

Biotech Daily

Friday July 3, 2020

Daily news on ASX-listed biotechnology companies

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- * PETER HATFULL REPLACES ESENSE DIRECTOR PIERS LEWIS

MARKET REPORT

The Australian stock market was up 0.42 percent on Friday July 3, 2020, with the ASX200 up 25.2 points to 6,057.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell, and seven traded unchanged. All three Big Caps were up.

Osprey was the best for the second day in a row, up 2.8 cents or 127.3 percent to five cents, with 701.5 million shares traded. Genetic Signatures climbed 12.4 percent; Oncosil was up 8.7 percent; Next Science rose 7.7 percent; Prescient was up 6.7 percent; Cochlear and Optiscan improved five percent or more; Amplia was up 3.8 percent; Compumedics, CSL, Universal Biosensors and Uscom rose more than two percent; Dimerix, Nanosonics, Proteomics and Resmed were up more than one percent; with Avita, Clinuvel and Telix up by less than one percent.

Alterity again led the falls, down 1.2 cents or 19.7 percent to 4.9 cents, with 109.0 million shares traded. Impedimed lost 6.2 percent; Cyclopharm fell five percent; Antisense, Pharmaxis and Resonance were down more than three percent; LBT, Neuren, Paradigm and Pro Medicus shed more than two percent; Mesoblast, Opthea, Polynovo and Pro Medicus were down more than one percent; with Cynata, Starpharma and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: MESOBLAST

By TIM BOREHAM

ASX Code: MSB

Nasdaq code: MESO (American depositary receipts)

Share price: \$3.37

Market cap: \$1,967.9 million

Shares on issue: 583,949,612

Chief executive: Prof Silviu Itescu

Board: Joseph Swedish (chairman), Prof Itescu, William Burns, Donal O'Dwyer, Michael Spooner, Shawn Cline Tomasello, Dr Eric Rose

Financials (nine months to March 2020)*: revenue \$US31.5 million (up 113 percent), loss of \$US45.3 million (previously a \$US69.1 million deficit), cash balance \$US60.1 million** (up 19%).

March quarter: revenue \$US12.2 million (up 870%), loss of \$US17.2 million (previously \$US27.1 million loss)

* \$US1.00 = 68 Australian cents; ** Before \$US90 million capital raising

Identifiable major holders: Prof Itescu 11.8%, M&G Investments 10.86%, Thorney Holdings 5%.

The world's biggest listed pure-play stem cell developer has a busy slate of clinical work, notably in therapies for advanced heart failure, chronic back pain and graft-versus-host disease (GvHD).

Now these programs are approaching a thrilling denouement and, as the Demtel man enthused, there's more: Mesoblast is also undertaking an expanded coronavirus trial after a 12-patient effort showed promising results in treating acute respiratory distress syndrome (Ards), the usual cause of death with Covid-19.

The patients received infusions of Mesoblast's allogeneic (off the shelf) mesenchymal stem cell candidate, remestemcel-L, acquired from Osiris for \$106 million in 2013.

Meanwhile, results from two phase III trials are expected this (September) quarter: a 566patient effort for chronic heart failure and a 404-patient trial for chronic lower back pain caused by disc degeneration. And in September, the US Food and Drug Administration will rule on whether or not the company can market its GvHD therapy on American shores.

Mesoblast founder and CEO Prof Silviu Itescu notes that across all its therapies the company is targeting the most severe cases where alternative therapies don't exist.

Stem cells for dummies

Mesoblast's proprietary process selects precursor and stem cells from the bone marrow of healthy adults, creating a master cell bank. This cell kitty is then expanded into thousands of doses for off-the-shelf use, without the need for tissue matching.

Mesoblast is targeting a common market across all its disease indications: inflammation. In the case of heart disease, tissue macrophages (cells) churn our inflammatory factors that damage heart muscle and cause fibrosis and vascular dysfunction.

The stem cells respond to severe inflammation by switching the culprit macrophages 'off' and converting them to nice cells that actually protect the heart muscle.

"This is the central mechanism in each of our disease states: heart failure, back pain, GvHD and rheumatoid arthritis," Prof Itescu says.

"We have the potential to make a big difference in some very big disease states where inflammation is central."

