



# Biotech Daily

Tuesday September 13, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH EVEN: GENETIC SIGNATURES UP 7%  
- CYNATA DOWN 9%**
- \* **IMUGENE TO RAISE \$80m FROM 2 UNNAMED INSTITUTIONS**
- \* **PARADIGM RIGHTS RAISE \$20.3m; TOTAL \$66m**
- \* **LBT SELLS 7 APAS INDEPENDENCE UNITS IN 8 MONTHS**
- \* **ELLUME \$140m DEBTS, NEXT STEPS**
- \* **OVENTUS ADMINISTRATORS AIM TO RELIST, CAPITAL RAISING**
- \* **AVITA: 'RECELL RE-PIGMENTS 56% OF VITILIGO LESIONS'**
- \* **NEUREN: US FDA ACCEPTS TROFINETIDE RETT NDA FOR REVIEW**
- \* **ADHERIUM, CARECENTRA PARTNER FOR COPD, ASTHMA**
- \* **INVION TELLS ASX: 'DATA NEEDED ANALYSIS BEFORE RELEASE'**
- \* **ALLAN GRAY TAKES 13.8% OF STARPHARMA**
- \* **SHENASABY, CALLAHANS DILUTED TO 6.5% OF BOTANIX**
- \* **GAYLE MCGARRY, CAPERI BELOW 5% OF BOTANIX**
- \* **IMMUTEP CSO, CMO PROF FRÉDÉRIC TRIEBEL EXECUTIVE DIRECTOR**
- \* **AUSCANN TO LOSE CEO LAYTON MILLS**
- \* **HERAMED APPOINTS EMILY SLADE DIRECTOR**
- \* **AROA APPOINTS DR CATHERINE MOHR DIRECTOR**
- \* **CLARITY APPOINTS PROF JEFFREY NORENBERG CSO**

## MARKET REPORT

The Australian stock market was up 0.65 percent on Tuesday September 13, 2022, with the ASX200 up 45.2 points to 7,009.7 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and three were untraded.

Genetic Signatures was the best, up six cents or 6.6 percent to 97 cents, with 10 (ten) shares traded; followed by Avita up 9.5 cents or 5.2 percent to \$1.925 with 326,470 shares traded.

Amplia, Clinuvel, Impedimed and Neuren improved more than four percent; Alcidion and Dimerix were up more than three percent; Imugene and Nanosonics rose two percent or more; Compumedics, Next Science and Pro Medicus were up more than one percent; with Cochlear, Mesoblast, Opthea, Resmed and Telix up by less than one percent.

Cynata led the falls, down 3.5 cents or 9.1 percent to 35 cents, with 54,312 shares traded.

Universal Biosensors lost 7.1 percent; Kazia and Patrys were down four percent or more; Orthocell fell 3.75 percent; Actinogen, Medical Developments, Oncosil and Prescient shed more than two percent; Antisense, Emvision and Pharmaxis were down more than one percent; with CSL, Paradigm, Proteomics and Volpara down by less than one percent.

## IMUGENE

Imugene says it has “firm commitments” to raise \$80 million in a placement at 20 cents a share to two unnamed institutional investors.

Imugene said the offer price of 20 cents a share was an 11.1 percent discount to the last close on September 9, and a 12.0 percent discount to the 5-day volume-weighted average price up to and including September 9, 2022.

The company said that the two institutional investors would receive one option for each two shares purchased exercisable at 33 cents each, by March 31, 2026.

Imugene said that the shares issued in the placement were 6.8 percent of its existing shares on issue.

The company said that if all 200 million options were exercised, it would provide a further \$66 million in funding.

Imugene said that capital raised in the placement would be used to “provide an extended runway for Imugene’s deep pipeline of clinical programs”.

Imugene managing-director Leslie Chong said the placement would “strengthen the company’s balance sheet and give ourselves an unimpeded runway to progress the numerous clinical trials that we have ongoing”.

“By having these multiple shots on goal well-funded gives them the best chance of success, which we expect will translate into shareholder value and improved patient outcomes,” Ms Chong said.

The company said that the Melbourne-based Bell Potter Securities was the lead manager for the placement.

Imugene was up half a cent or 2.2 percent to 23 cents with 39.7 million shares traded.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says shareholders applied for about 23 percent of its underwritten \$20.3 million one-for-15 rights offer at \$1.30 a share, taking the total raised to \$66 million.

Last month, Paradigm said it expected to raise \$45.7 million in an institutional placement and a further \$20.3 million in the underwritten rights offer (BD: Aug 15, 2022).

The company said the funds were for its phase III program and new drug application related activities, business and product development activities, and working capital.

Today, Paradigm said that the shortfall would be placed by the underwriter, the Melbourne-based Bell Potter Securities, or sub-underwriters.

Paradigm fell one cent or 0.8 percent to \$1.28.

