Biotech Daily

Friday September 24, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.37 percent on Friday September 24, 2021, with the ASX200 down 27.6 points to 7,342.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged. All three Big Caps fell.

Dimerix was the best, up three cents or 10.7 percent to 31 cents, with 3.9 million shares traded. Amplia climbed 7.7 percent; Orthocell was up 6.25 percent; Actinogen, Osprey and Pharmaxis improved more than four percent; Antisense, Compumedics, Oncosil, Paradigm and Patrys rose more than two percent; Nanosonics and Opthea were up more than one percent; with Immutep and Starpharma up by less than one percent.

Uscom led the falls, down one cent or 6.9 percent to 13.5 cents, with 10,000 shares traded. Nova Eye and Telix lost more than five percent; Cochlear, Impedimed and Next Science fell four percent or more; Imugene, LBT, Resmed and Universal Biosensors were down more than three percent; Cynata, Optiscan, Polynovo and Proteomics shed two percent or more; Genetic Signatures, Neuren, Prescient and Pro Medicus were down one percent or more; with Clinuvel and CSL down by less than one percent.

DR BOREHAM'S CRUCIBLE: TESTING THE COVID ASSAY DEVELOPERS

By TIM BOREHAM

Ellume: public unlisted

Anteotech (ADO): share price 26.5 cents, market cap $517 million, revenue (12 months to June 30, 2021) $2.4 million, up 90 percent, one year share gain 243 percent, movement since January 3, 2020 - 54 percent

Genetic Signatures (GSS): share price $1.505, market cap $215 million, revenue (12 months to June 30, 2021) $28.3 million, up 150 percent, one year share loss -22percent, share movement since January 3, 2020 - up 57 percent

Atomo Diagnostics (AT1): share price 29 cents, market cap $164 million, revenue (12 months to June 30, 2021) $6.7 million, up 25 percent, one year share loss -2.7percent, share movement since listing on April 16, 2020 – 75 percent

Lumos Diagnostics (LDX): share price 96 cents, market cap $144 million, revenue (12 months to June 30, 2021) $25 million, share loss since July 5, 2021 listing -23 percent

Rhinomed (RNO): share price 36 cents, market cap $91 million, revenue (12 months to June 30, 2021) $3.9 million, up nine percent, one year share price gain - 157 percent, share movement since January 3, 2020 – 70 percent

TBG Diagnostics (TDL): delisted (see below).

Despite the "grave risk to public health" posed by wrongly administering or reading point-of-care Sars-Cov-2* tests, such rapid assays are likely to become the norm as New South Wales and Victoria join The Great Reopening.

* Severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) is the virus that causes Covid-19. For simplicity we are calling all these Sars-Cov-2 tests Covid tests.

Sooner, rather than later, the local Therapeutic Goods Administration will decide on whether to allow rapid Covid self-administered tests that can be used at home (or elsewhere) without the involvement of a healthcare specialist.

We can safely assume a positive decision, given that Federal Health Minister Greg Hunt has flagged the regulator's assent "in coming months, if not weeks".

The TGA has already approved around 30 rapid antigen tests, but medicos are required to interpret the results.

Assent also seems inevitable because rapid tests are already approved in other key jurisdictions including US and Europe. Aldi sells off the shelf tests in its German stores (they sell for 25 Euros, or $A39 for a pack of five if you really want to know).

Early on in the Covid crisis, ASX-listed healthcare diagnostics companies were quick to jump on the rapid-testing bandwagon. Some have succeeded, some are kind of getting there and others have fallen off the rolling conveyance with a thud.

This week, Lumos Diagnostics had a setback when the US Food and Drug Administration (FDA) “deprioritized” the company’s application for approval of emergency use of its Covid test.

Does that mean the corona-crisis is over?

Explaining the tests

The gold standard is the polymerase chain reaction (PCR) test, which involves queuing up for the ‘brain stab’ swab to winkle out mucus samples from the back of the nose. The test goes to the lab and the quarantining subject has to wait to be advised of the result (turnaround times vary from hours to days).

But as vaccination rates creep up and folk emerge from “under the doona” (Tr: duvet, eiderdown) there’s going to be a greater, ongoing emphasis on the easy but less reliable rapid tests.

These assays can be molecular or antigen based. The former detects viral proteins in the viral DNA and the latter detect antigens expressed by the body during acute infection. A rapid molecular test is quicker than PCR but “a lot slower” than antigen.

Other serological (blood assay) tests look for tell-tale antibodies in the claret, but these biomarkers can take two weeks to be present post infection, and that tells you about disease, not the virus. The rapid antigen tests are considered good for positives, but not so good for false negatives.

