

Biotech Daily

Friday April 30, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was down 0.8 percent on Friday April 30, 2021, with the ASX200 down 56.5 points to 7,025.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Actinogen was the best, up 0.8 cents or 13.8 percent to 6.6 cents, with 17.5 million shares traded. Universal Biosensors climbed 7.5 percent; Mesoblast was up 6.8 percent; Cynata and Immutep improved more than four percent; Nova was up 3.1 percent; Compumedics, Next Science and Volpara rose more than two percent; Kazia, LBT, Medical Developments, Pharmaxis and Prescient were up more than one percent; with Cyclopharm and Neuren up by less than one percent.

Osprey led the falls, down 0.1 cents or 5.3 percent to 1.8 cents, with 5.4 million shares traded. Antisense, Impedimed, Proteomics and Resmed fell more than four percent; Patrys was down 3.7 percent; Clinuvel, Imugene, Oncosil, Orthocell and Resonance shed more than two percent; with Avita, Cochlear, Dimerix, Genetic Signatures, Nanosonics, Opthea, Paradigm, Polynovo and Starpharma down by one percent or more.

DR BOREHAM'S CRUCIBLE: ANTEOTECH

By TIM BOREHAM

ASX code: ADO; Share price: 43.5 cents; Market cap: \$815.25 million

Shares on issue: 1,874,141,347

Chief executive officer: Derek Thomson

Board: Dr Jack Hamilton (chairman), Dr Geoff Cumming, Christopher Parker, (Matt

Sanderson resigned on April 22, 2021

Financials (December 2020 half year): revenue of \$600,000 (up 550%), cash outflows \$1.46 million (previously \$1.1 million outflows), cash of \$6.43 million (up 100%)

Main shareholders: Levenson Investments 5.2%, First Cape Management 3.1%, Marcolongo super fund 2.8%, Fossil Super Pty Ltd 1.9%

Anteotech chief Derek Thomson admits there is no shortage of Covid-19 tests out there, which poses the question of why the 'surface chemistry' outfit is joining the aspiring entrants at a time when vaccination programs are being rolled out in earnest (except here, of course).

Mr Thomson argues the testing market can't be seen as an amorphous mass. Clinical testing for Covid-19 might peak - it hasn't yet - but the screening market will only grow as borders re-open and mass gatherings return.

A minor technical detail

The test for the bug itself is an antigen test for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), while Covid-19 ias the illness caused by the virus and a Covid-19 test is an antibody blood test showing whether the user has developed antibodies to the virus or the vaccine. 'Covid' is common usage for both.

Now, back to the story

Many of us have had a polymerase chain reaction, or PCR test for Sars-Cov-2 (or Covid-19) which is considered the gold standard for reliability. But the tests have to go to the lab for analysis, resulting in the need for the subjects to isolate until they get their results.

"I think [rapid testing] will be the bigger part of the market and will have some longevity to it," Mr Thomson says.

In March, Anteotech won Conformité Européenne (CE) mark approval for its portable antigen rapid test (ART), which the company claims is more reliable than rival assays.

The company has already been supplying raw material for its unlisted Brisbane-based peer Ellume, which is rolling out a home-based test.

Anteotech also has other strings to its bow, including a research program to improve the efficacy of lithium-ion batteries.

With the Indian pestilence raging on, Anteotech this week took advantage of its buoyant share price by unveiling a circa \$16 million capital raising: \$12 million by way of a placement and \$4 million through a share plan (see 'financials and performance').

About Anteotech

Known initially as SSH Medical, the company listed in April 2000 with pretty much the same tech as it has now (nano-polymer technologies). But it didn't really go anywhere until 2018, when the board honed its focus under new chairman Jack Hamilton.

The then Anteo Diagnostics was primarily focused on its "molecular glue" (see below) before acquiring Belgium's diagnostics company Diasource for \$34 million in 2015, changing its reporting currency to Euros and then selling it for \$24 million in September 2017 and returning to Australian dollars. In October 2017, it jumped 178 percent to 2.5 cents on a refocus on lithium-ion batteries

After the brief reign of CEO and energy expert Harley Frankfurt, financial whiz Mr Thomson joined in August 2019 with a clear agenda to commercialize the business.

