capital to execute our Visabl-AFL trial to support [US Food and Drug Administration] approval of our products in the US and the Visabl-VT trial to support expanded indications to treat ventricular tachycardia in Europe".

Imricor said it was pursuing other additional alternative means of financing.

Imricor was up 7.5 cents or 20.3 percent to 44.5 cents.

PACIFIC EDGE

Pacific Edge says Novitas has delayed implementing a local coverage determination that would have removed US Medicare coverage of its Cxbladder tests.

On Monday, Pacific Edge said its Cxbladder urine test for bladder cancer might lose its US insurance cover from July 17, 2023, with some patients having to pay directly for the test (BD: Jul 3, 2023).

Last month, Pacific Edge said its Cxbladder test for bladder cancer would cease to be covered by Medicare in the US from July 17, 2023 (BD: Jun 7, 2023).

Today, Pacific Edge said that details were "being worked out" but that there was a commitment that the local coverage determination would not proceed as is.

Pacific Edge chief executive officer Dr Peter Meinjtes said the company was pleased with the outcome.

"We are confirmed in our position that a more robust procedure that includes open meeting and public comment was needed and thank Novitas for the opportunity to discuss the substance of their evidentiary review of Cxbladder products," Dr Meinjtes said. Pacific Edge was up 8.3 cents or 95.4 percent to 17 cents with 5.3 million shares traded.

DORSAVI

Dorsavi says it will add an artificial intelligence-based video tracking function to the recently released Run module of its Vimove wearable patient bio-feedback sensor. In April, Dorsavi said that it had upgraded its Vimove monitoring and management bio-feedback sensors with a Run module for assessment while running (BD: Apr 26, 2023). Today, the company said the updated Run module was scheduled to be released in September 2023.

Dorsavi was up 0.2 cents or 13.3 percent to 1.7 cents.

INOVIQ

Inoviq says it has a three-year agreement with Madison, Wisconsin's Promega Corporation to sell their respective products as a packaged deal.

Inoviq said that, under the agreement, it would sell its Exo-Net exosome capture technology with Promega's nucleic acid purification products.

The company did not disclose commercial terms of the deal.

Inoviq said that the co-marketing enabled the products to deliver exosomes to customers for manual and high-throughput exosome isolation and nucleic acid.

Inoviq chief executive officer Dr Leearne Hinch said that together the companies could "provide innovative exosome solutions to researchers, pharmaceutical companies and clinical diagnostic labs" helping exosome isolation, biomarker discovery and diagnostics research".

Inovig was up 12 cents or 14.6 percent to 94 cents.

REGENEUS

Regeneus has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 88.8 percent from 0.9 cents to 1.7 cents today, July 6, 2023, and noted a "significant increase" in trading volume.

Regeneus said it was "in the advanced negotiation process to merge with Cambium Medical Technologies LLC, as disclosed to ASX on April 28," (BD: Apr 28, 2023).

Regeneus was up 0.8 cents or 88.9 percent to 1.7 cents with 1.4 million shares traded.

PHARMAUST

Pharmaust says a dog in its trial of monepantel for canine lymphoma had passed 365-days with "stable disease and continued excellent quality of life".

In March, Pharmaust said the dog had passed 240-days with stable disease, disease assessed by administering veterinarians as a less than 30 percent increase or less than 20 percent decrease in tumor size (BD: Mar 7, 2023).

Today, the company said its commercial strategy for treating B-cell lymphoma would be to induce stable disease for four to six months with minimal side effects, so that the family and dog could enjoy their limited time together.

Pharmaust said that dogs with B-cell lymphoma had a poor prognosis and without treatment it was often fatal in a few weeks.

"Even though chemotherapy can offer extended survival, typically around 12 months, it is only palliative and often results in an unacceptable adverse events profile and substantial costs," the company said.

Pharmaust was up 0.1 cents or 1.3 percent to eight cents with 1.5 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has ethics approval to begin a 116-patient, bio-availability and bio-equivalence, trial to assess the pharmaco-kinetics and tolerability of IHL-42X. Incannex said the phase I trial of its marijuana-based IHL-42X would take place at Adelaide's CMax Clinical Research, with data to go to future marketing submissions for IHL-42X for obstructive sleep apnoea.

The company said the results would "form a critical component" of a future new drug application with the US Food and Drug Administration.

The company said the trial would assess the two active ingredients in IHL-42X, dronabinol (a generic name for delta-9-tetrahydrocannabinol or THC) and acetazolamide, compared against respective US Food and Drug Administration reference-listed drugs, as well as the effect of food on the pharmaco-kinetics of both.

Incannex said patients would complete four single dose treatment periods, dosed with IHL-42X under both fasting and fed conditions, with blood collected during a 48-hour period and concentrations of ingredients analyzed.

The company said the trial would be conducted in parallel to the investigational new drug application trial.

Incannex was up half a cent or 4.8 percent to 11 cents with 3.3 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos has requested a trading halt "pending an announcement ... regarding a capital raising".

Trading will resume on July 10, 2023 or on an earlier announcement. Lumos last traded at 8.6 cents.

LUMOS DIAGNOSTICS

The Sydney-based GZ Family Holdings says it has reduced its shareholding in Lumos from 24,930,614 shares (9.12%) to 21,930,614 shares (6.89%).

GZ Family Holdings said it bought 2,000,000 shares on April 26 for \$36,027 or 1.8 cents a share and on July 5 sold 5,000,000 shares for \$334,749 or 6.7 cents a share.

SOMNOMED

Somnomed says it has appointed Darren Collins as its chief financial officer, replacing four year chief financial officer Herve Fievet, effective from August 1, 2023.

Somnomed said Mr Collins trained with KPMG and had worked in Australia, Asia and the US.

Somnomed was unchanged at 95.5 cents.