Biotech Daily

Thursday April 30, 2020

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 2.39 percent on Thursday April 30, 2020, with the ASX200 up 129.0 points to 5,522.4 points. Thirty of the Biotech Daily Top 40 stocks were up, three fell, six traded unchanged and one was untraded.

LBT was the best, up one cent or 9.5 percent to 11.5 cents, with 416,167 shares traded. Kazia and Next Science climbed more than eight percent; Optiscan was up 7.9 percent; Avita, Mesoblast, Proteomics and Volpara rose six percent or more; Alterity, Compumedics and Polynovo improved more than five percent; Genetic Signatures, Paradigm, Pro Medicus and Uscom were up four percent or more; Clinuvel, Imugene, Pharmaxis and Resonance were up more than three percent; Dimerix, Ellex, Immutep, Nanosonics, Telix and Universal Biosensors rose more than two percent; Amplia, Cochlear, Cynata, Orthocell and Starpharma were up more than one percent; with Neuren up 0.7 percent.

Prescient led the few falls, down 0.3 cents or 6.5 percent to 4.3 cents, with 1.6 million shares traded. Resmed lost 3.5 percent; CSL fell 1.95 percent; with Medical Developments and Opthea down by less than one percent.

DR BOREHAM'S CRUCIBLE: ATOMO DIAGNOSTICS

By TIM BOREHAM

ASX code: AT1

Share price: 48 cents; **Market cap:** $269.3 million; **Shares on issue:** 561,077,807

Chief executive officer and founder: John Kelly

Board: John Keith (chairman), Dr Paul Kasian, Dr Curt LaBelle, Connie Carnabuci

Financials (December half 2020)*: revenue $937,000, loss of $2.04 million. Financial year 2018-19: revenue $540,000, loss of $4.8 million; post-IPO cash balance of $31.8 million

***** The company listed on April 16 2020

Identifiable major shareholders: Dalraida Holdings Pty Ltd (John Kelly) 13.1%, Global Health Investments Fund LLC 11.4%, Walker Group 10.4%, Perennial Value Management 6.4%, Ellerston Capital 6.1%.

Luck's a fortune, eh?

Atomo's ASX listing had been in the offing for months, based on its rapid blood-based diagnostic device for HIV that's the only self-administered HIV assay approved by the local Therapeutic Goods Administration.

Then along came Covid-19 and a rush of "urgent inbound inquiries" from European, US and Chinese diagnostic companies, keen to evaluate the Atomo devices for their own Covid-19 rapid antibody tests.

The said antibodies are an immune response to the underlying virus, Sars-Cov-2.

While plenty of diagnosis and device houses globally are developing Covid-19 assays - or at least promising to do so - Atomo is off and racing. The devices already are being shipped to Europe under a 'white label' arrangement with French diagnostics house NG Biotech SAS, with US tie-ups likely as well.

A key feature of the underlying device is that it allows for self-administration, thus reducing the risk to healthcare workers.

Atomo's platform can be tweaked for any number of purposes, including bacterial-versus-viral and pregnancy tests.

Malaria, hepatitis C and Ebola tests are also being targeted.

“We knew we could accommodate these other test strips quite easily,” Atomo founder and CEO John Kelly says. “Once the pandemic happened, we were able to get a working test developed quite quickly as the test device already existed.”

Keep it simple, stupid

A native of Northern Ireland’s scenic North Antrim Coast and with a background in product development, Mr Kelly co-founded Atomo because the existing blood-based tests resembled a clumsy chemistry set suited only for professional use. Even in this context, those tests made well-documented errors.

He says product development was dominated by “PhDs in microbiology or molecular chemistry” concerned - not surprisingly - about the science of it all.

“No-one was focused on the end user,” he says.

“When everyone else in the market was saying ‘It’s all about the chemistry’, Atomo decided it was all about ease of use, aesthetics and ergonomics.”

Testing times

Atomo has sold more than 1.3 million tests to date, mainly for HIV assays.

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 (such as with the NG Biotech tie-up for the Covid-19 strips).

Atomo distributes its self-administered HIV test via Mylan Pharmaceuticals under an agreement covering 130 countries (Mylan being one of the biggest providers of HIV medicine). The company sells direct to consumers in Australia.

Under the overriding moniker of Atomo Rapid, the devices are sold under the Pascal and Galileo names. Newton and Franklin are digital enabled point-of-care devices still under development.

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 virus have disappeared (or in asymptomatic patients).

Given South Korean Covid-19 patients have been detected with reinfection - or perhaps the disease never properly left their bodies - such detection is becoming crucial in controlling the blight.

