



# Biotech Daily

Wednesday August 31, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: CLINUVEL UP 16%; AMPLIA DOWN 13%**
- \* **VICTORIA, GEOFF CUMMING \$325m PANDEMIC THERAPEUTICS CENTRE**
- \* **ALTHEA REVENUE UP 78% TO \$20.5m; LOSS DOWN 19% TO \$12m**
- \* **MESOBLAST REVENUE UP 37% TO \$14.9m; LOSS DOWN 7.6% TO \$133m**
- \* **HYDRIX REVENUE UP 38% TO \$10.4m; LOSS DOWN 43% TO \$5.5m**
- \* **PHARMAXIS REVENUE DOWN 56% TO \$10m; LOSS DOWN 34.8% TO \$1.9m**
- \* **RHINOMED REVENUE UP 134% TO \$9.1m; LOSS DOWN 39% TO \$5.2m**
- \* **TOTAL BRAIN REVENUE UP 128% TO \$8.4m; LOSS UP 74% TO \$14.5m**
- \* **RESONANCE REVENUE UP 1.3% TO \$3.8m; PROFIT TO \$1.1m LOSS**
- \* **AMPLIA RECEIVES \$1.8m FEDERAL R&D TAX INCENTIVE**
- \* **VANDERBUILT BURN PIT BRONCHIOLITIS TRIAL BACKS 4D MEDICAL**
- \* **BOTANIX REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **EPSILON REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **LBT: RESEARCH BACKS APAS INDEPENDENCE SPEED, ACCURACY**
- \* **OVENTUS ADMINISTRATORS SACK STAFF, CUT COSTS, LOANS**
- \* **MICROBA 'PARTNER EQUIPMENT' DELAYS MAP315 COLITIS TRIAL**
- \* **DAVID PETRIE REPLACES MAYNE DIRECTOR IAN SCHOLES**
- \* **PATRY'S APPOINTS CO SEC STEFAN ROSS DIRECTOR**
- \* **MEDLAB LOSES LAURENCE MCALLISTER**

## MARKET REPORT

The Australian stock market fell 0.16 percent on Wednesday August 31, 2022, with the ASX200 down 11.5 points to 6,986.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded.

Clinuvel was the best, up \$2.81 or 16.2 percent to \$20.17, with 362,254 shares traded.

Imugene and Mesoblast climbed more than eight percent; Antisense was up 7.1 percent; Volpara improved 5.8 percent; Dimerix and Patrys were up more than three percent; Telix rose 2.8 percent; Cochlear, Nanosonics, Opthea, Paradigm and Pro Medicus were up more than one percent; with Proteomics up by 0.5 percent.

Amplia led the falls, down 1.5 cents or 13.0 percent to 10 cents, with 22,175 shares traded.

Alcidion and Kazia lost more than six percent; Oncosil and Resonance were down five percent or more; Cynata fell 4.3 percent; Avita and Starpharma were down more than three percent; Cyclopharm shed 2.1 percent; Actinogen, Pharmaxis, Polynovo and Universal Biosensors were down more than one percent; with CSL, Genetic Signatures, Neuren and Resmed down by less than one percent.

## VICTORIA GOVERNMENT

The Victoria Government says that with Karori Capital chair Geoffrey Cumming it will provide \$325 million for a pandemic preparedness and therapeutics centre.

The State Government said that Mr Cumming would donate \$250 million to the University of Melbourne to establish the centre - the largest philanthropic donation to Australian medical research – and it would provide \$75 million over 10 years to “track the design and development of life-saving treatments”.

A Victoria Government media release said that Mr Cumming was a “Canadian philanthropist and businessman” and Karori Capital was a private investment firm based in New Zealand.

The media release said that the Cumming Global Centre for Pandemic Therapeutics would be based at the Peter Doherty Institute for Infection and Immunity in Parkville before being located at the Australian Institute for Infectious Diseases, expected to open in 2027.

In 2020, the Victoria Government said it would invest \$155 million to establish a \$550 million Institute of Infectious Disease, incorporating the Burnet Institute, in the Parkville precinct to “lead the fight against future pandemics” (BD: Nov 13, 2020).

Today, the State Government said the Centre for Pandemic Therapeutics would focus on developing, testing and commercializing treatments to tackle infectious diseases, and would attract research experts to Victoria.

Victoria Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the “generous donation demonstrates absolute confidence in Victorian medical researchers to develop breakthrough treatments”.

Mr Cumming said the aim of the Centre and his donation was “to minimize the impact of future pandemics and create greater societal resiliency internationally in the decades ahead”.

## ALTHEA GROUP

Althea says revenue for the year to June 30, 2022 is up 77.8 percent or \$20,521,000, with net loss after tax down 19.4 percent to \$12,124,000.