"I was selected on the basis that the building blocks of a business were there but someone needed to put it together, Ikea style," he says.

The chosen gambit was to convert the raw materials diagnostic business into a test developer in its own right.

Five years before the virus struck, Anteotech had already become involved with Ellume, which was developing its own so-called "quantum dot" technology.

Anteotech enjoyed a significant ramp-up in profile after Ellume's test was approved in the US. In February, the company won a \$US235 million (\$A305 million) contract to supply the US armed forces with tests. After all, you can't fight the enemy on an empty stomach or when you're gasping for breath.

'Double-sided sticky tape'

Anteotech makes lateral flow immunoassays, which are simple devices aimed at detecting a pathogen in a liquid sample without the need for costly lab equipment.

A non-technology person, Mr Thomson explains the underlying nano-polymer product, Anteobind, as "double-sided sticky tape". Thanks, Derek!

He says a particle surface is usually unstable and that's especially the case for Europium, the element at the heart of the test.

"Europium is a highly sensitive fluorescent element," Mr Thomson says. "When shone under [ultra violet] light, the antigen lights up like a Christmas tree, there's absolutely no doubt you are positive."

But an effective test depends on the antigen being 'captured' and the unstable Europium particles don't do this well.

"So, you need a double sided 'sticky tape', one side to stick to the particle and the other to stick to the antigen."

The enhanced particle stability also means the tests are reproducible and thus can be mass manufactured. In the case of Ellume, the addition of Anteobind gave them the ability to replicate the data dot technology, hitherto only achievable in the lab.

Spruiking the benefits

Anteotech's test consists of a small desktop reader, into which the cassette (containing the patient sample) fits. A result is available within 15 minutes.

Mr Thomson says other test developers using Europium have achieved something like 30 percent reliability; Anteotech claims 97.3 percent sensitivity (correct positive results) and 99.6 percent specificity (correct negative results). More commonly, visual tests use stable gold particles, rather than Europium (stock pregnancy tests, for instance).

The company sources its Europium from Germany's Merck GmbH. It's even more expensive than gold, but a small bottle will be enough for one million tests.

Eyeing broader markets

The company is in the process of signing up European distributors, probably on a country-by-country basis.

"The screening market is dynamic because it hasn't been around before, it's quite embryonic," Mr Thomson says. "There are some big government tenders and also some industry procurement exercises, notably in the airline market."

For the time being, at least, the US market is off limits because it's more crowded. Locally, the company is eyeing Australian Therapeutic Goods Administration approval, which would open up some Asian markets that accept the agency's certification.

The company has also fielded interest from mining companies operating in Papua New Guinea, where Covid-19 remains rampant. Another opportunity lies with vaccine manufacturers who need to test their product for quality control, and Anteotech is working on such a test for the Serum Institute of India, which was involved in developing the Astrazeneca vaccine and is now flat out meeting domestic demand.

Sepsis and other catastrophes

Anteotech's further plans lie in rolling out a "multiplex" test that combines Covid-19, influenza A and influenza B testing. Based on saliva rather than the 'brain stab' method with a long cotton bud, the test is expected to confer a strong competitive advantage.

The company is also eyeing a rapid test for sepsis, the non-viral life immune reaction (or overreaction) to infection that has killed more people than Covid-19.

"We are working on that test now and we will have it out late next year," Mr Thomson says. "There's no herd immunity for sepsis, so it's going to be around for a while."

Anteotech hopes to roll out its Covid test within the next three months, the multiplex test within six to nine months and the sepsis test next year.

Charging up the battery program

While Anteotech's share-price fortunes have been driven by the life sciences side, management urges investors not to overlook the company's battery program that uses the same (albeit tweaked) polymeric chemistry.

Because we're Biotech Daily rather than Renewables Weekly, we won't go into detail. But the short version is that Anteobind can enhance the glue (the binder) that sticks the anode materials together.

Anteotech has also developed Anteox, which changes the binder from a benign glue to an electrochemically charged component of the battery. The ultimate purpose is to enable the batteries to have more capacity relative to their volume and weight.