Technically speaking, the tests are lateral flow immunoassays. This involves a liquid sample (blood) being absorbed into a sample pad, ensuring accurate and controlled flow. Reagents bind to the target substance, creating a colored line in the case of a positive test (sadly, the pregnancy tests do not distinguish blue for boy and pink for girl).

As of mid-April, NG Biotech had placed orders for 947,200 Covid-19 test devices. Or more specifically, devices for Covid-19 testing purposes. The NG order book covers Britain as well as its homeland, with the Gallic military a key client.

NG Biotech has the right - but not the obligation - to buy 2.46 million tests this year.

Atomo through the ages

Based in a nondescript warehouse on Parramatta Road in Leichardt, Western Sydney, Atomo was founded by Kelly and directors of ID&E Pty Ltd in 2010 (product innovators George Sidis and Richard Sokolov).

The HIV self-test was evaluated in March 2015 and was launched in South Africa in late 2016 to “establish performance and market data.” The land of the springboks was an appealing location, because of the big market for HIV testing, as well as lower regulatory barriers to commercialization.

In 2014, the Atomo Rapid test won ‘best in show’ at the health device equivalent of Crofts: the Medical Design Excellence Awards.

In 2015. the Global Health Investment Fund proffered a $US6 million loan to Atomo and in 2016 chipped in $US4.3 million of equity. The fund is backed by the deep-pocketed Bill and Melinda Gates Foundation.

Atomo’s board business bent

Mr Kelly was chief operating officer of the ASX listed Unilife and was instrumental in devising the world’s first glass prefilled syringe with a retractable needle.

The good bit is that Sanofi Aventis acquired the rights to the device in for $US47 million. The bad bit is that Unilife itself entered bankruptcy protection in mid-2017, having made one or three promises too many.

By that time Mr Kelly had long left the building.

At Resmed, he developed the Swift and Activa sleep apnoea masks.

“At Resmed and Unilife we got a good sense of what we needed to do and not to do,” Mr Kelly says with a fine sense of diplomacy.

Atomo chairman John Keith is managing director of BNP Paribas and director Dr LaBelle is president of the Bill and Melinda Gates backed social impact venture, the Global Health Investment Fund.

Dr Kasian was executive chairman of Genetic Technologies. As general counsel at the Australian Broadcasting Corporation, fellow director Ms Carnabuci keeps Aunty’s numerous litigious enemies at bay.

Finances and performance

Atomo's atomic initial public offer (IPO) involved issuing 150,000,010 shares (to be precise) to raise $30 million, at 20 cents apiece. Post-IPO the company has just over 560 million shares on issue - including 155 million escrowed for two years and 58 million voluntarily escrowed for six to 12 months.

There are also 30.5 million unlisted options, exercisable at price hurdles between three cents and 25 cents. That sounds like money for jam, but the three cent options were merely 'at the money' when issued in 2012, while the 25 cents paper was well out of the money.

Atomo's December half revenue of $937,000 compares with $540,000 for the whole of 2018-'19 and $287,000 in 2017-'18. Similarly, the reported loss contracted from $4.8 million in 2018-'19 to $2.04 million for the six months to December 31, 2019.

Atomo's revenues to date pertain mainly to sales of the HIV test, in Europe, Africa, Central and South America and southeast Asia.

Mr Kelly says the pricing of the tests depends on the market and the channel. But a rule of thumb is $US10 to $US25 per test here and in Europe and $US3 to $US5 a test in poorer countries.

Atomo has 'prequalified' status with the World Health Organisation for the HIV self-tests, which in effect qualifies the company as a vendor to the health body's third world health programs. The higher volumes inherent in such contracts help to offset the lower margins.

And speaking of which, Atomo currently operates on a gross margin of around 50 percent. Management has targeted a margin in the high 50s, which is all the more obtainable with the Covid-19 test.

Mr Kelly says Atomo should break even in the "relatively near term" and doesn't expect to have to raise capital in the near future - which is just as well.

"We outsource manufacturing and oversee it with a small technical team," Mr Kelly says. "We are not bloated; we do not have hundreds of employees."

In their short, listed life Atomo shares have traded between 40 cents (April 24) and 56.5 cents (April 20).

Mr Kelly accounts for about 13 percent of the company, while property developer and enthusiastic biotech investor Lang Walker holds 10.4 percent.

Former Macquarie Bank chief Allan Moss has a modest holding, having also invested in cancer diagnostic outfit Sienna Diagnostics.

The dawn of the Atomo-ic age?

Ultimately, the company is striving for what Mr Kelly dubs the equivalent of "Intel Inside" status: "If it's not on an Atomo device, it's not fit for purpose."

Management expects HIV revenues to continue to grow strongly, with potential other applications for ailments including anaemia, allergies and celiac (gluten intolerance) disease.

