

Biotech Daily

Monday August 24, 2020

Daily news on ASX-listed biotechnology companies

VALE LIVING CELL'S PROF BOB ELLIOT (3.1.1934 - 21.8.2020)

- * ASX UP, BIOTECH DOWN: PRESCIENT UP 16%;
 - OPTHEA, OPTISCAN DOWN 12.5%
- * CORRECTION: ADALTA
- * SOMNOMED REVENUE DOWN 2.7% TO \$57m, LOSS UP 1013% to \$438k
- * KAZIA: US ORPHAN STATUS FOR PAXALISIB FOR GLIOMA, DIPG
- * 61 MEDICAL, 41 MEDICAL, QUEENSLAND ACCELERATE DEVICES
- * OPTHEA PLANS NASDAQ IPO
- * CYNATA BEGINS CYMERUS COVID-19 TRIAL
- * IDT LISTS VACCINE MANUFACTURE INFO FOR FEDERAL GOVERNMENT
- * BOSCH AUTOMATIC MATERIALS LINE FOR CSL BEHRING
- * AZURE BEGINS FOOD ADDITIVES MANUFACTURE
- * ECOFIBRE COMPLETES \$59m TEXINNOVATE ACQUISITION
- * EXOPHARM REQUESTS CAPITAL RAISING TRADING HALT
- * M&G CLAIMS TO REDUCE TO 9.9% OF MESOBLAST
- * AUSTRALIAN ETHICAL BELOW 5% IN PHARMAXIS
- * PERENNIAL TAKES 7.6% OF MICRO-X
- * PETER MEURS TAKES 5% OF ADALTA
- * LAZARD REDUCES TO 5% OF MAYNE
- * IMMURON EXEC VICE CHAIR PETER ANASTASIOU REDUCES TO 5.3%
- * G MEDICAL ASX DELISTING EGM

MARKET REPORT

The Australian stock market was up 0.3 percent on Monday August 24, 2020, with the ASX200 up 18.4 points to 6,129.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell and six traded unchanged.

Prescient was the best, up 1.1 cents or 15.9 percent to eight cents, with 12.45 million shares traded.

Cynata climbed 14.6 percent; Antisense and Kazia were up more than 11 percent; Polynovo was up 8.3 percent; Resonance rose 7.1 percent; Nanosonics and Orthocell were up more than five percent; Pro Medicus was up 4.4 percent; Clinuvel and Osprey were up more than three percent; Mesoblast, Paradigm and Telix rose more than two percent; Impedimed and Resmed were up more than one percent; with Volpara up 0.4 percent.

Both Opthea and Optiscan led the falls, down 5.9 percent to \$2.40 and 4.8 cents, respectively, with 2.2 million shares and 544,822 shares traded, respectively.

Alterity, LBT and Pharmaxis lost more than five percent; Genetic Signatures fell 4.6 percent; Compumedics, Cyclopharm, Medical Developments and Nova Eye were down three percent or more; Actinogen, Dimerix and Next Science shed more than two percent; Avita, Imugene and Starpharma were down more than one percent; with Cochlear, CSL, Neuren and Proteomics down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says that founder, Prof Robert Elliott, has died peacefully at home, at the age of 86.

A letter from Living Cell chair Dr Bernie Tuch said all at the company were saddened to hear of his death and the medical, scientific and biotechnology communities in New Zealand had lost a tireless researcher and a visionary pioneer.

Dr Tuch said that long before he founded the company, Prof Elliott was at the forefront of child health research in New Zealand and his research into cystic fibrosis and type 1 diabetes was world renowned.

Dr Tuch said that Prof Elliott contributed to other biotechnology success stories including A2 Corp and Somnaceutics.

Living Cell said that Prof Elliott trained as a paediatrician at Adelaide University and moved to New Zealand in 1970 to become the foundation professor and director of paediatrics at the University of Auckland.

The company said that Prof Elliott published more than 200 research papers and was an emeritus professor of child health research.

Living Cell said that Prof Elliott co-founded the company, initially called Diatranz, with Auckland businessman David Collinson in 1987 aiming to commercialize his research into the xenotransplantation of pig Islets of Langerhans for type 1 diabetes.

Dr Tuch said the company was fortunate to have Prof Elliott on the board "right up until his death".

"At 86 years of age he was still coming up with new ideas," Dr Tuch said.

"Bob will be sorely missed; it was an honour to work with him," Dr Tuch said.

