Biotech Daily

Friday March 25, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTHEA UP 5.6%; TELIX DOWN 11%**

*** DR BOREHAM'S CRUCIBLE: ATOMO DIAGNOSTICS**

*** DOHERTY TRIALS 2 SARS-COV-2 VACCINES**

*** CHIMERIC PLACES $2.7m OF $6.4m SHORTFALL; TOTAL $14.4m**

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*** NUHEARA 20-TO-ONE CONSOLIDATION, STOCK RATIFICATION EGM**

MARKET REPORT

The Australian stock market was up 0.26 percent on Friday March 25, 2022, with the ASX200 up 19.1 points to 7,406.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell and six traded unchanged.

Opthea was the best, up six cents or 5.6 percent to $1.135, with 1.2 million shares traded, followed by Medical Developments up 5.3 percent to $3.97 and Actinogen up five percent to 10.5 cents.

Nova Eye and Volpara climbed more than four percent; Pharmaxis and Proteomics were up more than three percent; Alcidion, Kazia, Micro-X, Oncosil, Starpharma and Universal Biosensors rose more than two percent; with Cochlear up 0.6 percent.

Telix led the falls, down 53 cents or 11.2 percent to $4.21, with 6.2 million shares traded.

Emvision lost 10 percent; Immutep and Patrys fell more than seven percent; Imugene and Prescient were down more than five percent; Neuren fell 4.3 percent; Amplia, Antisense, Clinuvel, Cynata and Impedimed were down more than three percent; Next Science shed 2.8 percent; Avita, CSL, Nanosonics, Orthocell and Resmed were down one percent or more; with Compumedics, Cyclopharm, Genetic Signatures, Mesoblast and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: ATOMO DIAGNOSTICS

By TIM BOREHAM

ASX code: AT1

Share price: 12 cents; **Market cap:** $68.2 million

Shares on issue: 568,597,807 (159,907,470 in ASX escrow until April 2022)

Chief executive officer and founder: John Kelly

Board*: John Keith (chair), Mr Kelly, Dr Paul Kasian, Dr Curt LaBelle, Deborah Neff

***** Connie Carnabuci stepped down December 9, 2021

Financials (December half 2021): revenue $7 million (up 53%), net loss of $2.4 million (previously a $2.6 million deficit), cash on hand $13.7 million.

Financials (December quarter 2021): receipts $5.5 million, net cash outflows $422,000, quarters of available funding 32

Identifiable major shareholders: Dalraida Holdings Pty Ltd (John Kelly) 11.64%, Global Health Investments Fund LLC 11.4%, Ellerston Capital 8.7%, Walker Group 6.6%.

Has there been a better time to be a supplier of Covid-19***** rapid antigen tests (RATs) over the last six months? Yeah … and nah.

Naturally, demand skyrocketed when the walls of Fortress Australia tumbled down (WA hermit kingdom included) and the Omicron variety romped across our big brown land.

Surfing the tsunami of demand, Atomo saw its revenues rise by 53 percent in the December half of 2021, with a solid March quarter also expected.

But did this result in flow-on prosperity for shareholders? Nah - Atomo shares have lost more than 60 percent of their value over the last six months.

Pre-Christmas, rapid tests became accepted as an at-home testing method in preference to the more reliable polymerase chain reaction (PCR) tests for which people queued for hours … and, sometimes, more hours.

Authorities all but gave up on PCRs (a.k.a Patience Certainly Required) after a huge pathology lab backlog meant that Omicron victims were getting their results after their seven-day isolation period.

"It's an interesting environment for a diagnostics company," says Atomo CEO John Kelly.

***** Don't write in: strictly speaking the tests are for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the underlying virus that causes Covid-19.

Entering the Atomo-ic age

A native of Northern Ireland's scenic North Antrim Coast and with a background in product development, Mr Kelly co-founded Atomo in 2010 because the existing blood-based tests resembled a clumsy chemistry set suited only for professional use.

Atomo listed April 16, 2020, having raised $30 million at 20 cents apiece.

At that point, Atomo has sold more than 1.3 million Covid tests, globally. 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.

Technically speaking, the tests are lateral flow immune-assays. 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.

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

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.

