



Biotech Daily

Monday January 22, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PROTEOMICS UP 17%; MESOBLAST DOWN 7%**
- * **CSIRO OPENS 'INNOVATE TO GROW' PROGRAM APPLICATIONS**
- * **POLYNOVO UNAUDITED H1 REVENUE UP 65% TO \$49m**
- * **PACIFIC EDGE Q3 CXBLADDER TEST VOLUMES DOWN 8%**
- * **4D MEDICAL, PHILIPS XV LUNG IMAGING FOR US VETERANS**
- * **ANTERIS IMPLANTS 3 MORE CANADA DURAVR HEART VALVES**
- * **STARPHARMA: ITROM VIVAGEL MID-EAST, NTH AFRICA DISTRIBUTOR**
- * **BOTANIX: FDA OKAYS SOFDRA NDA RESUBMISSION**
- * **HERAMED: 2-YEAR HERACARE, HERABEAT DEAL WITH ADVISORS**
- * **VITURA SIGNS WHOLELIFE CANVIEW SOFTWARE AGREEMENT**
- * **PERENNIAL TAKES 14% OF GENETIC SIGNATURES**
- * **CRAIG CHAPMAN, NAMPAC TAKE 6% OF CONTROL BIONICS**
- * **BRIAN WALSH TAKES 5% OF CONTROL BIONICS**
- * **IMPEDIMED: 'DIRECTORS WANTED'**
- * **BIO-MELBOURNE: 3 WEEKS TO 5th MEDTECH SEMINAR**

MARKET REPORT

The Australian stock market was up 0.75 percent on Monday January 22, 2024, with the ASX200 up 55.4 points to 7,476.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell and 14 traded unchanged. All three Big Caps were up.

Proteomics was the best, up 13 cents or 16.7 percent to 91 cents, with 484,344 shares traded. Polynovo climbed 9.8 percent; 4D Medical, Medical Developments and Orthocell rose more than two percent; Compumedics, Cyclopharm and Opthea were up one percent or more; with Avita, Clinuvel, Cochlear, CSL, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Mesoblast led the falls, down two cents or 6.7 percent to 28 cents, with 9.7 million shares traded. Percheron (Antisense) lost five percent; Imugene fell 4.8 percent; Alcidion, Cynata, Genetic Signatures, Resonance and Starpharma were down more than three percent; Atomo and Dimerix shed two percent or more; Clarity, Emvision and Telix were down more than one percent; with Neuren down by 0.3 percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

CSIRO says its 'Innovate to Grow' 10-week, free online program to help small-to-medium sized businesses with research and development is open for applications.

The Organisation said participants would collaborate with a mentor from the CSIRO or a university to address technical and business challenges, research and development opportunities, research organization partnerships and crafting funding applications.

The CSIRO said the program would begin on March 14, 2024 and was available for a limited number of businesses in therapeutics and care, health system analytics, biomedical informatics and data modelling, diagnostics, biosensors, biomedical devices, drug discovery, vaccines, and biologic therapeutics.

CSIRO biomedical manufacturing research director Prof Susie Nilsson said "developing a sustainable product in the digital health and medical technology sectors is a challenging and often underestimated process".

"The daunting task of navigating stringent testing and product development processes can be particularly overwhelming for [small to medium-sized enterprises]," Prof Nilsson said.

"Innovate to Grow presents a unique opportunity for businesses to gain valuable insights from industry experts about how research and development collaboration can help take their technology to the next level," Prof Nilsson said.

"In particular the way in which businesses can advance from a research idea to a tangible [research and development] opportunity," Prof Nilsson said.

CSIRO small-to-medium-sized-enterprise connect program advisor Liz Crompton said the program had helped more than 500 businesses, and many of companies which completed the program had begun projects with research organizations like CSIRO within 12 months. The Organisation said participants might also be eligible for dollar-matched research and development funding through its Kick-Start program.

CSIRO said applications would close on February 18, 2024.

For more information and to apply, go to: <https://bit.ly/42o2Eoh> .

POLYNOVO

Polynovo says unaudited revenue for the six months to December 31, 2023 was up 65.4 percent to \$48.8 million, compared to the prior corresponding period.

Polynovo said it had record sales of its Novosorb wound care treatment for the six months to December 31, 2023, up 54.6 percent to \$42.2 million, with US sales up 41.2 percent to \$32.2 million and non-US sales up 122.2 percent to \$10.0 million.

The company said it received \$4.9 million from the US Biomedical Advanced Research and Development Authority (BARDA), up 133.3 percent from \$2.1 million in the previous corresponding period.

Polynovo chair David Williams said: "While I view profit as a 'nice to have', I am more excited by the significant near-term revenue growth possibilities from our expanding geographic footprint and the new ways surgeons have found to use our products".

"Profits will drop naturally out of the drive and success in expanding our geographies and products," Mr Williams said.

"All that aside, what I didn't expect so soon was an entry into Turkey, Middle East, Ukraine, and Israel," Mr Williams said.