Living Cell said that Prof Elliott was survived by his wife of more than 60 years, Betsy, their five children and 11 grandchildren.

SOMNOMED

Somnomed says revenue for the year to June 30, 2020 was down 2.7 percent to \$57,296,293 with continuing operations net loss after tax up 1,012.9 percent to \$438,310. Somnomed said that the total comprehensive loss was down 95.8 percent from \$15,939,637 to \$661,943 and "the core business generated a positive operating cashflow of \$5.6 million for the year compared to \$2.6 million in the prior year".

Somnomed company secretary Terry Flitcroft told Biotech Daily that \$420,000 difference in loss statements, primarily related to the discontinued US Renew Sleep Solutions. Somnomed said that the "business was making good progress to March 2020" with revenues and earnings before interest, taxation, depreciation and amortization on track to achieve guidance, but since March and in the three months to June 30, the impact of Covid-19 "meant that the final year end results were severely affected".

The company said revenue was from sales of its Somnodent product range for obstructive sleep apnoea, including \$32,354,051 in Europe, \$20,348,110 in North America and \$4,594,132 in the Asia Pacific.

Somnomed said diluted loss per share was down 93.7 percent to 1.77 cents, net tangible asset backing per share was up 89.4 percent to 19.94 cents and it had cash and cash equivalents of \$30,174,240 at June 30, 2020 compared to \$7,697,054 at June 30, 2019. Somnomed was up eight cents or 5.5 percent to \$1.54.

CORRECTION: ADALTA

There were four errors in Friday's article on Adalta.

The article referred to a "\$4.1 rights offer" which should have been \$4.1 million and the total funds raised and to be raised were not included in the cash position.

The Friday edition said that all of the GBP334,000 (\$A616,000) GE Healthcare was upfront, whereas GE provided GBP100,000 upfront.

The article said that Roche acquired Premedior "with potential \$US10 billion milestones" which should have said \$US1 billion milestones.

Finally, the sub-editor allowed a sentence to conclude with a preposition and the sentence should have read: "The one-for-four rights offer closes on September 2, after which Adalta should have \$11 million with which to play."

Biotech Daily is extremely disappointed with the Friday sub-editor who clearly is not meeting community standards and will be stood down while an investigation and review are conducted to ensure correct blame-shifting.

At this point, it is probably fair to say that regardless of the outcome of the review, it is all Dan Andrews fault.

Adalta was unchanged at 10 cents with 2.6 million shares traded.

KAZIA THERAPEUTICS

Kazia says the US Food and Drug Administration has granted orphan drug designation for paxalisib, or GDC-0084, for malignant glioma.

Earlier this month, Kazia said it had FDA rare paediatric disease designation for paxalisib for diffuse intrinsic pontine glioma (DIPG) and last week, was granted FDA fast track designation for paxalisib for glioblastoma (BD: Aug 7, 20, 2020).

Today, the company said orphan designation meant it could receive up to seven years of exclusivity, as well as grant funding, protocol assistance and financial benefits, including a waiver of new drug application fees and tax credits.

Kazia was up 11 cents or 11.2 percent to \$1.09 with 1.2 million shares traded.

61 MEDICAL

The Brisbane-based 61 Medical says it hopes to accelerate the development and commercialization of medical devices.

In a media release, 61 Medical said it was a subsidiary of the Bettlach, Switzerland-based medical device manufacturer 41 Medical AG.

The company said it was launched with the signing of a three-way memorandum of understanding between the Queensland Government, 61 Medical and 41 Medical.

61 Medical chair and former Liberal National Queensland Minister for Science, Information Technology, Innovation and the Arts Ian Walker told Biotech Daily that the funding from the Labor State Government was confidential.

Mr Walker said that the in due course the company would be looking for \$10 million from Australian investors for a fund for projects.

The media release said that the agreement would support "the growth and resilience of Queensland's medical technology sector".

The company said that it would focus on manufacturing "high-value medical technology to provide intelligent, connected health care options, to help improve quality of life for patients" and hoped to fast-track the development and commercialization of technology breakthroughs.

Queensland Minister for State Development and Innovation Kate Jones said the State Government would support 61 Medical to set-up in Queensland.

"Queensland's biomedical industry contributes around \$1.86 billion to the state economy and employs approximately 10,700 people," Ms Jones said.

"Under the [agreement], 41 Medical and 61 Medical will set up a contract medical device development and manufacturing business in Queensland, bringing with them 41 Medical's extensive knowledge, expertise and international networks in the [medical technologies] sector," Ms Jones said.