Finances and performance

Anteo's recent half-year accounts acknowledged a "material uncertainty" about the company continuing as a going concern and in mid-April Mr Thomson admitted the balance sheet was "light on".

Struck at 26 cents a share, this week's capital raising should assuage any doubt. The placement is done and dusted, while the share placement plan (also at 26 cents) should be oversubscribed given there's currently a 46 percent gain on the table.

The last time the company raised funds was for \$2.15 million in March last year - at a miserable 1.5 cents a share, compared to last week's high of 41.5 cents. Before the placement, Anteotech's share register was overwhelmingly retail.

Development of the Covid-19 test was aided to the tune of \$1.4 million or so by the Queensland Government's Exported Goods and Supply Chain program. The company chalked up \$546,000 in December half-year sales, mainly by selling the baseline Anteobind 'ingredients'. Mr Thomson expects small revenues from the Covid-19 test this quarter, with more meaningful sales later in calendar 2021.

Don't forget the bread and milk (and Covid-19 test)

Discount store Aldi sells violins alongside canned pickles, so we shouldn't be surprised that it now stocks home Covid-19 tests in its German home market. Selling for 25 Euros (\$A39) for a pack of five, the assays sold out within hours of hitting the shelves in March. The German government allows one free test per citizen per week, but the Aldi kits are pitched more as a reassurance tool than a hospital-standard test.

"The jury is out as to whether they hinder or help," Mr Thomson says.

For Anteotech, the benchmark is the US wholesale price of \$US10-12 (\$A13-15.50) for similar tests, or \$US40-50 in the end user's hands. Not surprisingly, governments and insurers have been willing to subsidize the cost of such assays.

Sizing up the ASX chums

Of the ASX-listed Covid-19 test developers in the lateral flow assay space, Mr Thomson says Anteotech is closest to Atomo Diagnostics, which listed in April last year. Atomo already had a rapid blood-based test for HIV and quickly tweaked the device for Covid-19. Atomo's business model involves providing the device to other test manufacturers in the US and Europe.

Genetic Signatures was one of the first to get a Covid-19 test to market, based on the alternative science of lab-based molecular diagnostics. And TBG Diagnostics also sells a European-approved molecular test via a Chinese affiliate, but the story is a bit murky.

Dr Boreham's diagnosis:

Anteotech claims its assay ranks among the world's top five rapid tests for sensitivity, which will be a key selling point in an eventual market shake out.

"Of the high sensitivity tests, not many use saliva and that will also differentiate us," Mr Thomson says.

He says Anteotech has attracted interest from "people of all walks of life and locations," as evidenced by the strongly supported raising. But with the interest comes added scrutiny.

"We are under a lot of market pressure to get some revenue, because of our market cap," he says. "We do have to get our ducks in a row in terms of how we are going to make the business robust and not give us growing pains along the way."

Indeed. Investors haven't exactly held back while the company aligns these canards and it would do no harm to give management the breathing space to execute its plans.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As impressed as he is with double-sided sticky tape, he would pay big dollars for a technology that enables the user to locate the start of the reel or normal sticky-tape.

FEDERAL GOVERNMENT

The Federal Health Minister Greg Hunt says the first marijuana treatment - for epilepsy - will be listed on the taxpayer-subsidized Pharmaceutical Benefits Scheme (PBS).

In a media release, Mr Hunt said that from May 1, 2021 Australians with Dravet syndrome will have access to the oral liquid Epidyolex cannabidiol when used in combination with at least two other anti-epileptic drugs.

According to the website of the Cambridge, England-based GW Pharmaceuticals PLC it was the developer and marketer of Epidyolex, known as Epidiolex in the US, along with commercializing "the world's first plant-derived cannabinoid prescription drug, Sativex, or nabiximols, which was approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the US".

The media release from Mr Hunt said that Epidyolex was "only the second medicinal cannabis drug registered for supply in Australia, and the first one to be subsidized by the Australian Government on the PBS".

The media release said that Dravet syndrome was a rare, genetic epileptic encephalopathy that gave rise to seizures which don't respond well to standard medications.

The Federal Government said that the disorder began in the first year of life in otherwise healthy infants and about eight of 10 people with the syndrome had a gene mutation that caused problems in the way ion channels in the brain work.