The TGA notes that self-tests are most accurate when used on a symptomatic person within the first few days of showing symptoms when the viral load is highest, “although their accuracy invariably has been shown to be lower than that of the PCR tests.”

The regulator is not a big rap for serologic (antibody detection) tests, given they provide only a retrospective diagnosis: “It is expected that Covid-19 rapid antibody self-tests will continue to remain prohibited from supply in Australia.”

Ellume

Ellume is arguably the most advanced of the coronavirus detecting companies, with its rapid tests approved by the US Food and Drug Administration for emergency use. Unlike some of the other tests Ellume is not approved by the Australian Therapeutic Goods Administration, yet.

(Currently Federal Government law allows point-of-care antigen testing by health professionals, but not home testing.)

Ellume also has $300 million from the US Government to support production, not to mention deals done with two major airlines to test returning Americans, as well as distribution through US pharmacies.

As a public unlisted company, we don't have access to Ellume's historical financial data but the company said in February that it was on-track to procure about 200,000 Ellume Home Test Kits a day, which would sell for around $50 each.

Anteotech

Anteo's tests are lateral flow immunoassays, which are simple devices aimed at detecting a pathogen in a liquid sample, without the need for costly lab equipment. In other words, it's a rapid antigen blood test showing whether the user has the virus.

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

In March 2020, Anteo won Conformité Européenne (CE) mark approval for its tests, which the company claims are more reliable than rival assays. Yesterday, the company filed its application to the local TGA.

The tests are based on the highly sensitive fluorescent element, Europium, which lights up the antigens when subject to ultra violet light. Anteotech claims 97.3 percent sensitivity (correct positive results) and 99.6 percent specificity (correct negative results).

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

Anteo's further plans lie in rolling out a saliva-based test that combines Covid-19, influenza A and influenza B testing.

(And in something completely different - the company is also pursuing a research program to improve the efficacy of lithium-ion batteries, which doesn't have much to do with Covid but could power some of the tests, we suppose.)

Anteo enjoyed a significant ramp-up in profile after Ellume's test was approved in the US.

Anteo posted sales of $2.41 million in the year to June 30, 2021, up 90 percent but lost $6.2 million. Anteo's share performance has also been lacklustre: they peaked at 50 cents in late April, but now change hands for 29 cents, ascribing a $580 million market capitalization.

Genetic Signatures

With a portfolio of PCR-based tests for indications such as respiratory, gastro-enteric strains, flavivirus/alphavirus, antibiotic resistant bugs and sexually transmitted infections, Genetic Signatures is far from a one-trick pony.

But having moved swiftly to get its molecular-based rapid Covid test approved last March, the company's respiratory tests have become a more important part of the undersized equine repertoire.

Sold under the Easyscreen banner, Genetic Signatures' tests were developed (and made) in Australia and can be sold in more than 30 European countries.

Approved in Europe and locally in March last year, the Covid tests are able to detect whether a patient has the affliction, but its multiplex test can detect a range of respiratory illnesses - such as rhinovirus, influenza A and B, and the laboratory reporting the result with a throughput of 188 samples in about four hours, per instrument.

Genetic Signatures chalked up sales revenue of $28.3 million in the year to June 30, 2021, 150 percent higher. The company also managed a $1.75 million profit compared to the previous $2.08 million loss. June quarter revenues climbed 27 percent to $5.4 million.

Atomo Diagnostics

Luckily, Atomo already had a rapid blood-based diagnostic device for HIV - the only self-administered HIV assay approved by the TGA. Could the company's boffins tweak it into a Covid test? You betcha!

Atomo's business model involves providing the device to other test manufacturers in the US and Europe. Before you could say cytokine storm, the tests were being shipped to Europe under a 'white label' arrangement with French diagnostics house NG Biotech SAS.

The test can also be used for bacterial-versus-viral and pregnancy tests, with malaria, hepatitis C and Ebola tests also being targeted.

The tests are either a finished product in a nice package, or a naked device to which original equipment manufacturers can add their own test strip.

The tests take three steps, with a result in 15 minutes. While the pin-prick procedure requires more exposure to the virus than swab-based molecular lab-based tests, they can also test for antibodies after the symptoms and the virus have disappeared (or in asymptomatic patients).

Atomo reported revenue of $6.7 million in the year to June 30, 2021, 25 percent higher. Of this turnover, the Covid tests accounted for $3.68 million (55 percent) from the sale of 1.1 million units. Atomo lost $4.8 million on an underlying basis.