Althea said revenue came from sales and distribution of pharmaceutical and non-pharmaceutical marijuana-based products, with sales in Canada up 425 percent to \$7,961,000, up 17.1 percent in Australia to \$10,446,000, up 87.5 percent in the UK to \$2,062,000 and an initial \$52,000 in Germany.

Althea said diluted loss per share fell 34.05 percent to 3.99 cents, with net tangible assets per share down 17.6 percent to 7.15 cents, and it had cash and equivalents of \$6,205,000 at June 30, 2022, compared to \$6,388,000 at June 30, 2021.

Althea was up 0.3 cents or 3.1 percent to 9.9 cents.

## MESOBLAST

Mesoblast says revenue for the year to June 30, 2022 was up 37.0 percent to \$US10,214,000 (\$A14,880,000) with net loss after tax down 7.6 percent to \$US91,347,000 (\$A133,074,000).

Mesoblast said that revenue came from sales royalties for Temcell for acute graft-versus-host treatment in Japan and Alofisel for perianal fistulas in Crohn's disease in Europe, as well as a milestone payment of \$US1.2 million for Takeda's Alofisel approval in Japan.

The company said diluted loss per share was down 13.8 percent to 14.08 US cents, net tangible asset backing per share fell to negative 10.2 US cents, and it had cash and equivalents of \$US60,447,000 at June 30, 2022, compared to \$US136,881,000 in 2021.

Mesoblast was up seven cents or 8.9 percent to 85.5 cents with 1.8 million shares traded.

## HYDRIX

Hydrix says revenue for the year to June 30, 2022, was up 37.8 percent to \$10,441,120 with net loss after tax down 43.3 percent to \$5,546,389.

Hydrix said revenue was primarily from its services and materials business, with sales of Angel Medical's Guardian heart attack alert down 95.6 percent from \$71,620 to \$3,141.

The company said that diluted loss per share fell 53.4 percent to 3.19 cents, net tangible asset backing per share fell to negative 0.65 cents, and it had cash and equivalents of \$1,940,411 at June 30, 2022, compared to \$6,647,225 at June 30, 2021.

Hydrix was unchanged at 8.6 cents.

## PHARMAXIS

Pharmaxis says revenue for the year to June 30, 2022 was down 56.3 percent to \$9,922,000 with loss down 34.8 percent to \$1,936,000.

Pharmaxis said that the previous year's revenue included a milestone payment of \$14,017,000 from Chiesi Farmaceutici for Bronchitol (BD: Nov 2, 2020).

The company said that sales of Bronchitol for cystic fibrosis were up 11.1 percent to \$5,815,000, with Aridol lung function test sales up 11.5 percent to \$1,611,000, and it received a \$2,000,000 payment for the sale of Bronchitol and Aridol distribution rights to BTC Health (BD: Jul 1, 2021)

The company said diluted loss per share fell 42.9 percent to 0.4 cents, with net tangible assets per share 2.0 cents compared to the previous period's zero cents, and it had cash and equivalents of \$8,937,000 at June 30, 2022, compared to \$18,712,000 in 2021.

Pharmaxis fell 0.1 cents or 1.3 percent to 7.6 cents.

### RHINOMED

Rhinomed says revenue for the year to June 30, 2022, was up 133.8 percent to \$9,104,727 with net loss after tax down 38.9 percent to \$5,281,038.

Rhinomed said that revenue came from its Rhinoswab and Rhinoswab Junior Sars-Cov-2 test swabs, with Rhinoswab revenue totaling "just over \$3 million".

The company said that diluted loss per share was down 40.6 percent to 2.02 cents, with net tangible asset backing per share up 10.8 percent to 1.13 cents.

Rhinomed said that it had cash and cash equivalents of \$1,989,138 at June 30, 2022, compared to \$2,339,616 at June 30, 2021.

Rhinomed was up half a cent or 2.9 percent to 18 cents with.

### TOTAL BRAIN

Total Brain says revenue for the year to June 30, 2021 was up 127.8 percent to \$8,415,593 with net loss after tax up 74.3 percent to \$14,496,718.

Total Brain said revenue from services and access fees associated with its mental health assessment systems was \$3,738,135 compared to the previous year's \$21,785, with software licence fees up 27.4 percent to \$4,677,458.

The company said diluted loss per share was up 44.7 percent to 11.11 cents, net tangible assets per share was 7.67 cents for the previous year's 0.87 cents.

Total Brain said that it had cash and cash equivalents of \$713,499 at June 30, 2022, compared to \$1,427,349 at June 30, 2021.

Total Brain fell 0.1 cents or 2.5 percent to 3.9 cents with one million shares traded.

### RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2022, was up 1.3 percent to \$3,827,976 with last year's profit of \$585,858 turned to a \$1,141,777 loss.

Resonance said revenue came from its magnetic resonance imaging (MRI)-based Ferriscan liver iron concentrate diagnostic, as well as Hepafat and the Cardiac T2\* and clinical trial contracts.

The company said that revenue was up 120.6 percent to \$2,575,512 in North America up 10.9.4 percent to \$327,909 in the Asia-Pacific, but down 62.5 percent to \$920,743 in Europe, the Middle East, and Africa.

The company said that last year's diluted earnings per share of 0.13 cents turned to a diluted loss per share of 0.25 cents, with net tangible assets per share down 15 percent to 1.70 cents.

Resonance said that it had cash and cash equivalents of \$6,783,166 at June 30, 2022, compared to \$8,856,820 at June 30, 2021.

Resonance fell 0.4 cents or 5.4 percent to seven cents.

### AMPLIA THERAPEUTICS

Amplia says it has received \$1,843,004 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Amplia said the rebate related to research and development expenditure for the year to June 30, 2022.

Amplia fell 1.5 cents or 13.0 percent to 10 cents.

## 4D MEDICAL

4D Medical says a 20-patient trial at the Nashville, Tennessee-based Vanderbilt University shows its XV scan technology detects constrictive bronchiolitis.

4D said that XV confirmed diagnosis of constrictive bronchiolitis with less than 0.001 percent uncertainty, “setting it apart from conventional diagnostic methods such as lung imaging and [pulmonary function tests], and as a dramatically safer and less expensive alternative to surgical biopsy”.

The company said that “until now, highly invasive surgical biopsy has been the only way to diagnose [constrictive bronchiolitis], with [computed tomography] and pulmonary function testing appearing normal in this population”.

“The successful trial result opens the door for non-invasive and scalable XV technology to replace surgical biopsy as the preferred diagnostic tool for [constrictive bronchiolitis],” the company said.

4D chief executive officer Prof Andreas Fouras told Biotech Daily that the study was prospective, but used a group of US Army veterans “who already had their disease status, constrictive bronchiolitis, confirmed by biopsy”.

Prof Fouras said that there were 10 subjects and 10 controls.

According to clinicaltrials.gov the trial was titled ‘Utility of a Novel Imaging Algorithm (4DX) for the Diagnosis of Constrictive Bronchiolitis’.

The listing said that constrictive bronchiolitis was an uncommon lung disease that has been described in veterans of conflicts in Iraq and Afghanistan.

“Although these veterans have evidence of constrictive bronchiolitis on lung biopsies, non-invasive tests such as pulmonary function tests are often normal,” the website said.

“This study will determine whether analysis of fluoroscopy images using the 4Dx XV Ventilation Analysis software developed by 4D Medical will be able to detect constrictive bronchiolitis in Veterans better than [pulmonary function tests],” the site said.

4D said the US PACT Act provided \$US280 billion in additional healthcare benefits over 10 years for veterans exposed to burn pits and other harmful toxins and required the Veterans Health Administration to provide toxic exposure screening to each of the nine million Veterans enrolled in its health care program (BD: Aug 11, 2022).

In the company’s media release, Prof Fouras said that “validating the utility of our XV technology in application to [constrictive bronchiolitis] in such a setting of excellence builds upon recent successes confirming the value of our core product to clinicians”.

“With the passage of the PACT Act, it is imperative clinicians be able to rapidly and effectively screen large numbers of veterans safely, efficiently and economically,” Prof Fouras said.

4D Medical was up 18 cents or 36.0 percent to 68 cents with 7.2 million shares traded.

## BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt pending an announcement “in relation to a potential capital raising”.

Trading will resume on Friday September 2, 2022, or on an earlier announcement.

Botanix last traded at eight cents.

## EPSILON HEALTHCARE

Epsilon has requested a trading halt “pending the completion of a capital raising”.

Trading will resume on Friday September 2, 2022, or on an earlier announcement.

Epsilon last traded at 3.3 cents.

## LBT INNOVATIONS

LBT says two publications support its APAS Independence automated plate assessment system for laboratory efficiency gains and faster results.

LBT said that the APAS Independence auto-validated and released results without user intervention and reduced urine culture plate reading times

The company said that a four-month study University of California San Diego was “the first study to independently prove with statistical rigor the positive impact to laboratory processing times as a result of implementing the APAS Independence”.

The article, titled ‘Comparison of the APAS Independence Automated Plate Reader System with the Manual Standard of Care for Processing Urine Culture Specimens’ was published in the journal, Microbiology Spectrum, and an abstract was available at:

<https://pubmed.ncbi.nlm.nih.gov/35972280/>.

