



# Biotech Daily

Thursday August 11, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: COMPUMEDICS UP 14%; PHARMAXIS DOWN 4%**
- \* **CSIRO VACCINE, DRUG LABORATORY**
- \* **UNIVERSAL BIO H1 RECEIPTS DOWN 9% TO \$3m; LOSS UP 186% TO \$9m**
- \* **ARGENICA APPLIES FOR ARG-007 TRIAL**
- \* **CLARITY HIRES 3D IMAGING FOR 64-CU SAR-BIS-PSMA**
- \* **4D MEDICAL WELCOMES US PACT ACT ON VETERANS' RIGHTS, 4D IMAGING**
- \* **ALLEGRA COVID-19 REVENUE WARNING**
- \* **ANATARA POULTRY TRIAL 'INCONCLUSIVE'**
- \* **AROA AGM 24% OPPOSE DIRECTORS OPTIONS**
- \* **COMPUMEDICS 4m SHARE BUYBACK**
- \* **MEMPHASYS EXTENDS 'CAPITAL RAISING' SUSPENSION**
- \* **OPTHEA REQUESTS 'FUNDING' TRADING HALT**
- \* **PARADIGM REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **PROTEOMICS REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **QUEST REDUCES TO 6.7% OF KAZIA**
- \* **INVESTORS MUTUAL BELOW 5% IN MAYNE**

## MARKET REPORT

The Australian stock market was up 1.12 percent on Thursday August 11, 2022, with the ASX200 up 78.3 points to 7,071.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and four were untraded. All three Big Caps were up.

Compumedics was the best, up three cents or 14.3 percent to 24 cents, with 75,359 shares traded. Actinogen, Prescient and Starpharma climbed more than six percent; Resonance rose 5.6 percent; Genetic Signatures and Nova Eye improved four percent or more; Avita, Mesoblast and Micro-X were up more than three percent; Cochlear, Cyclopharm, Medical Developments, Polynovo, Telix and Volpara rose more than two percent; Amplia, Clinuvel, Nanosonics, Resmed and Universal Biosensors were up more than one percent; with CSL and Pro Medicus up by less than one percent.

Pharmaxis led the falls, down 0.3 cents or 3.85 percent to 7.5 cents, with 302,536 shares traded. Atomo, Impedimed and Next Science lost more than three percent; Alcidion, Antisense and Orthocell shed more than two percent; Immutep, Imugene and Neuren were down more than one percent; with Emvision down by 0.6 percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION  
FEDERAL GOVERNMENT, VICTORIA GOVERNMENT, MTP CONNECT

The CSIRO says a \$23.1 million laboratory at Melbourne's Monash university will "bolster the nation's ability to produce vaccines and drug treatments onshore".

The CSIRO said the National Vaccine and Therapeutics Lab would turn vaccine and drug candidates into products to be manufactured in large quantities for clinical trials.

"The ability to do this in Australia, rather than needing to go overseas, has been the missing link in Australia's biomedical science sector being able to produce vaccines and drugs here," the Organisation said in a media release.

The CSIRO says the laboratory was commissioned following the success of a pilot facility in the early stages of the Covid-19 pandemic, when it scaled-up vaccine candidates that had been developed onshore as part of a national strategy to combat this emerging threat.

The Organisation said the facility was funded by the Federal and Victoria Governments and officially opened by the Federal Minister for Industry and Science Ed Husic.

CSIRO chief executive Dr Larry Marshall said that most vaccine and drug candidates previously needed to be sent overseas to be produced in large quantities for clinical trials, "adding burdensome costs that have crushed many Australian businesses and researchers as the invention languishes on the lab bench".

Dr Marshall said the laboratory would help companies bridge the 'valley of death' between the laboratory bench and making a product that had an impact on people's lives.

The CSIRO said that the laboratory provided "a significant boost to Australian translational research capacity and advanced manufacturing in biotechnology to benefit ... [companies] and the research sector".

CSIRO biomedical manufacturing research director Prof Susie Nilsson said the facility was "designed and constructed in accordance with the current licencing requirements of the Australian Therapeutic Goods Administration to produce a variety of biologics, including recombinant proteins and peptides, and viral products".