Mesoblast's patchy history

Backed by the Pratt family's listed investment vehicle Thorney Investments, Mesoblast debuted on the ASX in 2004 and reached a peak valuation of \$2.5 billion in 2011 before suffering a reality check.

Culprits included a phase II heart trial that failed to meet primary endpoints, a badly executed Nasdaq listing and Israel pharma house Teva Pharmaceutical's decision to walk away from a heart program partnership in 2016.

Mesoblast dual listed on the Nasdaq in November 2015, accompanied by a \$US63 million capital raising.

Mesoblast's Ards and GvHD programs are based on mesenchymal stem cell assets acquired from US pharma group Osiris Therapeutics in October 2013.

Mesoblast's own-developed cells are called mesenchymal precursor cells and they are being developed for rheumatoid arthritis and diabetic nephropathy, as well as the aforementioned heart failure and lower back pain programs.

Covid-19: an 'Ard one to crack

Acute respiratory distress syndrome (Ards) is bought on by an excessive immune response to the virus in the lungs.

The immune cells produce inflammatory cytokines, which destroy lung tissue and can also damage the liver, kidney and heart.

"Remestemcell-L has the potential to tame the cytokine storm in Ards and may offer a lifesaving treatment for those unfortunate individual sufferers of Covid-19 Ards," Prof Itescu says.

Mesoblast's Covid-19 proclamations have been coming so thick and fast that it's been 'Ard(s) just to keep up.

But the core excitement cluster was around Mesoblast's April 23 disclosure of the results of the trial at New York's Mt Sinai Hospital, covering moderate to acute Ards cases.

Under the compassionate use protocol, the patients were treated with two infusions of remesterncel-L over the first five days.

The results? Nine of the 12 patients came off a ventilator within a median 10 days, with 83 percent survival (the Grim Reaper's spin on this is that two of them died).

In comparison, only nine percent of patients at one reference hospital (38 out of 445 patients) were able to come off the ventilator with standard-of-care treatment.

Another US hospital reported that only 38 patients of 320 – or 12 percent - survived.

But the jury's out

Of course, 12 people good and true are adequate numbers for a jury, but sub-optimal to comprise a statistically significant trial.

Thus, the company is enrolling 300 patients in a phase III, randomized, controlled trial of severe Ards patients at 30 sites.

The first patients were dosed in early May, with about 15 sites established as the company 'chases' the disease from the north-east to the southern states.

Mesoblast chief medical officer Prof Fred Grossman says the company is carefully choosing "hot spots" such as Alabama which, as of late May had the 'no vacancy' signs outside its intensive care wards.

"The sites are recruiting quite quickly," he says. "There is a tremendous interest in this study."

The trial leaders will undertake an interim analysis at 30 days, and when 30 percent of patients have reached their primary endpoint.

At that point the trial can be dumped on futility grounds, or expanded to the control group because it appears to be working.

Remestemcell-L has investigational new drug (IND) status with the US Food and Drug Administration, meaning the company swiftly can initiate trials on patients with "very dismal" prospects.

Have a heart

Long-suffering Mesoblast investors will recall that the company's shares tumbled 28 percent in November 2018 after a 159-patient trial of Rexlemestrocel-L (Revascor) for end-stage heart failure did not meet its primary endpoint of weaning patients from left ventricle assist devices (LVADs or heart pumps).

The company claimed the endpoint was set by the independent !!! investigators and was of little real clinical interest.

What really mattered was that the trial showed reduced gastrointestinal bleeding by 76 percent and hospitalizations by 65 percent.

Investors are now nervously awaiting the first readout of the broader 566-patient chronic heart failure trial across 59 US sites.

Mesoblast targeted patients with class three or four disease, the sickest 15 to 20 percent of patients who have failed standard-of-care drugs.

Class three patients have a 20 percent chance of dying within two years while with class four it's a case of flip a coin that you will be around in 12 months.

At this stage, Mesoblast retains its heart treatment rights except in China, where it is partnered with Tasly Pharmaceutical.

A pain in the ... back

Mesoblast's phase III back pain trial aimed to enroll 404 patients with lower back pain caused by degenerative disc disease.

The endpoint of the trial, dubbed MPC-06-ID, is an "improvement in pain and function" over 24 months.