LBT said that a second article, titled ‘Microbiology 2.0 – A “behind the scenes” consideration for artificial intelligence applications for interpretive culture plate reading in routine diagnostic laboratories’ was published in Frontiers in Microbiology and was available at: <https://www.frontiersin.org/articles/10.3389/fmicb.2022.976068/full>.

LBT scientific director Dr Steven Giglio said there was “growing acceptance and adoption of digital microbiology in the industry”.

“LBT have been at the forefront of this transition, and high impact articles in leading scientific literature, are critical to establishing credibility and trust with our customers,” Dr Giglio said.

“As the first peer-reviewed paper of its kind, this paper will become a key reference point as the industry advances,” Dr Giglio said.

LBT was up 0.4 cents or 5.3 percent to eight cents.

## OVENTUS MEDICAL (IN ADMINISTRATION)

Grant Thornton as administrators of Oventus says it reduced cost outlays and focused on preserving the value of the key assets and operational infrastructure.

Grant Thornton said that five staff had been retained in Australia to maintain the core operations and it had undertaken a review of trading and was “taking active steps to adjust these arrangements, including the re-negotiation of key trading contracts”.

The company said the measures would “better streamline the Oventus Group's workflow and improve the gross margin of the Oventus products”.

Grant Thornton said some in-house functions would be outsourced to third parties to lower costs, leases for under-used premises had been terminated in Australia and the US, operations in Canada were scaled back, and the group's US-based chief executive officer and chief financial officer had “exited” with management returned to Australia.

In January, Oventus said it had employed John Cox as its chief executive officer, starting on \$US375,000 (\$A534,257) (BD: Jan 31, 2022).

Grant Thornton said that Exvent studies in the US and Canada were being progressed.

The administrators said they were working on a “re-capitalization strategy with the aim of returning value to shareholders”, with a capital raise to coincide with a deed of company arrangement to “facilitate a return to creditors”.

Grant Thornton said it expected to receive details of the conditions the ASX would require for Oventus to be reinstated to trading.

The company said that Oventus had three convertible loan agreements, totalling \$300,000 with a further \$100,000 convertible loan expected, and the financial report for the year to June 30, 2022 would be delayed and was expected to be lodged by September 30, 2022.

Oventus last traded at two cents.



### [MICROBA LIFE SCIENCES](#)

Microba says its “partner in Europe ... [has] issues with a piece of processing equipment” and its trial of MAP315 for ulcerative colitis has been delayed until April 2023.

In May, Microba said it had appointed Brisbane’s Beyond Drug Development as the contract research organization for its phase I trial of MAP315, for ulcerative colitis, the most prevalent form of inflammatory bowel disease, with Melbourne’s Nucleus Network the preferred clinical trial site, and the Basel, Switzerland-based Bacthera to provide clinical doses of MAP315 for the randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of MAP315 in healthy adults, expected to begin “in late 2022” (BD: May 27, 2022).

Today, the company said the processing equipment was required for current good manufacturing practice production of clinical material, and the partner required additional time for implementation and qualification, extending the timeline to receive the material to begin dosing the phase I trial from December 2022 to April 2023.

The company said it was preparing for an ethics submission and clinical testing under the Australian Therapeutic Goods Administration clinical trials notification scheme and would submit a request for a pre-investigational new drug meeting application to the US Food and Drug Administration.

Microba fell one cent or 4.8 percent to 20 cents.

### [MAYNE PHARMA](#)

Mayne says David Petrie will replace deputy chair Ian Scholes as a director, effective September 1, with Mr Scholes retiring at the end of September.

Mayne said Mr Petrie was currently the Stratford Advisory Group principal, and was previously Merrill Lynch Melbourne managing-director and head of investment banking. The company said Mr Petrie held a Bachelor of Laws and a Bachelor of Commerce from the University of Melbourne.

Mayne Pharma chair Frank Condella said he thanked Mr Scholes “for his outstanding commitment and service to Mayne Pharma over the last 15 years”.

Mayne was up two cents or 7.1 percent to 30 cents with 20.6 million shares traded.

### [PATRYS](#)

Patrys says it has appointed company secretary Stefan Ross as a non-executive director, effective from today.

Patrys said Mr Ross had more than 10 years of experience in accounting and secretarial services for ASX listed companies and held a Bachelor of Business from the Australian Catholic University.

Patrys was up 0.1 cents or 3.85 percent to 2.7 cents.

### [MEDLAB CLINICAL](#)

Medlab says director Laurence McAllister has resigned to pursue “new interests”.

Medlab fell \$1.14 or 8.6 percent to \$12.06.