"The humanitarian side to our business, especially in conflict zones, is strong and enormously satisfying," Mr Williams said. "What was not anticipated was charities, unrelated governments, and other[s] paying for us to supply [Novosorb biodegradable temporizing matrix] to conflict zones."

Polynovo was up 15.5 cents or 9.8 percent to \$1.74 with 3.7 million shares traded.

PACIFIC EDGE

Pacific Edge says processed Cxbladder tests for the three months to December 31, 2023 were down 7.7 percent on the prior corresponding period to 7,172 tests.

Pacific Edge said the decrease was “largely reflecting the reduction in the commercial team” from 34 to 17 sales employees “amid continued uncertainty over whether Cxbladder will retain [US] Medicare coverage”.

Last year, the company said its Medicare administrative contractor Novitas delayed implementing non-coverage determination changes which would have removed reimbursement for Cxbladder urine-based genomic biomarker tests for bladder cancer in the US, and it had contested the changes (BD: Jul 6, Jul 28, Sep 29, 2023).

Today, Pacific Edge said processed Cxbladder test volumes in the US for the three months to December 31, 2023 were down 17.7 percent to 6,040 tests, compared to the previous three months, and that Asia-Pacific test volumes fell 4.9 percent to 1,132 tests, compared to the previous three months, with “tests per clinician were down on the prior quarter, but in line with seasonal expectations”.

Pacific Edge was untraded at 10 cents.

4D MEDICAL

4D says it will work with Amsterdam’s Koninklijke Philips NV to expand commercialization of its XV lung imaging technology in the US Department of Veterans Affairs.

In November, 4D Medical said it had an agreement with Philips to include XV technology in its US catalogue, with the partnership allowing Phillips to offer 4D Medical’s lung imaging as a screening option for veterans exposed to burn pits (BD: Nov 29, 2023).

Today, the company said both parties would focus on offering its 4-dimensional lung imaging to the US Department of Veterans affairs “as a critical solution for veterans exposed to burn pits and other airborne hazards on deployment”.

4D Medical said both parties intended to “formalize a reseller agreement”, which included its XV technology and Imbio portfolio as a third-party service in Philips’ catalogue to other US-based Federal agencies and commercial organizations in North America, as well as other countries, but did not state the commercial terms of the deal.

4D Medical chief executive officer Prof Andreas Fouras said “the size and reach of Philips will dramatically accelerate the scaling of our offering within ... [Veterans Affairs]”.

4D Medical was up 1.5 cents or 2.4 percent to 63.5 cents with 1.4 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says its Duravr biomimetic transcatheter heart valve (THV) has been transplanted in three more patients under Health Canada’s special access program.

Last year, Anteris said the Duravr THV device had been used for the first time in a valve-in-valve procedure at the Institut de Cardiologie de Montreal (BD: Jul 31, 2023).

Today, the company said six patients had been treated under Health Canada’s special access program, which allowed medical staff to use unlicensed medical devices for emergency use when conventional therapies had failed, were unavailable, or unsuitable.

The company said its transcatheter valve-in-valve replacement was performed by implanting a transcatheter heart valve within a failing bio-prosthetic aortic valve.

Anteris chief executive officer Wayne Paterson said it was “important that we study the effects of Duravr in this patient population to better understand if the best-in-class results we see in newly treated aortic stenosis is also seen in this difficult to treat population”.

Anteris was up 12 cents or 0.7 percent to \$16.50.

STARPHARMA HOLDINGS

Starpharma says the Dubai-based Itrom Pharmaceutical Group will sell its Vivagel BV for bacterial vaginosis in 13 countries in the Middle East and North Africa.

Starpharma said Itrom specialized “in bringing new and breakthrough pharmaceutical products to the [Middle East and North Africa] region”.

The company said in the Middle East and North Africa region, the prevalence of bacterial vaginosis among the female population of 238 million women was 25 percent “indicating a high need for new effective therapeutic approaches and a significant opportunity for Vivagel BV”.

Starpharma said the agreement had an initial seven-year term, it would manufacture and supply Vivagel BV to Itrom for sale, distribution and marketing, and that it included performance obligations and customary termination provisions.

The company said it expected sales to begin by December 31, 2024, but did not state the commercial terms of the agreement.

Starpharma chief executive officer Cheryl Maley said the company was “pleased to have signed a sales and distribution agreement with Itrom, who have shown great enthusiasm for bringing the product to market quickly and with strong support.”

“In this region, the relatively high prevalence of [bacterial vaginosis] among the female population represents a high unmet need,” Ms Maley said.

Starpharma fell half a cent or 3.1 percent to 15.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has accepted the resubmission of its Sofdra new drug application (NDA), including revisions to its instruction leaflet.

In September, Botanix said the FDA denied its application, requesting printed ‘instructions of use’ changes “followed by another short human factors validation study before the NDA can be resubmitted”; and later, said that the FDA had approved it to resubmit the application (BD: Sep 26, Dec 4, 2023).