The media release said the mutation was "new" and not usually inherited.

The Government said that while there had been "very few well-designed clinical trials using medicinal cannabis, the evidence to support its use in the treatment of certain childhood epilepsies is the strongest".

The Government said that about 116 patients a year would benefit from the listing of Epidyolex, and would otherwise pay more than \$24,000 a year for the treatment, but with the PBS listing would pay \$41.30 per script or \$6.60 with a concession card.

ADHERIUM, RESPIRI

Respiri says it has offered to exchange one Respiri share for seven Adherium shares valuing Adherium at 2.25 cents a share or \$19.14 million.

In March, Adherium said it had raised \$18 million in placement at 1.5 cents led by Trudell Medical and Bioscience Managers (BD: Mar 18, 2021).

Last night after the close of market, Respiri issued the offer and said that the exchange rate was a 50.2 percent premium to Adherium's closing share price of 1.5 cents at close of trade on April 28, 2021.

Adherium said that Respiri's "unsolicited, conditional, off-market, takeover offer for Adherium shares" was under consideration and advised shareholder to "take no action" until the board made a recommendation.

Respiri said that if the takeover offer was accepted, it would leverage its US Food and Drug Administration-cleared Wheezo asthma monitor to monetize Adherium's technology in the US respiratory market.

Respiri said that the acceptance of the offer would de-risk investors' holdings in Adherium, noting that Respiri's share price has increased by 81 percent in the past 12 months, while Adherium's share price has fallen 61 percent.

Adherium was up 0.1 cents or 6.25 percent to 1.7 cents with 12.5 million shares traded. Respiri was unchanged at 12.5 cents with one million shares traded.

MESOBLAST

Mesoblast says that a subgroup of 123 patients in its remestemcel-L for Covid-19-related acute respiratory distress syndrome trial had a 46 percent reduced mortality.

Last December, Mesoblast said the data safety monitoring board had recommended halting the trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards) following a third interim analysis of 180 patients which found that the trial was "not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment" (BD: Dec 18, 2020).

Last year, the company said it had a potential up-to \$US1,355 million (\$A1,858.3 million) deal with Novartis for its remestemcel-L for Ards and the US Food and Drug Administration had granted fast track status to remestemcel-L for Covid-19 related Ards (BD Nov 20, Dec 2, 2020).

Today, Mesoblast said an analysis of the 222 ventilator-dependent Covid-19 patients with moderate or severe Ards which had completed the trial showed that a subgroup of 123 patients under the age of 65 years showed a reduced mortality rate of 46 percent at day 60 after remestemcel-L treatment, for both moderate and severe Ards cases (p = 0.048). The company said that in the under 65-year-old subgroup the "benefit was further increased when remestemcel-L was used with dexamethasone as part of standard of care" showing an up to 75 percent mortality reduction (p = 0.006).

Mesoblast said that the mortality reduction was accompanied "by increased days alive off mechanical ventilation and reduced days in hospital".

Mesoblast chief medical officer Dr Fred Grossman said that "the mortality benefit observed with remestemcel-L in ventilator-dependent patients younger than 65, particularly in combination with dexamethasone, has the potential to change the treatment regimen in this critical patient population".

"As cases continue to surge in younger patients across the US, we plan to meet with the FDA to discuss next steps in the regulatory process," Dr Grossman said. Mesoblast that that its agreement with Novartis remained subject to certain closing conditions, including time to analyze the results from this Covid-19 Ards trial. Mesoblast was up 12.5 cents or 6.8 percent to \$1.955 with 14.6 million shares traded.

NOVA EYE MEDICAL

Nova Eye says it has enrolled the first patient in its up-to 160-patient 'Magic' trial of its Itrack canaloplasty microcatheter compared to the Omni device for glaucoma. In March, Nova Eye said it had started the 12-month, prospective, randomized, single-masked multi-center ab-interno glaucoma study investigating canaloplasty (Magic) trial at eight US centres, which would enrol patients with mild to moderate, uncontrolled primary open-angle glaucoma on one to four medications (BD: Mar 2, 2021).