"Our team at the lab will produce drugs in partnership with local industry and enable our partners to progress to both phase one and phase two clinical trials in Australia, and also has the necessary accreditation for Australian companies to participate in clinical trials globally," Prof Nilsson said.

MTP Connect said that the facility gave companies and researchers "access to accredited manufacture of biologics to the standard required for in-human studies and will see a boost to Australia's capability to manufacture vaccine and drug candidates".

MTP Connect said the development of the facility was supported with \$1.1 million from its Growth Centre Project Fund and leveraged a further \$3.4 million in industry co-contributions and state government funding, bringing the total value of the MTP Connect contribution to \$4.5 million.

MTP Connect chair Sue MacLeman said the facility "fills a gap in biomedical capabilities for sovereign advanced manufacturing ... strengthens Australia's biologics advanced manufacturing capability and will support increased productivity and competitiveness".

"Manufacturing onshore can be faster and more cost effective than manufacture overseas, meaning more Australian discoveries could move from the bench, through clinical trials and eventually into the clinic - leading to better health outcomes for patients and more economic value from Australian research being captured in Australia," Ms MacLeman said.

MTP Connect chief executive officer Stuart Dignam said the laboratory "started with a business plan, lab design and purchase of equipment [and] has led to the opening of a facility of national importance for Australia's biomedical efforts and our clinical trials industry".

## UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2022, fell 9.1 percent to \$3,083,787 with net loss after tax up 185.9 percent to \$9,178,939.

Universal Biosensors said that revenue from sales of its Xprecia Stride coagulation analyzer test strips to Siemens was down slightly due to Siemens running existing stock levels down, but was somewhat offset by increasing revenue from its wine testing devices. The company said that revenue from services was down 11.6 percent to \$725,345 compared to the previous corresponding period.

Universal Biosensors said its research and development spend was up 124.7 percent to \$6,326,574 for the six months to June 30, 2022, compared to the previous corresponding period.

The company said that of the \$6.3 million total research and development expenditure, \$4.5 million was “non-recurring and a one-time investment in the veterinarian blood glucose product, Xprecia Prime, including clinical and development trials, Tn antigen biosensor and Sentia products.

Universal Biosensors said diluted loss per share was up 150 percent to 5.0 cents; net tangible asset per security was up 25 percent to 15 cents a share; and it had cash and equivalents of \$31,556,056 at June 30, 2022 compared to \$18,864,249 at June 30, 2021. Universal Biosensors was up half a cent or 1.5 percent to 33 cents with 1.7 million shares traded.

## ARGENICA THERAPEUTICS

Argenica says Adelaide’s Bellberry will review an ethics submission for its 32-healthy person, ascending-dose, phase I trial assessing the safety and tolerability of ARG-007. Argenica said it expected review of its submission for the randomized, controlled trial of intravenous ARG-007 to take between four and six weeks.

Argenica managing-director Dr Liz Dallimore said the company was “excited to submit our ethics application ... for approval of this first-in-human study of ARG-007”.

“The culmination of close to 10 years of scientific research on our lead candidate has led us to this moment and we are looking forward to the outcome of the submission in due course,” Dr Dallimore said.

Argenica said AG-007 had been designed to reduce brain tissue death following a stroke. Argenica was up six cents or 13.3 percent to 51 cents.

## CLARITY PHARMACEUTICALS

Clarity says the Little Rock, Arkansas-based 3D Imaging will supply it with 64-copper SAR-bis-PSMA (prostate-specific membrane antigen).

Clarity said the agreement would increase production and allow for “excess capacity in the supply of Clarity’s differentiated PSMA product in advance of two potential diagnostic phase III trials in the US, ensuring reliable and seamless supply”.

The company said that 3D Imaging would manufacture and distribute the 64-u SAR-bis-PSMA from Little Rock, located close to the FedEx hub.

Clarity executive chair Dr Alan Taylor said that the company was distinguished “from the current generation of radio-pharmaceuticals that have many logistical limitations due to very short half-lives”.

