



Biotech Daily

Thursday May 27, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: ALTERITY UP 11%; IMUGENE DOWN 10%**
- * **VICTORIA APPOINTS MICHAEL KAPEL mRNA CEO**
- * **BLUECHIP BOXTRACKER WINS ISBER GONG**
- * **VOLPARA REVENUE UP 57% TO \$19m, NET LOSS DOWN 14% TO \$16.5m**
- * **DIMERIX: 'FDA TRAVERE FSFG KNOCK-BACK NO CHANGE TO PROGRAM'**
- * **TGA APPROVES 2 USCOM MONITORS**
- * **TGA APPROVES NEXT SCIENCE BLASTX ANTI-MICROBIAL WOUND GEL**
- * **MAYNE: FDA GRANTS NEXTSTELLIS 5-YEAR EXCLUSIVITY**
- * **MTP CONNECT: BIOINTELECT, CICADA FOR REDI INDUSTRY TRAINING**
- * **RECCE: 'R327 EFFICACY AGAINST E COLI, IN-VITRO'**
- * **LITTLE GREEN \$2.5m DEMECAN MARIJUANA ORDER**
- * **INVION TO RELEASE 1.1b VOLUNTARY ESCROW SHARES**
- * **IMMURON REQUESTS 'ACQUISITION' TRADING HALT**
- * **IMUGENE'S PAUL HOPPER, LESLIE CHONG SELL SHARES, EXERCISE OPTIONS**
- * **VANGUARD BELOW 5% OF POLYNOVO**
- * **SMART TOP, XIANHUI MENG INCREASE, DILUTED TO 21% OF USCOM**
- * **POKIES BRUCE MATHIESON INCREASES, DILUTED TO 9.2% OF RESPIRI**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Thursday May 27, 2021, with the ASX200 up 2.4 points to 7,094.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell and 10 traded unchanged.

Alterity was the best, up 0.3 cents or 11.1 percent to three cents, with 8.3 million shares traded. Telix climbed 5.2 percent; Cyclopharm, Optiscan, Paradigm and Volpara improved four percent or more; Proteomics was up 4.8 percent; Next Science, Orthocell and Uscom were up more than three percent; Mesoblast and Opthea rose more than two percent; Actinogen was up 1.1 percent; with Avita, Cochlear, Kazia, Medical Developments, Nanosonics, Polynovo and Pro Medicus up by less than one percent.

Imugene led the falls, down 4.5 cents or 9.6 percent to 42.5 cents, with 326.8 million shares traded. Immutep lost 5.2 percent; Cynata fell 4.1 percent; Patrys was down 3.85 percent; Amplia, Antisense and Proteomics shed more than two percent; both Clinuvel and Compumedics were down 1.25 percent; with CSL, Genetic Signatures, Resmed and Starpharma down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says Michael Kapel has been appointed chief executive officer of mRNA Victoria, which will manufacture messenger RNA (mRNA) coronavirus vaccines. A media release from the Victoria Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that the State Government would provide \$50 million to secure a local supply of mRNA vaccines.

The media release did not say where the facility would be built but did say that Victoria's chief scientist Dr Amanda Caples would convene the mRNA Victoria advisory group to provide advice on steps to support the project.

The State Government said that Mr Kapel would "oversee the establishment of commercial-scale mRNA manufacturing capability in Victoria within the next 12 months". The media release said that Mr Kapel was the former Commissioner to the Americas for the Government of Victoria, where he oversaw a network of trade and investment offices across the US, Canada and South America.

The Government said that "mRNA has not only created a new frontier for vaccine development, but become a promising new weapon in the fight against cancer and other diseases".

"Developing mRNA capability in Victoria will provide vaccine security, support local manufacturing and create a more robust defence against future pandemics," the State Government said.

The State Government said it would work collaboratively with the Federal Government "given its recently announced investment in end-to-end mRNA manufacturing in Australia". Telix Pharmaceuticals chief executive officer Dr Christian Behrenbruch told Biotech Daily that "\$50 million is a good start".

"A production scale mRNA manufacturing facility could be built and operating in 12 months but it would cost more like \$200 million including the staff and operating costs over five years," Dr Behrenbruch said.

Research Australia chief executive officer Nadia Levin told Biotech Daily that while the Victorian approach was "exciting, we need a national approach".

"We have excellent mRNA research being undertaken in New South Wales as well as Victoria, but also in Queensland and Western Australia," Ms Levin said.

"It needs a comprehensive national approach to utilise the research capabilities we already have and to ensure that we have economies of scale," Ms Levin said.

"This is a perfect opportunity to truly collaborate for a key sovereign capability that can set the standard for Australia to capitalize on the future of bio-medicines," Ms Levin said.

BLUECHIIP

Bluechiip says the International Society for Biological and Environmental Repositories (ISBER) has awarded its Boxtracker the 'Outstanding new product award'.

Bluechiip said that ISBER was "the leading network in the ... biobanking and biorepository community".

The company said the Boxtracker was one of nine products evaluated by the panel which selected Boxtracker because it met "a previously unknown market need and drives innovation".