As with the heart trial, results are imminent and it's a toss-up as to what release will hit the ASX announcements feed first.

The company is liaising with its global back pain partner Grunenthal GmbH about the clinical protocol for a European phase III confirmatory trial.

Graft-versus-host disease

In Japan, Mesoblast is partnered with JCR Pharmaceutical for its approved GvHD treatment called Temcell - and it's off and racing in that smallish but enthusiastic market.

Meanwhile, the company is angling to enter the US market for a similar GvHD treatment, branded Ryoncil.

GvHD afflicts about half of the 30,000 patients annually undergoing allogeneic bone marrow transplant, typically for blood cancers, with their bodies rejecting the 'alien' transplant.

In March, the FDA granted priority review with a September 30 'action date', but we might have a good idea of the outcome in August.

Why? Because that's when the FDA's relevant advisory committee meets to vote on the matter - and the (virtual) gathering is open to the public.

A date is yet to be set. While advisory committee views are not binding on the FDA, they usually presage the final decision.

If approved, Mesoblast could be selling Ryoncil in the US by the time we're carving the Christmas turkey (badly, in the case of your columnist).

Finances and performance

Buoyed by the Covid-19 results, Mesoblast in May wasted no time tapping institutional investors for an idle \$US90 million in a placement.

Mesoblast already had a healthy cash balance of \$US60 million.

The raising was struck at \$3.20 a share, a modest seven percent discount to the prevailing price.

The funds, in the main, will be used to scale-up manufacturing of remestemcell-L and to support the phase III trial, as well as for "working capital and general corporate purposes".

The company also has \$US67 million available through existing financing facilities and partnerships.

Mesoblast reported revenue of \$US31.45 million for the nine months to March 2020, up 113 percent.

The reported loss narrowed 34 percent to \$US45.3 million, reflecting curtailed research and development spend by \$US7.5 million, or 15 percent.

The revenue included \$US5.9 million of JCR royalties from Temcell sales in Japan and milestone revenue of \$US25 million.

The company stands to pocket up to \$US150 million of royalties and milestones from Grunenthal prior to any European launch of Revascor.

Successful sales could result in up to \$US1 billion in milestone payments.

Over the last decade, Mesoblast's ASX shares have traded as high as \$9 (October 2011) and as low as \$1.03 (December last year).

Mesoblast was elevated to the ASX200 index on June 12.

Dr Boreham's diagnosis:

To the Meso-sceptics the company has promised far too much with limited commercial success, while raising \$1 billion since listing 16 years ago.

Dare we say that Mesoblast now looks more focused and to be getting somewhere?

When we last covered Mesoblast in March 2019, Prof Itescu said he was "95 percent" certain the company would do what no other Aussie biotech in phase III had done: win FDA drug approval.

Well, Clinuvel has stolen that "Aussie first" honor, but Mesoblast is well placed to get over the line with a GvHD treatment in the US, which presents a market eight times the size of Japan's.

It's certainly rare for a biotech to expect results for three major trails and a key regulatory decision in the space of months.

If the heart and back pain results are definitively positive and the FDA green lights GvHD, the company hits the jackpot. If two or more of them bomb ... let's not go there.

Your ultra conservative columnist regards the Covid-19 stuff as the icing on the cake with an outside chance of success, especially given the hundreds of other programs in the coronavirus-busting sector.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he hopes to become proficient in turkey carving by December 25.

COCHLEAR

Cochlear says the US Food and Drug Administration has approved its Kanso-2 and Nucleus-7 sound processors, Custom Sound Pro and Nucleus Smartnav.

Cochlear said the Nucleus Kanso-2 was "the world's smallest off-the-ear cochlear implant sound processor" with direct streaming from compatible Apple or Android devices and could connect to the Nucleus smartphone application for device control.

Cochlear chief executive officer Dig Howitt said the Nucleus Kanso-2 had the "latest connectivity features and a simple design that is comfortable and discreet".

"It really is designed to help cochlear implant recipients enrich their lives," Mr Howitt said. The company said the Nucleus-7 Sound Processor was compatible with its Nucleus-22, which would allow Nucleus-22 implant recipients to upgrade Cochlear's behind-the-ear sound processor and access direct smartphone connectivity.