“In a field with all too many unforeseen product-supply limitations and outages, we are building a reliable supply network with excess capacity,” Dr Taylor said.

Clarity was up 1.5 cents or 2.4 percent to 63 cents.

## US WHITE HOUSE, 4D MEDICAL

The US White House says President Joe Biden has signed into law the Pact Act for the expansion of benefits and services for toxicity-exposed veterans.

President Biden said that passage and signing of the 'Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (Pact) Act' was "the least we can do for the countless men and women, many of whom may be in the room for all I know, who suffered toxic exposure while serving their country".

4D Medical head of communications Clinton Rodgers told Biotech Daily the company welcomed the signing into law of the Pact Act which included the use of four-dimensional imaging for a range of respiratory illnesses.

In July, 4D Medical said that the Pact Act, in conjunction with another bill currently before the US congress, called for the evaluation of four-dimensional lung function x-ray, and it was the only known company to provide that service (BD: Jul 27, 2022).

4D Medical said that passage of both the Pact Act and 'HR 8294 Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2023' would fund a program to evaluate "emerging technology using existing x-ray imaging equipment to derive four-dimensional models of lung function".

Overnight in the US, President Biden said that the Pact Act addressed the needs of US veterans of the wars of Iraq and Afghanistan caused by "breathing in toxic smoke from burn pits".

"I was in and out of Iraq over 20 times, and in Fort Basra and all those ... places," President Biden said.

"Burn pits the size of football fields that incinerated wastes of war, such as tires, poisonous chemicals, jet fuel, and so much more," President Biden said.

President Biden said that breathing the toxic fumes caused symptoms including headaches, numbness, dizziness and cancer and his son Beau Biden was one of the servicemen to suffer for it.

"The Pact Act is the least we can do for the countless men and women ... who suffered toxic exposure while serving their country," President Biden said.

He said the Act "expands access to healthcare and disability benefits for veterans harmed by toxic exposure ... [and] empowers the Department of Veterans Affairs to move quickly to determine a service member's illness and related military service to see if they qualify". President Biden said the Pact Act meant access to life insurance, home loan insurance, tuition benefits and help with healthcare.

"It means new facilities, improved care, more research and increased hiring and retention of healthcare workers treating veterans," President Biden said.

"I have directed the Department of Veterans Affairs to treat all 23 presumptive conditions as - in this law - as applicable the moment I sign this Bill, and I'm urging the veterans of those decades of war to promptly file for your claims," President Biden said.

A White House 'Fact Sheet' said the legislation "removes the need for certain veterans and their survivors to prove service connection if they are diagnosed with one of 23 specific conditions".

"This greatly reduces the amount of paperwork and need for exams that veterans diagnosed with one of these conditions must complete before being granted access to health care and disability compensation," the White House said.

"This list includes 11 respiratory related conditions, along with several forms of cancer," the White House said.

The 'HR 8294 Appropriations Act, 2023' has been passed by the US House of Representatives and is currently under consideration by the US Senate.

4D Medical was up one cent or 1.5 percent to 66 cents.

### ALLEGRA ORTHOPAEDICS

Allegra says it has revised its forecast revenue to \$2,900,000 due to “Covid-19 challenges”, but expects its trading loss to remain about \$900,000.

In January, Allegra said it expected 2022 revenue of between \$3,200,000 to \$3,500,000 (bd: Jan 19, 2022).

Today, the company said the impacts on revenue had been largely the result of ongoing cancellation of elective surgeries “caused by nursing shortages, bed shortages and Covid-19 related illnesses”.

Allegra was untraded at 17 cents.

### ANATARA LIFESCIENCES

Anatara says the trial of its bromelain-based poultry feed formulation were “inconclusive” and discussions on future development were “ongoing”.

In an ‘Operational update’, Anatara said that a poultry trial “with a leading [unnamed] Australian producer using ANR-pf in broilers ... delivered mixed results that suggested to both parties that a commercial product pathway requires further investigation”.

The company said that the need to address anti-microbial resistance across animal production remains a strong focus in the industry.

Anatara said that it had been “re-contacting more than 300 potential participants” for a broader gastrointestinal re-programming (Garp) complementary medicine trial criteria of irritable bowel syndrome (IBS) modified to exclude only the constipation subset.