“We see the opportunity for over the counter [devices] and self-help in a range of applications,” he says. “But for the next six months we will focus on delivering scale and contracts for Covid-19.”

While most device makers strive for 510k (devices) approval from the US Food and Drug Administration, Atomo bypassed the US HIV market as expensive and time consuming.

But Mr Kelly says the Covid-19 test changes everything. “We are talking to US companies and we are especially keen to be first to get self-test approval,” he says. “The situation is still pretty fluid.”

While reagent materials are supplied by a South African party, the company has built its own packing and assembling facility in Cape Town. The facility currently is being certified. The devices themselves are built in China and the US by a manufacturing partner.

Dr Boreham’s (global lateral flow assay) diagnosis:

Atomo estimates the value of medical ‘global lateral flow assay’ revenues at $US2.47 billion in 2019.

The World Health Organisation estimates 183 million HIV rapid diagnostic tests were procured in 2017, excluding China, with demand expected to exceed 500 million by 2021.

Furthermore, The WHO estimates 700,000 people died in 2019 from antibiotic resistant bacterial infections.

Is that number for real? You better you better you bet. (Ask Pete Townshend.)

We stress that Atomo doesn’t have the HIV rapid blood diagnostic field to itself, with the prospectus listing three HIV self-test providers, all of which are WHO prequalified.

They are Chembio Diagnostics and Orasure Technologies of the US; and Canada’s Biolytical Labs.

But in building a simpler mouse trap, Atomo should catch more mice at a time when the market is richly rewarding much more tenuous links with the virus crisis that isn’t going away in a hurry.

“We think Covid-19 will be around for a number of years,” Mr Kelly says. “It’s not an Ebola type situation that disappeared in the short term.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He speaks for his generation in hoping the current pandemic will simply f-f-fade away.

MESOBLAST

Mesoblast says it has begun enrolling a 300-patient, phase II/III trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards).

Last week, Mesoblast said that 10 of 12 ventilator-dependent Covid-19 patients treated with its allogeneic mesenchymal stem cell product had survived in a trial at New York's Mt Sinai Hospital, with nine no longer requiring ventilator support (BD: Apr 24, 2020).

Today, the company said the randomized, placebo-controlled trial of ventilator-dependent patients would be conducted at more than 20 US medical centers and it expected to complete enrollment within three to four months.

Mesoblast said patients would receive either two intravenous infusions of remestemcel-L within five days, or a placebo, as well as maximal care.

The company said the primary endpoint was all-cause mortality within 30 days of randomization and the key secondary endpoint was the number of days off mechanical ventilator support.

Mesoblast said the trial would be conducted in collaboration with the Cardiothoracic Surgical Trials Network, established by the US National Institutes of Health's National Heart, Lung and Blood Institute.

Mesoblast chief executive Prof Silviu Itescu said that based on the initial results of remestemcel-L treatment under compassionate use in New York, there was an urgent need for the robust randomized, placebo-controlled trial to definitively determine whether the cell therapy could reduce the mortality of patients with Covid-19 Ards on ventilators.

"There are limited treatment options for ventilator-dependent patients with acute respiratory distress syndrome, the principal cause of mortality in Covid-19 infection," Prof Itescu said.

Mesoblast was up 20 cents or 6.3 percent to $3.36 with 12.0 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has record quarterly revenue of $1.8 million for the three months to March 31, 2020, up 71 percent, and expects April sales of $1.7 million.

Genetic Signatures said revenue was up due to sales of its new Easyscreen Sars-Cov-2 detection kit in Australia and Europe, under regulatory exemptions it received earlier this month (BD: Apr 1, 14, 2020).

Today, the company said it had cash and cash equivalents of $39,163,000 compared to $40,441,000 million at December 31, 2019.

Genetic Signatures was up nine cents or 4.7 percent to $1.99 with 635,126 shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has completed treatment of 10 patients with Zilosul under a US Food and Drug Administration investigational new drug expanded access program.

Paradigm said patients were completing final checkups at six weeks post-final injection and it expected to report results by October 2020.

The company said the FDA had also granted it orphan drug designation for muco-poly-saccharidosis type 1 (MPS-1) complications, including pain and arthropathy, and it would receive tax credits for qualified clinical testing, a waiver of new drug application user fees and eligibility for seven-year marketing exclusivity.

Paradigm chief executive officer Paul Rennie said access program completion was a "milestone, especially during the current health conditions created by Covid-19".

Paradigm was up 7.5 cents or four percent to $1.95 with 2.9 million shares traded.