"61 Medical will help sharpen Australia's competitiveness by improving its advanced manufacturing capability, particularly in the [medical technologies] space," Mr Walker said. "The Covid-19 pandemic has demonstrated the need for more advanced manufacturing

capability in Australia, particularly a self-sufficiency in medical manufacturing."

"Our focus on local production means researchers can be confident in the process and quality and can maintain a close eye on the manufacturing process, which is difficult if the manufacturing is taking place overseas," Mr Walker said.

41 Medical chairman and owner Prof Robert Frigg said that Australia had "outstanding potential".

"We know Australia punches well above its weight in terms of medical research and innovation and we see an opportunity to help bridge the gap between that knowledge to market readiness that is often missing due to the costs and capabilities required, Prof Frigg said.

"The backing of 41 Medical guarantees Australian researchers direct access to a large international network for validation, industrialization, and supply chain, as well as access to large [medical technologies] companies," Prof Frigg said.

Queensland University of Technology Faculty of Health Prof Michael Schuetz said 61 Medical was "filling the innovation gap in Australia".

"61 Medical will have an extensive capacity for manufacturing medical devices, which is essential to fill the existing gap to bring our smart innovations into patient care in Queensland and Australia," Prof Schuetz said.

The media release said the company was investigating several opportunities for a pipeline of investment-ready opportunities when it begins operations in January 2021. 61 Medical is a private company.

OPTHEA

Opthea says it has submitted a draft registration to the US Securities and Exchange Commission for a potential initial public offering of American depositary shares (ADSs). Opthea said that a Nasdaq listing would support its product development activities, including its phase III trials of OPT-302 for wet age-related macular oedema. The company said the number of ADSs to be offered, the number of underlying shares, the price and the timing had not been determined, and it expected to begin an offer

following a review by the SEC and subject to market conditions, demand and approval.

The company said that it would remain listed on the ASX.

Opthea fell 15 cents or 5.9 percent to \$2.40 with 2.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has begun enrolment for its 24-patient trial of its Cymerus mesenchymal stem cells for adult Covid-19 patients in intensive care.

In May, Cynata said it had ethics approval for a 24-patient, open label, randomized, controlled trial to investigate safety, tolerability and hypoxaemia levels, caused by compromised lung function (BD: May 8, 2020).

Cynata was up 12 cents or 14.6 percent to 94 cents with 1.5 million shares traded.

IDT AUSTRALIA

Melbourne's IDT says it had made a formal submission to the Federal Government, detailing its current facilities and potential Covid-19 vaccine manufacturing capabilities. IDT said the Government had requested information for potential Covid-19 vaccine and treatment manufacturing and supply chains.

The company said its submission detailed its capabilities and included: sterile vial fill and finish of liquid and lyophilized products; bulk liquid formulation; cold chain management and storage; solid oral dose form manufacture for tablet or capsule; manufacture of active pharmaceutical ingredients and excipients; process and analytical method development; and in-house analytical and microbiological testing.

IDT chief executive officer Dr David Sparling said that the company had been involved in the Government's response during the initial phase of the Covid-19 crisis.

"We want to continue to play a role in Australia's Covid-19 response and we believe that the company is well placed to potentially assist with Covid-19 vaccine and treatment projects," Dr Sparling said.

IDT was up 1.5 cents or 8.8 percent to 18.5 cents with 1.7 million shares traded.

CSL

Bosch says its manufacturing division has a contract with CSL Behring to build a high-tech automatic materials handling line.

Bosch said CSL Behring currently used a manual-handling process to quality check blood plasma bags, to store them and to release them for processing in the manufacturing line. The company said it would install a material handling and inspection line to streamline the process and to allow more plasma bags to be packed at up to one per second. CSL fell 40 cents or 0.1 percent to \$295.12 with 789,703 shares traded.

AZURE HEALTH TECHNOLOGY (FORMERLY INVICTUS BIOPHARMA)

Azure says it has begun manufacturing the first batch of its food additives, NE1-Elite and NE1-Heart, for sale in the US, Australia and China.

Azure said both food additives, which were for delayed onset muscle soreness and as an antioxidant respectively, were based on annatto-derived delta tocotrienols and were delivered with its Melt3 or 'melt then swallow' platform.

The company said it expected to complete manufacturing of the first batch of more than 300,000 products, ready for sale in December 2020.

Azure is a public unlisted company.