Where Atomo fits in

In essence, Atomo currently supplies re-badged blood pinprick Covid RATs from the US manufacturer Access Bio.

A key limitation is that, to date, the tests have been for professional use: they need to be administered and interpreted by a health professional or someone within a company trained to do so.

Atomo is pursuing Australian Therapeutic Goods Administration (TGA) approval for a home-based variant and is working on commercializing a more precise swab-based rapid test for the home market.

Under a revised deal with Access Bio, struck last October, Atomo negotiated the right (but not the obligation) to purchase 20 million Access Bio tests by December 2022 - half of them professional tests and half of them home tests.

Mr Kelly said that unlike most other Access Bio distributors, Atomo was protected by clauses that require Access Bio to deliver the kits within a reasonable time.

Naturally, this helped Atomo when RAT supply was tight.

Well done, almost everyone ….

In early 2022, the TGA ordered a review of all 66 RAT tests approved locally, as well as those in the approval pipeline. The ubiquitous Doherty Institute was engaged to do the grunt work.

Not surprisingly, the TGA was keen to ascertain whether the tests actually work for both Omicron and likely future variants.

“Variants of the virus due to mutations in the protein target of the genome may alter the structure of a viral protein,” the TGA said. “As a result, tests kits may no longer be able to detect the virus, leading to false negative results.”

Well, the results are in … sort of.

On March 15, the agency reported the results from 80 kits, for which their manufacturers provided proof of efficacy.

Of these, only one test didn’t make the grade and was suspended from the Australian Register of Therapeutic Goods - Medi-Stats ANZ’s Cov Clear assay.

The TGA stresses the results are based on data provided by the manufacturer, with the results from the Doherty validation process released “as testing progresses”.

Finances and performance

Atomo reported revenue of $7 million (including a $1.65 million licence and settlement fee from Access Bio) for the December 2021 half year, up 53 percent year on year. This amount consisted mainly of $4.51 million from the Covid tests, $770,000 from the HIV tests and $1.65 million from Access Bio.

As a guide to the elevated sales trajectory, Atomo also reported revenue of $4.6 million for the December quarter, $3.2 million from product sales averaging 90,000 kits per month.

Management expects a robust third (March) quarter. After all, the company sold more tests in January than the 420,000 units sold in the whole of the December half.

From a base of 70 customers, the company added 50 more from sectors including resources, critical essential services and aged care.

Not surprisingly, Atomo’s profit margins on the kits improved and were expected to expand further.

“We are careful not have been seen to be taking advantage of the situation, but margins have improved into the third quarter,” Atomo chief finance officer Will Souter said in January. “We have a number of corporates, such as in the resources industry, who value having a good quality supply, a product they understand and support.”

Atomo shares have traded as high as 52 cents (just after listing in April 2020) and are currently changing hands at their lowest point in the company's short listed life.

Of course, Atomo is not the only life sciences play to see its valuation crunched as investors become more risk averse.

But for broker Canaccord, February's half-year numbers "disappointed on a number of fronts" including a lower-than-expected gross margin and higher operating costs flowing from supply chain issues.

Post announcement, the shares tumbled from 18 cents to 14 cents.

Bowling over the Grim Reaper

Mr Kelly also notes a "significant improvement" in the HIV self-test business, with the kits sold via distributors Viatris and Owen Mumford (Europe). The company reports keen demand from India, Africa and South East Asia.

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).

Under relaxed TGA rules here, the company can now supply to pharmacy channels as well as via its website.

Mr Kelly says the changes bring HIV in line with Covid.

"This playing field for rapid testing has now opened up," he says. "Until quite recently that was a market [that] regulators were supportive of and we think that offers a lot for us as a point of care test provider."

New products

Atomo's growth prospects include its rapid swab device, which simplifies the steps of swab home testing. This not only covers Covid market but is equally applicable to other infectious diseases such as sexually transmitted infections (STIs) and respiratory conditions such as the good ol' 'flu.

The company expects to make further announcements about what the product will look like and is also talking to potential commercialization partners.

"We are broadening our product base," Mr Kelly says. "Most demand during the pandemic has been for swab-based tests. Our tests are recognized for their utility and convenience and reliability. But we want to be in the largest section of the market and that's swab based."