The company said the change “led to an improvement in conversion from interest to enrolment”.

Anatara said that participant numbers were “short of the recruitment milestone anticipated by this point after the broadening of IBS patient criteria” but there were about 18 of the required 90 patients for the interim readout enrolled.

Anatara executive chair Dr David Brookes said that “Anatara, like many other biotechnology companies, has been challenged with trial recruitment over the last year or so”.

“While being disappointed to be behind in our anticipated recruitment milestone following the broadening of the Garp trial criteria, our team is confident that the findings of the continuing review process will allow ongoing momentum with enrolment,” Dr Brookes said. Anatara fell half a cent or 6.7 percent to seven cents.

### AROA BIOSURGERY

Aroa says its annual general meeting voted up to 24 percent dissent against the grant of options to directors.

Aroa said the resolutions to grant the options to Steven Engle, Philip McCaw, John Pinion, and John Diddams were opposed by more than 23 percent of votes with Mr Diddams options opposed by 29,693,734 votes (23.63%), with 95,984,151 votes (76.37%) in favor.

The company said the grant of options to chair James McLean was opposed by 12.12 percent of votes, long term incentive options for managing-director Brian Ward were opposed by 11.3 percent of votes, with the re-election of Mr McLean and Mr Engle and the auditor’s remuneration passed easily.

According to its annual report, Aroa had 342,724,208 shares on issue, meaning that the opposition towards granting performance rights to Mr Diddams amounted to 8.7 percent of the company, sufficient to requisition extraordinary general meetings.

Aroa was up 1.5 cents or 1.8 percent to 84.5 cents with 1.2 million shares traded.

### COMPUMEDICS

Compumedics says it will conduct an on-market buyback of up to 4,000,000 shares, starting on August 29, 2022 and running for up-to 12 months.

Compumedics said the “current share price does not accurately reflect the underlying value of the company’s assets and the share buy-back represents an opportunity to add value to the remaining shares on issue”.

The company said the timing and number of shares to be bought was subject to market conditions; and according to its most recent filing it had 177,162,948 shares on issue. Compumedics was up three cents or 14.3 percent to 24 cents.

### MEMPHASYS

Memphasys has requested a further extension to its voluntary suspension ‘pending release of an announcement to the ASX with respect to the capital raising’.

In July, Memphasys requested a trading halt pending an announcement “regarding a capital raising” and later requested a suspension “regarding a court application concerning ... cleansing notices” (BD: 27, 29 Jul, 2022).

Today, the company said it anticipated the announcement regarding the capital raising to be released “on or around August 15, 2022”.

Memphasys last traded at 4.5 cents.

### OPTHEA

Opthea has requested a trading halt pending an announcement “in relation to two connected transactions”: a non-dilutive funding agreement and an equity raising.

Trading will resume on August 15, 2022.

Opthea last traded at \$1.39.

### PARADIGM BIOPHARMACEUTICALS

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

Trading will resume on August 15, 2022.

Paradigm last traded at \$1.985.

### PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt “pending the release of an announcement regarding a capital raising”.

Trading will resume on August 15, 2022.

Proteomics last traded at 98 cents.

### KAZIA THERAPEUTICS

Quest Asset Partners says it has reduced its substantial holding in Kazia from 11,101,216 shares (8.80%) to 9,366,195 shares (6.72%).

The Sydney-based Quest said that between October 28, 2020, and August 10, 2022, it bought 2,110,832 shares for \$2,776,173 or \$1.315 a share and sold 3,831,998 shares for \$2,829,603, or 73.8 cents a share.

Kazia was unchanged at 25 cents.

## MAYNE PHARMA

Investors Mutual says it has ceased to be a substantial shareholder in Mayne Pharma, selling 43,470,870 shares in the company.

The Sydney-based Investors mutual said that it sold the shares between June 27 and August 10, 2022, it sold shares in Mayne, with the largest single sale 2,897,171 shares for \$1,094,261, or 37.8 cents a share.

Mayne was up two cents or 5.6 percent to 37.5 cents with 14.9 million shares traded.