Lumos Diagnostics

The FDA on Wednesday said it had "ceased review" of Lumos's rapid antigen test, Covidx, for emergency use, sending the shares down 12 percent.

Lumos remains in active dialogue with the regulator and is preparing additional data to support a fresh application, as you do. The test is already approved in Europe.

Lumos listed on July 5 this year, having raised a chunky $63 million.

The company's flagship product is not Covidx but Febridx, a finger-prick blood test that can distinguish between bacterial and viral infections (such as Covid) within 10 minutes.

Lumos is also developing Viradx "which simultaneously tests for Covid-19 and influenza and has the potential to satisfy an even greater public health need".

As extension products of Febridx, the company is developing Uridx for urinary tract infections and Sepsidx (for the often-fatal blood infection sepsis).

Of Lumos's revenue of $25 million in the 2020-'21 year, $22.7 million derived from commercial services (white-label assay and digital reader development and manufacturing for other parties). Lumos also posted a $14.5 million loss, but one has to break a few eggs to make an omelette.

Rhinomed

Honorable mention goes to the nasal appendage specialist, which hasn't devised a Covid test per se, but has come up with a more comfortable and faster way of deriving a sample.

The Rhinoswabs are low-tech, plastic clip-like devices that are inserted into the nostrils and collect the requisite snotty stuff from both nostrils.

Doherty Institute testing found "the eluted volume from Rhinoswab was found to be comparable to the commercially available [swab] when artificially dipped into a neat saliva solution and spiked with inactivated Sars-Cov-2 at both high and low virus burdens".

The Rhinoswabs works with existing PCR pathology test flows, but are also very relevant for the home testing market.

The New South Wales and Victorian health departments have ordered one million swabs each.

As Rhinomed notes, two billion tests have been carried out in the last 18 months, 26 million in Australia. Yep, that's one for every man, woman and child.

Management says the contract terms are confidential but confides the Victorian deal equated to 35 to 40 percent of its $3.9 million revenue in the year to June 2021 (up nine percent).

Okay, so let's say at the midpoint it's worth $1.56 million - and then double that for the New South Wales contract if Gladys isn't getting a better deal than Dan.

TBG Diagnostics

TBG appeared to have its ducks in a row last year, with a molecular test that won European approval via Chinese affiliate TBG Xiamen.

The neatly aligned canards now look more disorganized.

In April 2020, TBG Xiamen was preparing to ship its first batch of 20,000 kits to Europe, with a vaunted selling price of $US15-25 ($A20-30) per test. TBG Xiamen also received a "substantial order" from the US and was lodging a fast-track application with the US Food and Drug Administration.

TBG Diagnostics already had approved non Covid products in Taiwan and China via TBG Xiamen and its fully-owned subsidiary TBG Taiwan.

But last month, TBG shares were removed from the ASX boards because of unpaid listing fees.

Come to think of it, TBG shares have been suspended since March last year, relating to claims regarding both a Sars-Cov-2 and a Covid-19 test, so investors aren't missing much.

Dr Boreham's diagnosis:

Unless your diligent columnist is missing something – and he probably is – there's a fair inconsistency between the valuations of the Covid testing aspirants.

Genetic Signatures has way more revenue than Anteotech and even managed a modest profit.

Yet it's worth less than half of Anteotech, which appears to enjoy a generous valuation ascribed to the boffin-y lithium-ion battery stuff.

Lumos generates similar revenue to Genetic Signatures, albeit unprofitably, but is worth two-thirds less.

In the words of Anteotech CEO Derek Thomson: "Despite slowly increasing vaccination rates, the global market is still large and the demand for rapid testing remains very strong.

"The market is however very competitive, with a wide range of tests available … with a wide range of performance characteristics."

And we'll leave the final health warning to the TGA:

"The misinterpretations of serology-based and rapid antigen point-of-care test results present a grave risk to public health and could result in serious illness and death of the patient and other persons that the patient comes in contact with."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If taken too seriously, his musings present a grave risk to public health and could result in serious illness and death of the reader and other persons* with whom *the reader comes in contact - because we are, after all, grammarians.