Mr Howitt said the Nucleus-22 implant was Cochlear's first commercial implant, released in 1982, with more than 17,000 people around the world with a Nucleus-22 implant. "This upgrade means, that for the first time, people who have benefitted from their implant for almost 40 years can access direct smartphone connectivity as well as a smaller and lighter design," Mr Howitt said.

Cochlear said the Custom Sound Pro helped clinicians fit Cochlear sound processors, and the fitting software allowed for further patient engagement to improve patient experience. The company said the Nucleus Smartnav was a tool developed to assist surgeons in optimizing electrode placement during cochlear implant surgery.

Cochlear said the products showed its commitment to improving hearing and quality of life for people with hearing loss and enhancing support for healthcare professionals.

The company said the products would be released in the US and Western Europe "in the next few months, subject to local approvals".

Cochlear was up \$11.31 or 5.9 percent to \$204.00 with 348,903 shares traded.

AMPLIA THERAPEUTICS

Amplia says the institutional portion of its rights offer at 10 cents a share has raised \$2 million from investors including Platinum International Healthcare Fund.

Earlier this week, Amplia said it hoped to raise \$4 million in a fully-underwritten, three-forfive, pro-rata, non-renounceable rights offer at 10 cents a share (BD: Jul 1, 2020). Amplia chief executive officer Dr John Lambert said the company was "very encouraged to see such strong support and commitment from existing and new institutional investors as we commence our transition to becoming a clinical stage drug development company". The company said Taylor Collison was the underwriter and lead manager of the offer. Amplia fell 0.5 cents or four percent to 12 cents.

SUDA PHARMACEUTICALS

Suda says it hopes to raise \$3.56 million in a one-for-one, non-renounceable rights offer at 2.5 cents a share, a 34.3 percent discount to the 15-day volume-weighted average price. The company said participants in the offer would receive one free attaching option for every three shares purchased, exercisable at five cents by July 31, 2022.

Suda said the funds would be used to develop its platelet-reducing anagrelide, the remaining Oromist oral spray assets, any potential acquisition and for working capital. The company said the record date would be July 8, with the offer opening on July 13 and closing on July 22, 2020.

Suda fell 0.4 cents or 10 percent to 3.6 cents with 2.8 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it will licence marijuana strains from Dolce Cann Global for \$50,000 plus securities and royalties, and raise \$500,000 in a placement at 0.5 cents a share. Neurotech said it would use Dolce's marijuana strains to develop treatments for autism, epilepsy and attention deficit hyperactivity disorder.

The company said that it would pay the Griffith, New South Wales-based Dolce \$50,000 upfront by July 10, 2020, spend \$200,000 on development in accordance with an agreed budget, and issue Dolce with 99,000,000 Neurotech shares over three stages and 33,000,000 options exercisable at one cent each by January 31, 2023.

Neurotech said Dolce would receive royalties of 2.5 percent for the net sales of any results marijuana strain-based products.

The company said the placement had "firm commitments" and the funds would be used for the Dolce marijuana licence, to continue the development of Mente for autism and for general working.

Neurotech was up 0.3 cents or 30 percent to 1.3 cents with 170.2 million shares traded.

ECOFIBRE

Ecofibre says enrolment has begun for a US-based phase II trial of its Ananda Health cannabidiol for chemotherapy-induced peripheral neuropathy.

Ecofibre said the trial, conducted by Philadelphia's Lankenau Institute for Medical Research, would assess the efficacy of its cannabidiol (CBD) gel caps for breast, colon and ovarian cancer patients who received common types of neurotoxic chemotherapy. The company said it expected to complete the study in 2022.

Lankenau Medical Center's director of breast radiation oncology Dr Marisa Weiss said "we are proud to be the first in the United States to study the impact of hemp-derived full spectrum CBD on [chemotherapy-induced peripheral neuropathy], a condition that affects approximately 25 to 50 percent of paediatric and adult cancer patients undergoing neurotoxic chemotherapy".