## LBT INNOVATIONS

LBT says that with subsidiary Clever Culture Systems it has sold seven Apas automated plate assessment system Independence instruments this year.

Previously, LBT chief executive officer Brent Barnes told Biotech Daily that the standard retail price per unit was \$US300,000 (\$A436,566) with a further \$US20,000 (\$A29,103) per year licence fee, but that varied with each deal (BD: May 18, 2021).

In August, the company said that revenue for the year to June 30, 2022 was up 37.4 percent to \$2,900,000.

Today, LBT said it had shipped and sold its fifth Apas instrument to the Waltham, Massachusetts-based Thermo Fisher Scientific, as part of the initial purchase arrangement announced in March (BD: Mar 16, 2022).

The company said that it completed a direct sale of an Apas Independence to the Schüttorf-based LADR Group, which operated more than 80 laboratories in Germany.

LBT managing-director Brent Barnes said “coming out of the Covid-19 global pandemic and with global markets re-open, it’s really exciting to see the commercial progress made over the last nine months”.

LBT fell 0.4 cents or 4.65 percent to 8.2 cents.

## ELLUME (IN ADMINISTRATION)

Documents provided by Ellume’s voluntary administrators, the Sydney-based FTI Consulting, say the company has \$140 million in liabilities (BD: Sep 1, 2022).

The FTI creditors meeting slide deck said that assets included \$1.5 million in cash, \$37 million in plant and equipment, with inventory to be confirmed, with liabilities including \$89 million for convertible noteholders, \$49 million for creditors and \$1.69 million in employee entitlements for a “headcount” of 215 staff.

Ellume said its US business was not subject to the voluntary administration and would continue to trade its business as usual until further notice.

The FTI slide deck said that it expected to hold a second creditors meeting by October 7, unless extended, to decide to wind-up the company, execute a deed of company arrangement or end the administration.

FTI said it would continue to operate the business on a “business as usual” basis to either recapitalize via a deed of company arrangement or going concern sale.

The administrators said they had liaised with the US subsidiary, Ellume USA LLC, regarding a contract with the US Department of Defence and ongoing production and expected a response from the Department of Defence by September 15, 2022.

FTI said there would be an extension of the convening period, if required.

Ellume is a public unlisted company.

## OVENTUS MEDICAL (IN ADMINISTRATION)

Oventus administrators Grant Thornton says a group of new and existing investors hope to recapitalize the business and remain listed on the ASX.

In June, Oventus said it had appointed Grant Thornton's Michael McCann and Graham Killer as voluntary administrators (BD: Jun 14, 2022).

In August, Grant Thornton said it had reduced costs and was preserving the value of assets and infrastructure, with five staff retained in Australia (BD: Aug 31, 2022).

Last night, Grant Thornton said it sought expressions of interest to buy Oventus and/or its assets and "the preferred interest came from a party representing various new and existing shareholders wishing to recapitalize the companies and maintain the business whilst operating through the existing structure including continuing the ASX listing".

The administrators said they were working with the preferred party on the recapitalization strategy with the aim of paying in full the claims of the creditors.

Grant Thornton said that a capital raise would be concurrent with a deed of company arrangement to be presented to creditors and voted on at the second meeting.

The administrators said the creditors meeting was expected to be held by December 2022, subject to the capital raising timetable and to fund trading and costs associated with recapitalization Oventus had four convertible loan agreements worth \$400,000.

Oventus last traded at two cents.

## AVITA MEDICAL

Avita says 56 percent of an undisclosed number of Recell treatments in its pivotal trial for vitiligo resulted in re-pigmentation of more than 50 percent of the treated area.

In August 2021, Avita said it had amended its pivotal trial of Recell for the re-pigmentation of stable vitiligo lesions, and that the new single-arm design would evaluate 23 subjects at 15 sites compared to the previously three-arm study of 84 subjects (BD: Aug 17, 2021).

Today, Avita said that the study compared re-pigmentation using Recell and narrow-band ultra-violet-B light with narrow-band ultra-violet-B light alone.

According to [www.clinicaltrials.gov](http://www.clinicaltrials.gov), Avita was the sponsor for a 49-patient study, titled 'A Prospective Blinded Within-Subject Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of Recell for Repigmentation of Stable Vitiligo Lesions'.

Avita said re-pigmentation was evaluated after six months of treatment and found that 56 percent of Recell treatments, versus 12 percent of control treatments, resulted in re-pigmentation of more than 50 percent of the treated area.

The company said that 36 percent of Recell treatments, compared to zero percent of control treatments, resulted in re-pigmentation of at least 80 percent of the treated area, "establishing super-superiority for the primary endpoint ( $p < 0.025$ )".

Avita said the results were the first from a US clinical trial and would "provide a foundation for communicating favorable clinical benefit" for a US Food and Drug Administration approval for a pre-market approval supplement for vitiligo later this year.