FEDERAL GOVERNMENT, MTP CONNECT

The Federal Government and MTP Connect say that $5.2 million has been allocated for diabetes and cardiovascular research and $4 million for medical technologies.
Media releases from the Federal Health Minister Greg Hunt and MTP Connect said that $5.2 million would be granted to seven diabetes and cardiovascular disease research projects through the Targeted Translation Research Accelerator (TTRA), with $4 million for five “highly promising medical technology projects”.
MTP Connect managing-director Dr Dan Grant said the initial funding was “a substantial and targeted boost for the translation and commercialization of Australian research into diabetes and cardiovascular disease.
“These seven highly promising research projects selected in Victoria, New South Wales and Queensland have the potential to transform diabetes and cardiovascular disease outcomes and reduce the burden of disease on individuals, families and the community,” Dr Grant said.
Dr Grant said the $5.2 million “attracted an additional $9.1 million in matching contributions, injecting a total of $14.3 million into the sector to tackle leading causes of death and disability in Australia”.
“A distinguishing feature of the TTRA program is the emphasis on translation with our program partners Andhealth, Medical Device Partnering Program and Uniquest, providing mentoring and commercialization advice to applicants and those receiving funding,” Dr Grant said.
MTP said the next TTRA funding round with up to $6 million available would open shortly with details at: www.mtpconnect.org.au/programs/TTRA/ResearchProjects.
The Federal Government-funded organization said that the $4 million for medical technology projects had attracted an additional $5.1 million in industry contributions and came from the fourth round of the Biomedtech Horizons program.
Dr Grant said the funding round “focused predominantly on the development of pre-commercial prototypes that … entering human clinical trials”.
Dr Grant said the projects included devices for blindness and vision impairment, improved neonatal resuscitation, precision monitoring of foetal complications during birth, real-time atrial fibrillation/cardiac monitoring for patients at home and patient matched spinal implants.

COCHLEAR

Cochlear says a complaint for patent infringement has been filed by the University of Pittsburgh in the US District Court for the Western District of Texas, Waco division.
Cochlear said the complaint named it and US subsidiaries Cochlear Americas Corp and Cochlear Clinical Services LLC as defendants.
The company said it believed that none of its products infringed the University’s patent and would defend the lawsuit.
Cochlear said its legacy products and related patents predated the University’s patent by several years.
The company said the earlier legacy products and patents embodied the alleged invention of the patent and, accordingly, Cochlear believed the patent was invalid.
Cochlear said that the asserted patent was related to a wireless energy transfer system, filed at the US Patent Office in 2009 and would expire in 2030.
Cochlear said the lawsuit was not expected to disrupt its business or customers in the US.
Cochlear fell $11.31 or 4.8 percent to $225.73 with 176,284 shares traded.

ADHERIUM

Adherium says it has a $US650,000 ($A890,536) AstraZeneca contract to supply its Hailie sensor and software for a two-year US clinical study.
Adherium said the sensors and software would "track the usage of the investigational inhaler medications via the study participants' phones" over the two-year study.
The company said the contract was on "usual commercial terms and … in addition to the 10-year master supply and development agreement" (BD: Aug 27, 2015.
Adherium chief executive officer Rick Legleiter said the company had a "longstanding clinical study supply relationship with Astrazeneca to support the collection of objective clinical trial data using Adherium's Hailie technology".
"This is welcome revenue as Adherium progresses its strategy focusing on a provider and payor model and expanding its revenue base over multiple channels," Mr Legleiter said.
Adherium was unchanged at 1.7 cents with 49.3 million shares traded.

IMMURON

Immuron said it won't acquire a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) company, and vice executive chair Peter Anastasiou has resigned.
In May, Immuron requested a trading halt "in connection to a planned acquisition" and took the halt to a voluntary suspension (BD: May 27, 31, 2021).
In July, the company said it had asked for in-principle advice from the ASX regarding a "proposed major transaction" (BD: Jul 8, 2021).
Today, Immuron said it proposed buying an unnamed private biotechnology company "focused on the development of innovative vaccine technologies … [which] would have added significant value to the company and shareholders potentially delivering a much-needed, Australian-developed Covid-19 vaccine candidate".
Immuron said it was unable to satisfy the pre-conditions for the acquisition "due to the expiration of the existing contractual timetable and will not proceed with the proposed acquisition in its present form".
The company said there were no break fees, but professional fees associated with the transaction over the past four months were about $450,000 plus GST.
Separately, Immuron said Mr Anastasiou became a major shareholder in 2013, was appointed a director in May 2015 and vice-executive chair in August 2015.
Immuron fell two cents or 12.5 percent to 14 cents with 2.8 million shares traded.