Given the product is an accessory to current tests, any regulatory approval is expected to support numerous applications.

Advance Australia where?

With import terminals groaning with container loads of imported RATs, a pertinent question is whether Australia should develop its own RAT-making capacity - and whether that's something Atomo might pursue.

"The short answer is: no," Mr Kelly says.

"We have spoken to Federal and State Governments at various times over the last 15 months, with a view to onshore production.

"The response has been unfortunately quite lacklustre and disappointing and I believe other manufacturers have voiced other frustrations about the lack of foresight from government."

So as the man said: that's a hard 'No'.

Dr Boreham's diagnosis:

When we last covered Atomo in April 2020, shortly after the stock listed, Mr Kelly presciently opined that Covid-19 would be around for a number of years.

"It's not an Ebola type situation that disappeared in the short term," he said.

Atomo is one of the few ASX-listed Covid-testing exposures, the others being Anteotech, Genetic Signatures, Lumos and pathology group Australian Clinical Labs, as well as the yet-to-list Ellume.

As Atomo gnaws away at the RAT market, a moot point is how long the sales boom will last. The emergence of another sub-variant, renewed lockdowns in China and stubbornly high case numbers suggests that once again we may have been lulled into complacency.

As with hand sanitizer, profits are likely to be crimped as the market becomes glutted with RAT tests.

So, investor attention will turn to the other applications for the Atomo tests as well as the company's penetration of the burgeoning telehealth market.

Mr Kelly notes the whole Covid RAT thing has normalized at-home testing and "transformed the landscape for home-based healthcare".

He adds: "We are in a great position to expand on that demand, not just for HIV and Covid but into consumer health and STI applications as well."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does possess a number of rapid tests and still gives a RAT's about Covid.

THE DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Doherty Institute says it will begin a 114-person, phase I trial of two Australian-made vaccines for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

The Doherty said it wanted healthy people aged 18 to 70 years of age in Victoria to volunteer for the randomized, double-blind, placebo-controlled, first-in-human trial, which would provide a side-by-side comparison of the two vaccines developed in Melbourne, with the Monash University Institute of Pharmaceutical Sciences (MIPS).

The Institute said the vaccines, one mRNA-based and the other protein-based, both targeted the same area at the tip of the Sars-Cov-2 spike protein, called the receptor binding domain (RBD).

The Doherty said that the receptor binding domain not only enabled the virus to enter and infect the body's cells, but was also an area that elicited the response of more than 90 percent of neutralizing antibodies in the body's response to Sars-Cov-2 infection.

The Institute said both were proof-of-principle variant vaccines, presenting the Beta variant - which was of the greatest concern when these vaccines were designed - to the immune system.

The Doherty said that the Beta variant had two of the same key receptor binding domain mutations as the Omicron variants, BA.1 and BA.2, which it said "may also improve immunity to Omicron".

The Doherty Institute's head of vaccine and immunization Prof Terry Nolan said that the trial would "assess the safety and efficacy of a single dose of these vaccines as a fourth dose of a Covid-19 vaccine".

"Participants must have had their third dose at least three months prior to the study commencing," Prof Nolan said. "People who have been infected with Covid-19 are also eligible provided they had their infection at least three months prior, and have had their third vaccine dose."

"What's also unique about this gold standard, randomized, double-blind, placebo-controlled trial is that it will be the first time a side-by-side comparison will be undertaken of two new Covid-19 vaccine platforms," Prof Nolan said.

The University of Melbourne's Dr Georgia Deliyannis, who performed most of the receptor binding domain (RBD) protein vaccine experiments at the Doherty, said that in pre-clinical trials, the vaccine induced high levels of receptor binding domain-specific antibodies, including high neutralizing antibodies, following two doses.

"Immunity induced by the RBD protein vaccine protects against virus challenge in a mouse model of Sars-Cov-2 infection, even 100 days following the boost," Dr Deliyannis said. "As well as inducing strong neutralizing antibody immunity to the Beta variant in mice it also retains its potential to neutralise the original ancestral strain, and preliminary in-lab studies have demonstrated neutralising activity against other variants including Delta and Omicron."

The Doherty said Monash Institute of Pharmaceutical Sciences' Prof Colin Pouton led the development of the receptor binding domain mRNA vaccine.