Today, the company said the first patient was enrolled at the Glendale-based Eye Physicians & Surgeons of Arizona by principal investigator Dr Shamil Patel.

Nova Eye said that the patients would receive the Itrack canaloplasty microcatheter or the Omni surgical system device to assess the Itrack canaloplasty as a standalone procedure "to eliminate the confounding effect of cataract surgery".

The company said it expected to publish the completed 12-month results by the end of 2022.

Nova Eye was up one cent or 3.1 percent to 33 cents.

AUSCANN GROUP (MERGED WITH CANNPAL)

Auscann says results from a trial of 46 dogs with osteoarthritis show that its marijuana-based CPAT-01 is safe, effective and improves lameness, pain and quality of life. Auscann said that CPAT-01 was a liquid, oral formulation of tetrahydrocannabinol (THC) and cannabidiol (CBD) developed by Cannpal, which Auscann acquired last month (BD: Nov 16, 2020; Mar 18, 2021).

The company said that the phase IIa randomized, double-blind, placebo-controlled clinical trial treated 46 dogs diagnosed with osteoarthritis with either a placebo or a dose of 0.27mg/kg, 0.54mg/kg or 0.9mg/kg of CPAT-01 for eight weeks.

Auscann said that lameness was assessed by veterinarians, and CPAT-01 groups outperformed the placebo groups at each dosing level, with a "significant improvement" compared to baseline in the highest dosing group.

The company said that the placebo group dogs had worse mobility after 56 days of treatment while all CPAT-01 dosed dogs improved, with a significant improvement in the 0.54mg/kg group (p < 0.1).

Auscann said that dog owners assessed pain scores and quality of life, with the CPAT-01 groups showed reduced pain compared to placebo after 56 days.

The company said that the CPAT-01 showed a statistically significant improvement in quality of life after 14 days compared to the placebo group (p < 0.1).

Auscann said it would use the data to receive formal guidance on its ongoing US development and regulatory plan for CPAT-01.

Auscann was unchanged at 13 cents with 1.4 million shares traded.

ANALYTICA

Analytica says the US Patent and Trademark Office has granted a patent for its Pericoach pelvic floor exercise system for vaginal muscle strength.

Analytica said the patent, titled 'Intra vaginal device to aid in training and determining muscle strength' would protect the use of motion sensors in its pelvic floor exercise device until October 16. 2035.

The company said the Pericoach pelvic floor exercise system had patent protection in Australia with patents pending in other jurisdictions including Europe.

Analytica fell 0.05 cents or 14.3 percent to 0.3 cents with 3.65 million shares traded.

AMPLIA THERAPEUTICS

Amplia has requested a trading halt pending an announcement "in connection with a capital raising".

Trading will resume on May 4, 2021 or on an earlier announcement. Amplia last traded at 28.5 cents.

ACRUX

Acrux says it has it has received a \$406,209 research and development tax incentive from Ausindustry for an Advance and Overseas Finding application.

Acrux said the funds related to expenditure through its subsidiary Acrux Commercial Pyd Ltd for the year to June 30, 2019 and the year to June 30, 2020.

The company said it had Federal Government approval for a 43.5 percent tax incentive for its subsidiary Acrux Pharma Pty Ltd for the same period, expected by June 30, 2021. Acrux was unchanged at 14 cents.

MICRO-X

Micro-X says it has repaid a \$3 million "debt facility" to the South Australian Government Financing Authority and has no outstanding corporate debt.

Micro-X said the facility had been drawn-down in full at a 7.75 percent interest rate, or about \$230,000 in interest a year.

The company said the loan was taken out in August 2016 and the repayment date had been extended to December 31, 2021, but it had elected to accelerate repayment and reduce the interest expense.

Micro-X managing-director Peter Rowland said that the loan had "enabled Micro-X to establish a world-class ISO13485-accredited manufacturing and engineering operation in Tonsley at an early stage and this foundation will support the rapid growth we are now planning as we take our exciting new medical and security products, designed and manufactured here in Adelaide, to global markets".

Micro-X fell one cent or 2.9 percent to 33 cents with 1.1 million shares traded.

CELLMID

Cellmid says it has received Chinese import permits from the National Medical Products Administration for its Jo-Ju and Lexilis branded shampoos.