In December, the company said it had resubmitted the application for sofipronium bromide gel, or Sofdra, for excessive sweating, to the FDA (BD: Dec 21, 2023).

Today, Botanix said the FDA had designated the resubmission a “class two response” meaning it expected approval following a six-month review by “late June 2024”.

Botanix chief executive officer Dr Howie McKibbin said the resubmission meant that “commercialization activities in preparation for launch can be appropriately designed to ensure a rapid launch of Sofdra, following successful approval from FDA”.

Botanix fell half a cent or 2.9 percent to 17 cents with 6.8 million shares traded.

HERAMED

Heramed says it has a two-year deal for two private obstetricians to use its Heracare and Herabeat pregnancy monitoring platforms and join its medical advisory body.

Heramed said that Perth’s Joondalup Health Campus’ Prof Paul Porter and Dr Kym Jones would support Heracare and engage with clinical teams, as well as healthcare providers, hospitals, private obstetric facilities and general practitioners.

Last year, the company said it had a three-year deal with Joondalup Obstetrics and Gynaecology Group to use Heracare foetal heart monitor (BD: May 11, 2023).

Today, Heramed said Prof Porter and Dr Jones were involved in the Heracare clinical trials, as well as the rollout of Heracare at Joonadalup Health Campus.

Heramed was untraded at 2.5 cents.

VITURA HEALTH

Vitura says it will provide the Brisbane-based Wholelife Pharmacy a specially-branded version of its Canview marijuana healthcare sales management software.

Vitura said Wholelife had 22 shops, with 10 more planned to open in 2024, and provided medication to 14,000 patients as “one of Australia’s leading medicinal marijuana dispensing networks”.

The company said Wholelife patients would register a Wholelife-branded Canview platform, where its customers could access prescriptions and payments.

Vitura said its wholly-owned subsidiary Burleigh Heads Cannabis would distribute Wholelife’s branded products under the agreement, which would be sold and distributed on the Wholelife-branded Canview platform.

Vitura did not state the commercial terms of the agreement.

The company said that the Wholelife branded version of Canview was “expected to increase the volume of products prescribed and distributed through the Canview platform, and the number of patients and prescribers registered and using the platform”.

Vitura was up one cent or 4.1 percent to 25.5 cents.

GENETIC SIGNATURES

Perennial Value Management says it has increased its substantial holding in Genetic Signatures from 20,894,990 shares (12.67%) to 23,399,014 shares (14.19%).

The Sydney-based Perennial said that between January 12 and 18, 2024, it bought and sold shares on market, with the single largest purchase of 656,040 shares on January 18 for \$242,735, or 37.0 cents a share.

Genetic Signatures fell 1.5 cents or 1.85 percent to 82.5 cents.

CONTROL BIONICS

Craig Chapman says he has become substantial in Control Bionics with 10,000,000 shares, or 5.86 percent of the company.

The Brisbane-based Mr Chapman said that with the Weechook Family trust and Nampac Discretionary Trust, he bought the 10,000,000 shares for \$400,000, or 4.0 cents a share, on January 19, 2024.

Last week, Control Bionics said it had placed the \$1,032,396 shortfall from its non-renounceable rights offer at 4.0 cents a share, taking the total raised to \$2.659 million (BD: Jan 21, 2024).

Control Bionics was up 0.6 cents or 14.3 percent to 4.8 cents.

CONTROL BIONICS

Brian Walsh says he has become substantial in Control Bionics with 8,937,151 shares or 5.23 percent of the company.

The Leeton, New South Wales-based Mr Champ said that on November 29, 2023 he bought 8,937,151 shares for \$130,768 or 1.46 cents a share.

According to Commsec, Control Bionics traded at 3.8 cents on November 29, 2023, with its 52-week lowest price 3.3 cents on December 12, 2023.

IMPEDIMED

Impedimed says it is still looking for one or two directors to join its board and “expects to announce the appointment ... in the coming months”.

Impedimed said its board comprised of executive chair and interim chief financial officer McGregor Grant, managing-director and interim chief executive officer Dr Parmjot Bains and three non-executive directors Christine Emmanuel-Donnelly, Janelle Delaney and Andrew Grant.

Impedimed was unchanged at 13.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its medical technology seminar ‘Innovations in Cardiovascular Health: Bridging Technology and Care’ will be held in three weeks.

In March, the Bio-Melbourne Network said that with the Australian Medical Technologies Manufacturing Centre it would host seminars supporting the Victorian medical technology manufacturing sector (BD: Mar 14, 2023).

Today, the Network said the seminar included speakers from Monash University, Monash Heart and Hydrix Medical who would discuss “accelerating cardio-vascular medical technology innovation, manufacturing advancements and how innovators are changing the landscape of healthcare”.

The Network said the event would be held at the conference room, Level 2, Victorian Heart Hospital, 631 Blackburn Road, Clayton on February 13, 2024 from 4:30pm to 7:15pm (AEDT).

For details and registration, go to: <https://bit.ly/3NA1I9S>.