DIMERIX

Dimerix says that India's Central Drug Control Organization has recommended approval of its 600-patient, phase III trial of DMX-200 for Covid-19.
In May, Dimerix said the Drug Controller General of India had postponed review meetings and approvals, due to staff having the Covid-19 (BD: May 12, 2021).
Today, the company said multiple clinical sites in India had been initiated and were ready to begin recruitment.
Dimerix said the Clarity 2.0 protocol was an "investigator initiated, prospective, multi-centre, randomized, double blind, placebo-controlled study" with the first patient expected to be dosed in "the next few weeks" on approval.
Dimerix said the primary endpoint of the study would be an eight-point clinical health score measured on treatment day-14 and participants would be treated for up to 28 days with longer term outcomes assessed at 26 weeks.
Dimerix was up three cents or 10.7 percent to 31 cents with 3.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that data from its phase II trial shows that ATL1102 significantly modifies biomarkers for Duchenne muscle dystrophy.

Last year, Antisense said its nine-patient trial of ATL1102 for Duchenne muscular dystrophy met its safety primary endpoint and indicated some efficacy, supporting a phase IIb trial (BD: May 22, 2021).

Today, the company said data presented at the World Muscle Society meeting, titled 'ATL1102 treatment in non-ambulant boys with DMD modulates latent TGF-beta-binding protein-4, and thrombospondin-1, two disease genetic modifiers of ambulant DMD, and CXCL16'.

Antisense said that "at the end of the 24-week dosing period, ATL1102-treated patients demonstrated a statistically significant mean reduction in thrombospondin-1 (-49%) and increases in LTBP4 (20.7%), soluble CXCL16 (29.9%) and VCAM-1 (18.0%) compared to baseline levels ($p < 0.0005$).

Antisense said the protein changes observed in the plasma of the ATL1102-treated patients in the study was "consistent with the drug's positive effects on muscle function and strength reported in the ATL1102 phase II trial".

Antisense chief executive officer Mark Diamond said the "positive effects on the above proteins strengthens ATL1102's profile in the treatment of both non ambulant and ambulant DMD patients while positioning it as an exciting prospective therapeutic approach in other muscle and fibrotic conditions".

Antisense was up half a cent or 2.5 percent to 20.5 cents with 3.97 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for its phase III trial of pentosan polysulfate sodium (PPS) for patients with knee osteoarthritis pain.

Last month, Paradigm said that the US Food and Drug Administration had accepted five of six responses to questions about its investigational new drug trial application but wanted more information (BD: Aug 3, 2021).

Today, the company said it expected to receive a response from the FDA prior to the end of September for its application to begin the US arm of the study.

Paradigm said the primary endpoint of the Para OA 002 trial would be changes from baseline at day 56 in the Western Ontario and McMaster Universities Osteoarthritis Index (Womac) pain scale.

The company said the secondary outcomes included changes to baseline at multiple time points to day-168 in Womac pain and function, patient global impression of change and quality of life.

Paradigm said patient recruitment and screening would begin by the end of 2021 at eight sites.

Paradigm was up five cents or 2.4 percent to $2.10 with 903,226 shares traded.

INVEX THERAPEUTICS

Invex says it has requested a trading halt pending a market announcement relating to "a major collaboration, manufacturing and supply agreement for Exenatide".

Trading will resume on September 28, 2021, or on an earlier announcement.

Invex last traded at 68 cents.

PHARMAXIS

HSBC says it has increased and been diluted in Pharmaxis from 27,160,830 shares (6.89%) to 30,910,830 shares (6.82%).
The London-based Hong Kong and Shanghai Banking Corp (HSBC) said it bought 3,750,000 shares for eight cents a share and was diluted "following the various issues of shares".
In April, Pharmaxis said it would raise $4.4 million in a placement at eight cents a share (BD: Apr 14, 2021).
Pharmaxis was up half a cent or 4.2 percent to 12.5 cents.

NUHEARA

Perennial Value Management says it has reduced its substantial shareholding in Nuheara from 137,500,000 shares (7.98%) to 116,183,926 shares (6.73%).
The Sydney-based Perennial said between April 8 and September 22, 2021, it sold 21,316,074 shares for $827,218 or an average of 3.9 cents a share
Nuheara fell 0.1 cents or 3.45 percent to 2.8 cents with 3.8 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Dr Jack Hoblitzell head of pharmaceutical development.
Botanix said Dr Hoblitzell had more than 30 years of experience and was most recently head of technical operations at the Lake Forest, Illinois-based Assertio Therapeutics.
The company said Dr Hoblitzell previously held executive roles at Pfizer, King Pharmaceuticals, Ivax Pharmaceuticals and Teva Pharmaceuticals.
Botanix said Dr Hoblitzell held a Bachelor of Science in Pharmacy and a Doctor of Philosophy from the University of Rhode Island.
Botanix was unchanged at seven cents.