Cellmid said that once exported to China, the products would be distributed by Ourui Health Management.

Last year, Cellmid chief executive officer Maria Halasz said that the 10-year distribution agreement with Ourui was expected to contribute up to 40 percent of the company's revenue by June 30, 2023 (BD: Dec 14, 2020).

Cellmid fell 0.2 cents or 2.9 percent to 6.6 cents with 1.6 million shares traded.

CANN GROUP

Cann says it has dispatched 20,000 bottles of its 30ml marijuana extract to the Neuss, Germany-based luvo Therapeutics for distribution in Europe (BD: Jan 17, 2021).

Yesterday, Cann said that one of its Australian customers had begun a class III recall of 250 units of 50ml medicinal marijuana oil products (BD: Apr 29, 2021).

Today, the company said the shipment was a "significant milestone" for its export sale strategy and formed part of an initial order from luvo for 25,000 units.

Cann Group was up one cent or 2.1 percent to 49 cents with one million shares traded.

AVECHO

Avecho says it annual general meeting will vote to issue 17,971,397 options to chair Dr Gregory Collier and directors David Segal, Dr Ross Murdoch, Matthew McNamara. Avecho said Dr Collier would receive 5,990,465 options, with Mr Segal, Dr Murdoch and Mr McNamara to receive 3,993,644 options each, exercisable at 1.69 cents each.

The company said the options would vest in four equal tranches up-to 36 months following the date of issue, expiring 42 months after the date of issue.

Avecho said shareholders would vote to adopt the remuneration report, re-elect director Mr Segal, ratify the prior issue of shares and options, and approve a 10 percent placement facility.

The meeting will be held at Grant Thornton Australia, Level 22 Tower 5, Collins Square, 727 Collins St, Melbourne on May 31, 2021 at 1pm (AEST).

Avecho was up 0.1 cents or five percent to 2.1 cents with 1.8 million shares traded.

NOVA EYE MEDICAL

Australian Ethical Investment says it has increased its substantial shareholding in Nova Eye from 23,564,224 shares (16.40%) to 25,193,624 shares (17.53%).

The Sydney-based Australian Ethical said that between December 11, 2020 and April 28, 2021 it bought and sold shares with the single largest purchase of 514,254 shares for \$178,134 or 34.6 cents a share.

EXOPHARM

Exopharm chief executive officer Dr Ian Dixon says he had increased but been diluted from 27,975,294 shares (20.095%) to 28,175,294 shares (18.052%).

The Melbourne-based Dr Dixon said that on December 2, 2020 he received 200,000 shares as part of an annual bonus and was diluted on April 30 2021 following the issue of 166,667 shares.

Exopharm fell two cents or 2.6 percent to 76 cents.

ATOMO DIAGNOSTICS

Atomo says it has appointed Bondi Partners and former Federal Treasurer and US Ambassador Joe Hockey to advise it on US commercial strategy.

Atomo said that the Washington, DC and Sydney-based Bondi Partners and Mr Hockey would advise the entry of its telehealth and at-home test kit services to the US point-of-care test market, which was valued at \$US8 billion (\$A10.3 billion) a year.

The company said that it would grant Bondi Partners 4,000,000 unlisted options, vesting in two equal tranches on April 30, 2022 and October 31, 2022, exercisable respectively at 40 cents each and 60 cents each, and expiring on April 30, 2024.

Atomo was up one cent or 4.9 percent to 21.5 cents with 2.1 million shares traded.

MEDADVISOR

Medadvisor says director Jeff Sherman has resigned as a director and board representative of major shareholders HMS Holdings.

In 2019, Medadvisor said it raised \$17 million, including \$11 million from HMS, with the then HMS chief financial officer Mr Sherman joining the board (BD: Oct 7, 2019).

Today, the company said that Mr Sherman has left his position at HMS following the acquisition of HMS by Gainwell Technologies and the related transfer of certain HMS assets to Cotiviti.

Medadvisor chair Chris Ridd said that the company was working with Cotiviti to appoint a replacement director.

Medadvisor fell 1.5 cents or 4.55 percent to 31.5 cents.