Bluechiip said the Boxtracker and handheld reader were part of its advanced sample management system to "track and monitor samples while being handled outside of storage" to continuously monitor temperature during transport and handling processes while on dry ice or liquid nitrogen.

Bluechiip fell 0.1 cents or 3.3 percent to 2.9 cents with 1.5 million shares traded.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says revenue for the year to March 31, 2021 was up 56.7 percent to \$NZ19,747,000 (\$A18,606,359), with net loss after tax down 14.15 percent to \$NZ17,488,000 (\$A16,482,574).

Volpara said revenue came from the sales of its breast mammography software and subscription contracts.

The company said its diluted loss per share fell 30 percent to 7.0 NZ cents for the year to March 31, 2021, with net tangible asset backing per share fell 8.33 percent to 11 NZ cents, and it had cash and cash equivalents of \$NZ32,230,000 at March 31, 2021 compared to \$NZ31,378,000 at March 31, 2020.

Volpara was up five cents or four percent to \$1.30.

[DIMERIX](#)

Dimerix says a US Food and Drug Administration refusal of 'accelerated approval' to Traverre for focal segmental glomerulosclerosis (FSGS) does not affect its phase III plans. Dimerix said that the San Diego, California-based Traverre Therapeutics announced that "available data from the interim assessment of the Duplex study [in FSGS patients] would not be adequate to support an accelerated approval at this time".

The company said that the decision on Traverre did not affect its ongoing discussions with the FDA for its phase III study design in focal segmental glomerulosclerosis including the appropriate endpoints for accelerated approval.

Dimerix said that in February, Traverre reported positive interim data for its phase III focal segmental glomerulosclerosis study which showed 16 percent more patients achieved proteinuria reduction of 40 percent or more on sparsentan compared to irbesartan, Dimerix said it had reported 29 percent of patients achieving a reduction in proteinuria of 40 percent or more on its DMX-200 with irbesartan when compared to placebo, as well as compared to irbesartan as the standard-of-care.

Dimerix said it "remains eligible" for accelerated approval.

The company said the data on DMX-200 showed an "exceptionally strong" safety profile, with no serious adverse events and its clinical benefits outweighed any risks to date.

Dimerix was unchanged at 22 cents.

[USCOM](#)

Uscom says the Australian Therapeutic Goods Administration has provided "free sales certificates" for two of its haemo-dynamic monitoring devices.

Uscom said the monitoring devices, the Uscom O2 and Uscom Basic monitor were specialized forms of its non-invasive ultrasound cardiac output monitor, the Uscom 1A. Earlier this month Uscom said it had developed the Uscom O2 and Uscom Basic for sale in China (BD: May 4, 2021).

Uscom said at that time that the Uscom O2 was a high-end version of its Uscom 1A ultrasonic cardiac output monitor and included direct measurement of blood oxygen saturation which generated beat-to-beat measures of oxygen delivery - a "complex and critical measure of cardiovascular performance".

The company said its Uscom Basic was a de-featured device which would be marketed against lower functioning technologies in price sensitive tenders.

Today, Uscom executive chair Prof Rob Phillips said the approval was a "result of our internationalization and product diversification strategy initiated two years ago".

Uscom was up half a cent or 3.2 percent to 16 cents.

[NEXT SCIENCE](#)

Next Science says the Australian Therapeutic Goods Administration has cleared its Blastx anti-microbial wound gel for open wounds.

Next Science said the approval would allow the sales of Blastx in Australia as a hydrogel wound dressing for open wounds, with the first sales expected to begin next month.

Last year, the company said it had agreed with Minnesota's 3M to not renew the distribution agreement for Blastx (BD: Nov 23, 2020).

Today, Next Science said Blastx had 510(k) clearance from the US Food and Drug Administration and Conformité Européenne (CE) mark.

The company said Blastx used its Xbio technology to deconstruct the bacterial biofilm and defend the wound from re-colonization while maintaining a moist wound environment for healing, and it could be used in hospitals, pre-hospital, clinics and for homecare on non-healing wounds like diabetic foot ulcers, bed sores and venous leg ulcers.

Next Science was up six cents or 3.3 percent to \$1.87.

[MAYNE PHARMA GROUP](#)

Mayne Pharma says the US Food and Drug Administration has granted its combination oral contraceptive Nextstellis five-year exclusivity as a new chemical entity.

Mayne said the Nextstellis contraceptive pill contained 3mg of drospirenone and 14.2mg of plant-based oestetrol (E4).

The company said that a 2,000-women, phase II study concluded Nextstellis was "an effective oral contraceptive with a predictable bleeding pattern for most women and a low rate of adverse events".

Mayne chief executive officer Scott Richards said the data "validates Nextstellis as being a new and innovative oral contraceptive which is safe and effective and that combines a natural oestrogen (E4) with selective tissue actions together with the proven progestin drospirenone," Mr Richards said.

Mayne was up one cent or 2.8 percent to 37 cents with 7.3 million shares traded.

[MTP CONNECT](#)

MTP Connect says Biointelect and Cicada Innovations will provide training to address skill gaps in the medical technology, biotechnology and pharmaceutical sector.