Dr Weiss said this was believed to be the first phase II clinical trial using full-spectrum hemp extract for the treatment of chemotherapy-induced peripheral neuropathy that had received investigational new drug status from the US Food and Drug Administration. Ecofibre said it was planning a second phase II clinical trial that would evaluate moderatedose cannabidiol on agitation, sleep and mood in dementia patients, with patient enrolment expected in August.

The company said that, in addition to its US clinical trials, it would support research on low-dose full spectrum CBD in Australia later this year.

Ecofibre was up 17 cents or 7.2 percent to \$2.52.

OSPREY MEDICAL

Osprey has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 76.9 percent from a low of 1.3 cents to a high of 2.3 cents on July 2, 2020 and noted a "significant increase" in the trading volume. Osprey was up 2.8 cents or 127.3 percent to five cents, with 701.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has told the ASX that "due to a misunderstanding" its US public relations company released an announcement before it informed the ASX.

Genetic Technologies said the release of a "material and price sensitive" announcement to the US market before the ASX breached ASX regulatory restrictions.

The company said it had raised the error with the US public relations agency and confirmed it was aware of the requirement for all material and price sensitive ASX announcements to be released on the ASX prior to the US.

Genetic Technologies said that "on this occasion the US press release and generally the subsequent ... ASX market update did not have any material impact on [its] share price. Genetic Techno was up 0.05 cents or 8.3 percent to 0.65 cents, with 12 million shares traded.

CANN GROUP

Cann says it has received a \$1,975,000 grant from the Victorian Government to fund the electricity upgrades at its marijuana cultivation facility near Mildura.

Cann said the grant was awarded under the Victorian Government's Regional Jobs Fund, with Mildura facility potentially able "to generate 150 permanent jobs".

Cann Group was up 7.5 cents or 8.3 percent to 98 cents, with 1.1 million shares traded.

CANN GLOBAL

Cann Global says it has repriced its \$4,661,235 four-for-one rights offer prospectus from 0.55 cents to 0.5 cents a share, in order to comply with ASX requirements.

Cann said it was notified that "ASX operating rules and systems parameters stipulate a minimum price increment of 0.1 cent" and would immediately withdraw the offer, pending a repricing to comply with the requirement.

The company said that following the necessary changes, it intended to proceed with the pro-rata, non-renounceable, four-for-one rights offer which would offer one free attaching option for every two shares, exercisable at 1.2 cents until January 31, 2022.

Cann Global fell 0.1 cents or 16.7 percent to 0.5 cents, with 18.1 million shares traded.

MGC PHARMACEUTICALS

MGC says its extraordinary general meeting passed all resolutions, but with 23.47 percent opposed to the prior issue of secondary placement shares and options.

MGC said the ratification of 129,630,000 shares issued in its secondary placement, corner-stoned by Merchant Opportunities Fund, was opposed by 59,075,967 votes (23.47%) with 192,646,852 votes (76.53%) in favor (BD: Apr 28, 2020).

The company said the resolutions for the ratification of shares to OT Capital Mondiin, options for share plan participants, the secondary placement options, the issue of options to executive chairman Brett Mitchell and the issue of options to director Dr Ross Walker were passed by wider margins but opposed by more than 20 percent of votes. MGC said the ratification of the issue of shares to Canaccord and Cannvalate Pty Ltd were opposed by more than 18 percent.

The company's most recent Appendix 2A new issue announcement said it had 1,575,612,348 shares on issue, meaning that the largest opposition of 61,948,426 votes against the issue of option to Mr Mitchell amounted to 3.9 percent of the company, not sufficient to requisition extraordinary general meetings.

MGC was unchanged at 2.1 cents with 13.8 million shares traded.

OVENTUS MEDICAL

Oventus says shareholders will vote to increase the director remuneration pool 50 percent to \$600,000 and issue directors 6,900,000 options.

Oventus said the extraordinary general meeting proposed to increase the director remuneration pool from \$400,000 a year to \$600,000 a year, issue 5,000,000 options to chief executive officer Dr Chris Hart, 500,000 options each to directors Paul Molloy and Jason Nunn, and 300,000 options each to chairman Dr Melvyn Bridges and directors Sue MacLeman and Mr Sharad Joshi, exercisable at 40 cents within five years.

The meeting will be held online on August 4, 2020 at 11am AEST.

Oventus was up half a cent or 1.7 percent to 30.5 cents.