Avita chief executive officer Dr Mike Perry said vitiligo often had a severe impact on quality of life and was a therapeutic area with very limited treatment options.

"We are excited by our top-line data, as we are now closer to our goal of providing patients with a durable, clinically meaningful, one-time treatment for re-pigmentation," Dr Perry said. "Recell has the potential to address the unmet medical need for an estimated 1.3 million people in the US who suffer from stable vitiligo, and further, we envision a potential opportunity for Recell as part of a multi-modal treatment plan for patients achieving stability with [Janus kinase] inhibitor treatment."

Avita was up 9.5 cents or 5.2 percent to \$1.925.

## NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has accepted for review a new drug application for trofinetide for Rett syndrome, filed by Acadia Pharmaceuticals.

In July, Neuren said that its US partner, the San Diego, California-based Acadia had submitted a new drug application for trofinetide for Rett syndrome in adults and paediatric patients (BD: Jul 19, 2022).

Last year, the company said that a 187-patient, 12-week, doubled-blind, randomized, placebo-controlled, phase III trial of trofinetide showed statistically significant benefit for Rett syndrome compared to placebo (BD: Dec 7, 2021).

Today, Neuren said that the FDA had granted a priority review and assigned a prescription drug user fee act action date of March 12, 2023 and indicated that it would not hold an advisory committee meeting.

Neuren said that Acadia had exclusive rights to develop and commercialize trofinetide in North America but that it would receive potential milestone payments of up to \$US455 million (\$A663 million), double-digit percentage royalties on net sales, and one third of the market value of a rare paediatric disease priority review voucher if awarded by the FDA on approval of a new drug application for trofinetide.

The company said that if the NDA was approved it expected to earn \$118 million, plus royalties on net sales over 2022 and 2023, comprising a milestone payment in 2022 of \$US10 million, a payment in 2023 of \$US40 million following the first commercial sale of trofinetide in the US, and \$33 million in 2023 as its one third share of the market value of the priority review voucher.

Neuren said it would receive “double digit percentage royalties” on net sales of trofinetide in all indications and up to \$US350 million for a series of four thresholds of total annual net sales for all indications.

Neuren was up 27 cents or 4.3 percent to \$6.50 with 829,737 shares traded.

## ADHERIUM

Adherium says it has a partnership to integrate its Hailie monitoring platform into Carecentra’s artificial intelligence-driven ‘behaviour shaping’ platform.

Adherium did not disclose the commercial terms of the partnership but said it would use the New York-based Carecentra’s artificial intelligence (AI) platform, Mymobemap, and its Hailie platform to improve chronic obstructive pulmonary disease (COPD) and asthma care by creating a “transformative” disease management system.

The company said that Carecentra’s artificial intelligence platform used a “range of data points to sense rising health risks to nudge the patient and respiratory care teams to control exacerbations and improve outcomes”.

Adherium said patients would be connected to a remote monitoring system to capture data from multiple sources, including its inhaler sensors and the Carecentra system would combine “clinical, social, environmental, and behavioral data with digital biomarkers from devices to enable the [artificial intelligence] to interpret rising levels of risk”.

Adherium chief executive officer Rick Legleiter said that chronic obstructive pulmonary disease and asthma symptoms and breathing issues could be unpredictable and “digital tools to help patients and physicians stay connected and share real-time information is what connected care can do to transform lives”.

“Adherium’s partnership with Carecentra will leverage previously unavailable data for patients that need help before they have exacerbations and potentially find themselves in an emergency room or hospital,” Mr Legleiter said.

Adherium was untraded at 0.8 cents.

## INVION

Invion has told an ASX aware query that while it was aware of Photosoft therapy data, it needed time to analyze the data before releasing it to the market.

Last week, the company said its Photosoft light therapy showed a more than 99 percent inhibition of Zika virus, in vitro, and that a study showed Photosoft compounds to be effective against the virus and more than “100 times the activity” of the antibiotic monensin, which, though active against Zika virus, could not be used in humans due to its toxicity (BD: Sep 8, 2022).

In the aware query, the ASX asked Invion if it was aware of the results of its Photosoft study prior to releasing the announcement on September 8, and if it was, then why did it not release the information to the market at an earlier time?

Today, Invion said that while it was aware of the “preliminary raw data” on August 26, “significant further work was required to be undertaken by Invion to analyze and validate the raw data and conclusions with the clinical research organization which is located in Europe”.

The company said that the further work was completed “after market close on September 7 ... [and was] promptly released before market open on September 8”.

Invion was up 0.2 cents or 16.7 percent to 1.4 cents with 3.96 million shares traded.

## STARPHARMA

Allan Gray Australia says it has increased its substantial share-holding in Starpharma from 50,210,598 shares (12.32%) to 56,264,591 shares (13.78%).