In March, MTP Connect said it had identified 20 skill gaps in the biotechnology sector and would fund programs to address them (BD: Mar 10, 2021).

Today, the company said that skill gaps in product development and commercialization would be addressed under the Federal Government Researcher Exchange and Development within Industry (REDI) initiative.

MTP Connect said Sydney's Biointelect with ARCS Australia and Biodesign Australia would provide workshops on securing investment and industry collaboration for medical innovations which included therapeutics, medical devices and digital health solutions.

The company said that Sydney's Cicada Innovations would provide training workshops on identifying unmet market needs, understanding clinical context, and developing commercially viable products including therapeutics, medical devices, and digital health products.

MTP Connect said the workshops would be for practitioners, researchers, start-up companies and small and medium-sized enterprises.

The company said the training programs would be conducted in capital cities across Australia and would begin in July and run until December 2021.

RECCE PHARMACEUTICALS

Recce says in a pre-clinical study of R327 has shown efficacy against Escherichia coli bacteria, in -vitro.

Recce said its R327 affected the assembly of bacterial cell division components which required cellular energy to remain assembled and disrupted its “cellular bio-energetics”. The company said current antibiotics rarely retained bactericidal activities against nondividing or stationary-phase bacterial cells, while R327 showed “remarkable” activity against slow-growing bacteria which indicated potential anti-bacterial activity in biofilms. Recce was up 10.5 cents or 10.1 percent to \$1.145.

LITTLE GREEN PHARMA

Little Green says it has received a fourth order worth \$2.5 million from Berlin’s Demecan for about 21,300 units of its high tetrahydrocannabinol cannabis flower.

Last year, Little Green said it had a three-year agreement with Berlin’s Demecan to distribute its cannabis oils and dried cannabis flower (BD: Feb 27, 2020).

Today, the company said it had received orders from Demecan for about 47,800 units worth about \$5.7 million.

Little Green said the delivery was due by the end of the year.

Little Green was up 8.5 cents or 13.9 percent to 69.5 cents.

INVION

Invion says that 1,160,779,413 shares held in voluntary escrow will be released on June 1, 2021.

According to the company’s most recent Appendix 2A application for quotation of securities, Invion had 5,538,042,295 shares on issue.

Invion was unchanged at 1.1 cents with 8.2 million shares traded.

IMMURON

Immuron has requested a trading halt pending an announcement “in connection to a planned acquisition”.

Trading will resume on May 31, 2021 or on an earlier announcement.

Immuron last traded at 16 cents.

IMUGENE

Imugene’s Paul Hopper and Leslie Chong say they sold shares at about 47 cents and 37 cents a share, respectively, and exercised options at about 4.2 cents each.

On Tuesday, Mr Hopper said he had exercised 25 million options for \$1,070,000 or an average of 4.28 cents each, with managing-director Leslie Chong exercising 36.2 million options for \$1,517,000, or an average of 4.19 cents each (BD: May 25, 2021).

After the market closed on Tuesday, Ms Chong said that she sold 4,485,889 shares for \$1,648,431 or 36.75 cents a share.

Today, after the market closed, Mr Hopper said he had an indirect interest in the sale by Deborah Coleman of 1,500,000 shares for \$702,339 or 46.8 cents a share.

Imugene fell 4.5 cents or 9.6 percent to 42.5 cents with 326.8 million shares traded.

POLYNOVO

Vanguard Investments says it has ceased its substantial shareholding in Polynovo with 2,395,513 shares or 4.858 percent.

The Valley Forge, Pennsylvania-based Vanguard Investments said between March 18, 2020 and May 21, 2021 it bought and sold shares with the single largest sale 1,166,237 shares for \$2.77 a share.

Vanguard said that there was “no sell-down activity associated with this change [but the company] ceased to be the investment manager for an institutional client mandate and as a result has ceased to hold a relevant interest in the shares held within that mandate”.

Polynovo was up one cent or 0.4 percent to \$2.62 with two million shares traded.

USCOM

The British Virgin Islands-based Smart Top Overseas says it has increased and been diluted in Uscom from 30,823,649 shares (21.09%) to 32,368,208 shares (20.96%).

The substantial shareholder notice, signed by director Xianhui Meng, said that on December 3, 2019 Smart Top bought 1,000,000 shares for \$144,643 or 14.46 cents a share in a share issue and on May 22, 2020 acquired 544,559 shares on market for \$122,696 or 22.53 cents a share.

In September, Uscom said it would raise \$1,050,000 in a placement to management and major shareholders and would offer \$350,000 in shares to Mr Meng (BD: Sep 30, 2019).

RESPIRI

Investment Holdings says it has increased and been diluted in Respiri from 65,541,554 shares (10.05%) to 66,504,827 shares (9.20%).

Respiri said that major investor Bruce Mathieson was a director of Investments Holdings and the ALH Group.

The Melbourne-based Investment Holdings said between May 18 and 24, 2021 it bought 1,000,000 for \$95,110 or 9.5 cents a share and on October 23, 2020 sold 36,727 shares for \$7,712 or 21 cents a share.

Respiri fell 0.3 cents or 3.4 percent to 8.6 cents.