BTC HEALTH

The Sydney-based Naos Asset Management says it has increased its substantial shareholding in BTC from to 55,775,214 shares (22.66%) to 58,491,446 (23.76%). Naos said it acquired 2,716,232 shares on-market for \$239,329 or 9.2 cents a share. BTC was unchanged at 10 cents with 1.7 million shares traded.

INVEX THERAPEUTICS

Anthony Grist, Oaktone Nominees and Denlin say they have increased but been diluted in Invex from 3,225,000 shares (4.30%) to 3,585,200 shares (4.78%).

In their previous substantial shareholder notice, the Perth-based Mr Grist and Oaktone said they had reduced and been diluted in Invex from 4,000,000 shares (7.27%) to 3,543,750 shares (5.25%) (BD: Jun 2, 2020).

Today, Mr Grist and Oaktone said that on July 2, 2020 they bought 56,250 shares in a placement for \$73,125 or \$1.30 a share.

In May, Invex said it raised \$26.2 million through a placement to institutional, professional, and sophisticated investors at \$1.30 a share (BD: May 22, 2020).

Invex fell six cents or 4.65 percent to \$1.23.

ESENSE-LAB

Chifley Portfolios Pty Ltd and David Hunnon say they have become substantial in Esense with 62,500,000 Chess depository interests (CDIs) or 12.2 percent.

The Sydney-based Chifley and Mr Hunnon said that on April 2, 2020 they acquired the shares through the conversion of convertible notes for \$250,000 or 0.4 cents for each CDI. Esense was up 0.1 cents or five percent to 2.1 cents, with 10.7 million shares traded.

RECCE PHARMACEUTICALS

Recce says its founder, chief research officer and executive director Dr Graham Melrose has resigned from the company to begin his retirement.

Recce chief executive officer James Graham told Biotech Daily that Dr Melrose was 86 years young, and received a Bachelor of Science in 1955 and a Doctor of Philosophy in chemistry in 1960 from the University of Western Australia.

Recce non-executive chairman Dr John Prendergast thanked Dr Melrose and said that the company was "indebted to Dr Melrose for his innovation, dedication and passion in creating our products and participating in their development".

Recce fell 4.5 cents or six percent to 70 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed chief medical officer Dr Donna Skerrett as an executive director.

Paradigm said Dr Skerrett had more than 30 years' experience in transfusion medicine, cellular therapy and transplantation and was a director at the Philadelphia, Pennsylvania-based Fox Chase Cancer Centre and the Lewis Katz School of Medicine.

The company said that Dr Skerrett was previously the chief medical officer for Mesoblast and had been a director for multiple New York medical centres and committees, before joining Paradigm in 2019.

Paradigm said Dr Skerrett held a Bachelor of Arts from Philadelphia's University of Pennsylvania, a Doctor of Medicine from Philadelphia's Lewis Katz School of Medicine at Temple University and a Master of Science from New York's Columbia University Mailman School of Public Health.

Paradigm fell nine cents or 2.6 percent to \$3.41, with 1.9 million shares traded.

BIONOMICS

Bionomics says it has appointed Apeiron Investment Group managing-director Aaron Weaver as a director, effective from July 6, 2020.

In June, Bionomics said it hoped to raise \$22 million in a capital raising at four cents a share, including \$5,433,320 from a two-tranche agreement with the Malta-based Apeiron, following which Apeiron would own 19.9 percent of the company and would be able to nominate two directors to the board. (BD: Jun 2, 2020).

Today, the company said Mr Weaver was senior general counsel at Atai Life Sciences AG, and previously worked for London's Credit Suisse and Allen & Overy LLP. Bionomics said Mr Weaver held a Bachelor of Business Administration from the University of Queensland and a Master of Law from the Queensland University of Technology. Bionomics fell 0.4 cents or 6.1 percent to 6.2 cents.

ESENSE-LAB

Esense says it has appointed Peter Hatfull to replace Piers Lewis, who has resigned from the company.

Esense said Mr Hatfull had more than 40 years' experience as a director and executive, specializing in corporate governance and strategic planning.

The company said Mr Hatfull was a director and chairman of several listed and unlisted companies and previously worked for the then Coopers and Lybrand.