ECOFIBRE

Ecofibre says it has completed the \$US42,000,000 (\$A58,605,540) acquisition of the five businesses and assets of its North Carolina manufacturer Texinnovate.

Last month, Ecofibre said it had a conditional agreement to acquire five businesses with "deep technical expertise" across textile disciplines, including Triad Polymers, Trident Fibers, Fibex, Knitmasters and Texinnovate (BD: Jul 29, 2020).

Today, the company said it had completed the transaction for \$US10,500,000 in cash and the equivalent in shares and a \$US21,000,000 earnout, payable in three equal tranches of \$US7,000,000 three, four and five years from the completion date.

Ecofibre fell one cent or 0.4 percent to \$2.74.

EXOPHARM

Exopharm has requested a trading halt "pending the release of an announcement regarding a capital raising".

Trading will resume on August 28, 2020 or on an earlier announcement.

Exopharm last traded at 29.5 cents.

MESOBLAST

M&G Investments Funds says it has reduced its substantial shareholding in Mesoblast from 64,531,906 shares (11.04%) to 58,000,971 shares (9.91%).

Last week, the London-based M&G said it had reduced its holding from 65,668,769 shares (11.24%) to 59,684,727 shares (10.21%) (BD: Aug 21, 2020).

Today, M&G said that between August 7 and 20, 2020 it sold 6,690,935 shares for \$31,189,900 or \$4.66 a share.

Mesoblast was up 14 cents or 2.7 percent to \$5.25 with 6.7 million shares traded.

PHARMAXIS

Australian Ethical Investment says it has ceased to be a substantial shareholder in Pharmaxis.

Last week, the Sydney-based Australian Ethical said it had reduced its shareholding from 28,759,640 shares (7.30%) to 23,725,346 shares (6.00%) (BD: Aug 19, 2020).

Today Australian Ethical said that between August 18 and 20, 2020 it sold 4,065,179 shares for \$485,325 or 11.9 cents a share.

Biotech Daily calculates that Australian Ethical now holds 19,660,167 shares or 4.98 percent of Pharmaxis.

Pharmaxis fell 0.6 cents or 5.7 percent to 9.9 cents with 2.4 million shares traded.

MICRO-X

Perennial Value Management says it has increased its substantial shareholding in Micro-X from 22,739,288 shares (6.37%) to 27,234,757 shares (7.63%).

The Sydney-based Perennial said that between July 31 and August 19, 2020 it bought 4,495,469 shares for \$755,187 or 16.8 cents a share.

Micro-X fell one cent or 5.9 percent to 16 cents.

ADALTA

Peter Meurs and Meurs Holdings as trustee for the P&M Meurs Superannuation Fund says they have become substantial holders in Adalta with 10,356,001 shares (5.08%). The Melbourne-based Meurs Holdings said that the shares were acquired between July 19, 2018 and August 18, 2020 with the most recent acquisition 5,000,000 shares for \$500,000 or 10 cents a share and the first 3,333,333 shares for \$1,000,000 or 30 cents a share.

MAYNE PHARMA GROUP

Lazard Asset Management Pacific Co says it has reduced its substantial shareholding in Mayne from 101,805,753 shares (6.06%) to 84,212,863 shares (5.02%).

The Sydney-based Lazard said that it bought and sold shares between July 6 and August 20, 2020, with the single largest sale 8,064,047 shares for \$2,862,402 or 35.5 cents a share.

Mayne was up 2.5 cents or 7.35 percent to 36.5 cents with 9.6 million shares traded.

IMMURON

Immuron executive vice chair Peter Anastasiou says he has reduced his substantial shareholding from 12,742,956 shares (7.15%) to 11,778,269 shares (5.26%). The Blackburn North, Victoria-based Mr Anastasiou said that on June 26, 2020 he disposed of 964,687 shares at 8.2 cents a share in an off-market trade and a further 1,332,187 shares in a "movement between controlled holdings". Immuron fell one cent or 2.7 percent to 35.5 cents with 1.6 million shares traded.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says its extraordinary general meeting will vote to delist from the ASX. Earlier this month, G Medical said it had applied to delist from the ASX to list on the Nasdaq, which "would provide a more favorable valuation" (BD: Aug 14, 2020). The meeting will be held at its Tel Aviv Office, 3rd floor, 5 Oppenheimer Street, Rehovot, Israel on September 21, 2020 at 9am (Tel Aviv) or 4pm (AEST).

G Medical was unchanged at 4.1 cents with 9.6 million shares traded.