The Sydney-based Allan Gray said that between April 27 and September 8, 2022, it bought 9,581,027 shares for \$6,258,667 or an average of 65.3 cents a share and sold 3,527,034 shares for \$2,625,441 or an average of 74.4 cents a share.

Starpharma was unchanged at 58 cents with 1.1 million shares traded.

## BOTANIX PHARMACEUTICALS

Perth’s Shenasaby Investments Pty Ltd says its 70,738,187 share-holding in Botanix has been diluted from 7.33 percent to 6.52 percent.

The substantial shareholder notice said that the holders were Catherine Callahan, Elise Horgan and Shenasaby Investments Pty Ltd.

Botanix executive director Matthew Callahan told Biotech Daily that Ms Callaghan was his spouse and Ms Horgan was the director of his investment company, Shenasaby, that held Botanix shares.

Earlier this month, Botanix said it had “firm commitments” to raise up to \$7.5 million in an oversubscribed placement at 6.6 cents a share (BD: Sep 2, 2022).

Mr Callahan said that he had subscribed for shares in the placement, which were pending shareholder approval.

Botanix was unchanged at 6.6 cents with 1.3 million shares traded.

## BOTANIX PHARMACEUTICALS

The Perth-based Gayle McGarry and Caperi Pty Ltd say they have ceased their substantial holding in Botanix.

Ms McGarry and Caperi said on February 3, 2021 they sold 7,000,000 shares for \$1,249,698 or 17.85 cents a share.



### [IMMUTEP \(FORMERLY PRIMA BIOMED\)](#)

Immutep says it has appointed chief scientific and medical officer Prof Frédéric Triebel as an executive director, effective immediately.

Immutep said Prof Triebel had pioneered the LAG-3 field of immuno-oncology and had discovered the LAG-3 gene while working at Institut Gustave Roussy in Paris.

The company said Prof Triebel founded Immutep SA in 2001 and became chief scientific and medical officer in 2014, after it was acquired by the then Prima for \$32 million in cash shares and warrants (BD: Oct 2, 2014).

According to his LinkedIn profile, Prof Triebel held a Doctor of Medicine and a Doctor of Philosophy from Pierre and Marie Curie University in Paris.

Immutep was unchanged at 26.5 cents with 1.6 million shares traded.

### [AUSCANN GROUP](#)

Auscann says 18-month chief executive officer Layton Mills has retired to pursue “other business interests” and will support the company during his six-month notice.

Last year, Auscann said it appointed Cannpal managing-director Layton Mills chief executive officer following its acquisition of Cannpal (BD: Nov 16, 2020; Jan 17, 2021).

Today, the company said that Mr Mills would pursue other business interests and had been “integral to the continued progress of the company’s animal health pipeline, following the acquisition of Cannpal Animal Therapeutics”.

Auscann said it would appoint a new chief executive officer at an “appropriate time”.

Auscann was untraded at four cents.

### [HERAMED](#)

Heramed says it has appointed Emily Slade as a non-executive director, effective immediately.

Heramed said that most recently Ms Slade was head of legal and business affairs at Rendr and had worked for Ansell and Deliveroo Australia.

According to her LinkedIn page, Ms Slade held a Bachelor of Laws and a Bachelor of Arts from Melbourne’s Monash University.

Heramed fell half a cent or 2.6 percent to 19 cents.

### [AROA BIOSURGERY](#)

Aroa says it has appointed Dr Catherine Mohr as a non-executive director, effective from November 1, 2022.

Aroa said Dr Mohr had most recently worked at Intuitive Surgical Inc as head of the intuitive foundation and was previously a consulting assistant professor at the Palo-Alto, California-based Stanford University School of Medicine’s Department of Surgery where she completed her Doctor of Medicine.

The company said that Dr Mohr had served on several boards and also held a Bachelor of Science and a Master of Mechanical Engineering from Cambridge’s Massachusetts Institute of Technology.

Aroa fell half a cent or 0.65 percent to 77 cents.

## CLARITY PHARMACEUTICALS

Clarity says it has appointed Prof Jeffrey Norenberg as its chief scientific officer, effective immediately.

Clarity said that Prof Norenberg had more than 30 years of experience in radio-pharmaceuticals in the biotechnology and academic sectors, and was a professor emeritus at the University of New Mexico Health Science Center.

The company said Prof Norenberg had contributed to 11 patents, had published more than 100 articles and worked in clinical trials of investigational new drugs.

Clarity said Prof Norenberg most recently co-founded Iseek Biopharma and was head of Chemistry at Invicro, a contract research organisation.

Clarity said Prof Norenberg held a Doctor of Pharmacy from the University of Washington in Seattle and a Doctor of Philosophy from Erasmus University in Rotterdam, Netherlands.

Clarity fell 1.5 cents or 2.3 percent to 64 cents.