COGSTATE

Cogstate says the Alzheimer's Drug Discovery Foundation has awarded it $1.3 million for the early detection of memory impairment and decline.
Cogstate said that it would adapt the International Shopping List Test for smartphones and tablet computers, the Foundation would reimburse the company for technical development and scientific validation study costs and it would pay the Foundation a four percent royalty on the first $150 million in revenue and 2.5 percent royalty on all revenue thereafter.
Cogstate was up half a cent or 1.45 percent to 35 cents.

USCOM

Uscom says it has partnered with Tokyo's A&D (Analogue and Digital) to install an A&D module in its BP+ blood pressure monitors for hypertension and vascular health.
Uscom said it had been working with A&D for 12 months to develop, refine components for the BP+ and the new module would be included in all new BP+ devices.
Uscom executive chairman Prof Rob Phillips told Biotech Daily that the module included a specialized pump and software for the blood pressure monitor.
Uscom was up one cent or 4.35 percent to 24 cents.

THC (THE HYDROPONICS CO) GLOBAL GROUP

THC says it has a binding $4 million loan from Mitchell Asset Management to boost its cash balance without dilutionary equity capital raisings.
THC said the loan was mortgaged against its Southport Manufacturing Facility, was repayable on October 31, 2021 or earlier at the company's election and "otherwise on standard commercial terms" but did not state an interest rate or other terms.
THC was up half a cent or 1.6 percent to 32.5 cents.

NUHEARA

Nuheara has requested a trading halt pending "a capital raising".
Trading will resume on May 4, 2020 or on an earlier announcement.
Nuheara last traded at 1.6 cents.

ELIXINOL GLOBAL

Elixinol has requested a trading halt "pending an announcement … in connection with a capital raising, which comprises a fully underwritten … entitlement offer".
Trading will resume on May 6, 2020 or on an earlier announcement.
Elixinol last traded at 38.5 cents.

IMPEDIMED

Australian Ethical Investment says it has increased its substantial shareholding in Impedimed from 27,759,024 shares (5.43%) to 59,925,691 shares (7.84%).
The Sydney-based Australian Ethical said that between January 22 and April 14, 2020 it bought 32,166,667 shares for $1,734,011.29 or an average of 5.39 cents a share, including 23,476,471 shares for $880,367.66 or 3.75 cents a share in Impedimed's $18.2 million institutional and retail rights offer (BD: Apr 3, 28, 2020).
Impedimed was unchanged at 3.9 cents with 4.5 million shares traded.

BLUECHIIP

Bellwether Super Pty Ltd and director Jim Craig say they have become substantial shareholders in Bluechiip with 30,000,000 shares or 5.06 percent of the company.
The Middle Park, Victoria-based Bellwether said that between February 12 and April 29, 2020 it acquired 1,801,262 shares for $180,044 or an average of 10.0 cents a share.
Bellwhether was previously substantial in Bluechip (BD: Jul 18, 2017; Nov 20, 2019).
Bluechiip was up 0.2 cents or 3.3 percent to 6.2 cents with 1.1 million shares traded.

MEDIBIO

Medibio says it has submitted a US Food and Drug Administration 510k application for its Medsleep sleep stage identification software device.
Medibio said Mebsleep used artificial intelligence, deep learning algorithms and neural network methodology to identify the five sleep stages required for the accurate identification of sleep disorders and was 85 percent accurate compared to its chosen predicate device's 73 percent accuracy.
Medibio was up 0.1 cents or 16.7 percent to 0.7 cents with 4.4 million shares traded.

RESPIRI

Respiri says it is in discussions with Singapore's Practice Innovators International to integrate its Wheezo asthma detector into the GP Now telehealth platform.
Respiri said both companies were committed to entering into a binding joint development agreement by July 2020, to conduct field trials by October 2020 and to launch an integrated Asthmacare telehealth service by January 2021.
Respiri was unchanged at 6.9 cents.

NOXOPHARM

Noxopharm says that four of 15 patients show an abscopal response in tumors where Veyonda was not injected, following a combination therapy of Veyonda and radiation.
Last December, Noxopharm said that 10 of 15 patients with prostate cancer treated with Veyonda, or NOX66, and radiotherapy had "stable disease or better", with a partial response in one patient in its six-month phase IIb direct and abscopal response Darrt-1 study (BD: Dec 2, 2019).
Today, the company said soft tissue and bone secondary tumor patients were delivered 20 Gray (Gy) of radiation for five days to one or two symptomatic lesions and Veyonda daily for 10 to 14 days, with all measurable lesions followed up as part of the Darrt-1 study.
Noxopharm said it planned to conduct a phase II, controlled study in early 2021.
Noxopharm was up half a cent or 2.4 percent to 21 cents with 1.3 million shares traded.