Prof Poulton said that the research team "used similar strategies to formulate and manufacture the vaccine to those used by other global biotech manufacturers, but designed the mRNA to focus on the RBD, in alignment with the RBD protein vaccine.

"In common with the RBD protein vaccine, the RBD mRNA vaccine induced high levels of RBD-specific antibodies and protected against virus challenge in [mice]," Prof Poulton said. "We have good reason to think that both vaccines will perform well in the clinic."

Doherty director Prof Sharon Lewin said both vaccines were "efficient to produce and can be rapidly modified to incorporate distinct or multiple RBD mutations arising in future variants".

CHIMERIC THERAPEUTICS

Chimeric says it has placed $2.7 million of the $6.4 million shortfall from its recent one-for-3.15 retail rights offer at 17 cents a share, taking the total raised to $14.4 million.
On Wednesday, Chimeric said its retail rights offer raised $4.3 million of a hoped-for $10.7 million, taking the total raised at the time to $11.7 million (BD: Mar 23, 2022).
Chimeric executive chair Paul Hopper said on Wednesday that "in light of the current geo-political situation and challenging equity market conditions impacting the biotechnology sector, this capital raising result represents a strong outcome".
Today, the company said the offer's lead manager, Bell Potter, had placed $2.7 million, and it would not seek any further shortfall placements
Mr Hopper said the company was "extremely pleased with the progress the business has made since listing in early 2021, expanding the portfolio with very promising assets and announcing positive early data."
Chimeric was up half a cent or 3.45 percent to 15 cents with 1.7 million shares traded.

MICRO-X

Micro-X says it expects to receive a $900,000 milestone payment following the submission of data on its point-of-care stroke imaging system to the Australian Stroke Alliance.
Micro-X said the data, submitted ahead of schedule, showed that its computed tomography (CT) system could produce stroke imaging to current clinical standards for stroke detection.
The company said that submission of the data had unlocked the second milestone payment in the Medical Research Future Fund program to develop the point-of-care system and was "a major derisking of the CT development program".
Micro-X said the next focus would be engineering of the CT point-of-care stroke imager to refine both the hardware design and image algorithm software and in parallel, it would begin development of a carbon nano-tube mini x-ray tube for road or air ambulance.
The company said it was aiming for a reduction in the size of the mini x-ray tube from its current diameter of 150mm to 40mm.
Micro-X chief engineer Anthony Skeets said the milestone was "a significant de-risking … and provides both additional funding and confidence for us to progress to the next stage".
"This brings us another step closer to achieving our goal of introducing a game changer to pre-hospital stroke care globally, particularly in remote and rural areas, which will significantly impact stroke recovery and survival rates," Mr Skeets said.
Micro-X was up half a cent or 2.6 percent to 20 cents with 1.65 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has approved its NNZ-2591 for Pitt-Hopkins syndrome investigational new drug application and phase II trial.
Neuren said the up-to 20 children, phase II trial would examine the safety, tolerability, pharmaco-kinetics and efficacy of 13 weeks of treatment with NNZ-2591.
Neuren chief executive officer Jon Pilcher said the company was "excited to proceed with this ground-breaking trial in Pitt Hopkins syndrome and look forward to working with the community in the US".
Mr Pilcher said that Neuren had three INDs active for NNZ-2591 and was advancing "our plan to address multiple neuro-developmental disorders that have such high unmet need."
Neuren said the Pitt-Hopkins syndrome trial's top-line results were expected by July 2023.
Neuren fell 18 cents or 4.3 percent to $4.04 with 288,455 shares traded.

NUHEARA

Nuheara says its extraordinary general meeting will vote on a 20-to-one consolidation and the ratification of the issue of shares and options to investors.

Nuheara said the consolidation would reduce its share pool from 1,960,169,462 shares to 98,008,474 shares.

Last year, Nuheara said it raised $4.6 million in a placement, including $3 million from the US-based Healthcare 2030 (BD: Dec 23, 2021).

Today, Nuheara said it would seek to issue 65,328,846 shares to Healthcare 2030, as well as options to Argonaut Securities Pty Ltd and Ketom Pty Ltd.

Nuheara was up 0.1 cents or 8.3 percent to 1.3 cents with four million shares traded.