Biotech Daily

Friday March 3, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.39 percent on Friday March 3, 2023, with the ASX200 up 28.2 points to 7,283.6 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Pharmaxis was the best, up 0.5 cents or 11.1 percent to five cents, with 368,214 shares traded. Resonance rose 10.4 percent; Oncosil climbed 8.8 percent; Orthocell improved 7.7 percent; Alcidion, Dimerix, Medical Developments and Prescient were up four percent or more; Avita and Emvision improved more than three percent; Genetic Signatures, Immutep and Uscom rose more than two percent; Antisense and Resmed were up more than one percent; with Clinuvel, Cochlear, CSL, Opthea, Polynovo and Telix up by less than one percent.

Kazia led the falls, down two cents or 11.8 percent to 15 cents, with 559,228 shares traded. Actinogen, Atomo, Next Science and Universal Biosensors fell more than four percent; Impedimed was down 3.3 percent; Nova Eye, Starpharma and Volpara shed more than two percent; Mesoblast, Neuren, Paradigm and Proteomics were down more than one percent; with Nanosonics and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: BLUECHIIP

By TIM BOREHAM

ASX code: BCT

Share price: 2.8 cents; **Shares on issue:** 598,563,796; **Market cap:** $16.8 million

Financials (December quarter 2022): customer sales $280,000, receipts $527,000, cash burn $988,000, cash balance $575,000, quarters of available funding 0.64

Year to June 30, 2022: revenue $927,245 (up 170%), receipts $582,287 (down 52%), loss of $3.06 million (previous deficit $3.23 million)

Chief executive officer: Andrew McLellan

Board: Iain Kirkwood (chair), Mr McLellan, Michael Ohanessian, Andrew Cox

Identifiable major shareholders: One Funds Management (Saville Capital) 12.5%, Jencay Capital 5.3%, Iain Kirkwood 4.65%, Dr Stephen Frederick Woodford 3.95%, Bradan Investments (McGuirk Family) 1.95%, Michael Ohanessian 1.5%.

Do you know where your frozen semen or egg samples really are being stored – and is it under optimal conditions?

Bluechiip chief Andrew McLellan says biobanking customers would be shocked to see the rudimentary identification and tracking methods used for deep-frozen bodily samples - namely wonky bar codes and handwriting that would put a doctor to shame.

Or in the case of clinical trials, drug makers are spending squillions in the lab but they don't have traceability or control of the key samples underpinning their efforts.

The developer of a wi-fi-enabled, durable tagging system for bio-specimens, the Melbourne based Bluechiip is on a quest to help the $US1 billion ($A1.4 billion) a year sector lift its game. Bluechiip claims to be only company that can provide identification and temperature tracking for every sample, whether it's stored or transported.

The company has 33 granted patents in territories including the US, Europe and - of course - Australia.

"The tech is unique and it's completely owned by Bluechiip," Mr McLellan says.

Thiis iis Bluechiip

Bluechiip was founded in 2003 and listed on the ASX in 2011. And from the outset we stress the spelling is correct: the extra 'i' was inserted to overcome trade mark issues.

Over the two decades, Bluechiip has changed tack a few times in a commercial sense, but the underlying know-how has stayed the same.

The technology was invented by former Royal Melbourne Institute of Technology academic Dr Ronald Zmood, an expert in magnetic bearings, micro electro mechanical systems (MEMS) and control systems. Bluechiip was co-founded by Dr Zmood and son-in-law Brett Schwarz, the company's chief executive officer from listing to January 2014.

The Bluechiip device is a sensor embedded into bags or vials, recording the details (and temperature) of the specimens. The data is wirelessly conveyed to a reader (which looks like a TV remote) and is stored and displayed with associated software.

Currently, four million Bluechiip chips are in use and the company's European manufacturing facility has the capacity to churn out five million of them a year.

The company currently has 11 customers accounting for 13 labs, mainly in the US and Europe, with four in Australia. Clients include Australian Regenerative Medicine Institute at Melbourne's Monash University, Organa Bio, Crux Biolabs and long-time patron, Labcon.

Bluechiip has distribution networks in Europe and Asia, but is building direct "feet on the street" in North America.

The former head of the Advanced Manufacturing Cooperation Research Centre, Mr McLellan has been Bluechiip's CEO since January 2015.

Changing tack

In December 2021, Bluechiip launched its own range of consumables - primarily vials and blood bags - after winning approval from the US Food and Drug Administration (FDA), as well as European assent.

Mr McLellan describes the development as "extremely important" for Bluechiip, as it enables the company to fly its own flag.

"We are now able to sell our own products into the end-marketplace and we are doing that," he says. "It means we take control of our own destiny."

Having said that, the company has also signed a compact with medical device giant Fujifilm/Irvine Scientific, covering the in-vitro fertilization (IVF) market. It's expected the licencing and development agreement will move to a white-label arrangement, by which Bluechiip provides its sensors for Fujifilm/Irvine's consumables.

Tech talk

Bluechiip's sensors consist of a miniature chip with 52 mechanical beams, of varying lengths. Each is turned on or off at the point of manufacture, to create a unique identification with billions of combinations. Samples can be tracked individually, or as large groups.

A bit like a tuning fork, the metallic beams resonate with specific frequencies.

The company describes the system, based on MEMS technology, as a “generational change” on written labels; and an improvement on barcodes and radio frequency identification (RFID) tracking.

The chips can withstand temperatures to minus 196 degrees Celsius, the boiling point of nitrogen. This makes them ideal for cryogenically stored bio-specimens such as stem cells, cord blood and Walt Disney.

With no electronic parts of wires, the sensors can also survive auto-claving, gamma radiation, sterilization, humidification and centrifuging.

“About 25 percent of bio-banks are still using handwriting in some form,” Mr McLellan says. “At such low temperatures the frost has to be wiped off the labels and RFID just doesn’t work at such extremes.”

Bluechiip readers don’t require line of sight to the item to receive accurate data.

$US1 billion target market

Bluechiip says its addressable market is more than $US1 billion in direct revenue alone, with 40 percent in North America. The target markets are IVF and assisted reproductive technologies, clinical trials, cell therapies, bio-banking and vaccine development.

With well over 300 million samples stored at minus 196 degrees, Mr McLellan describes the opportunity as “significant”.

“In the case of clinical trials, even with just cell therapies, there are more than 1,000 trials going on, most of them in North America.”

A Bluechiip tube typically costs $US3.00 to $US4.00 apiece, compared with $US1.50 to $US2.00 for a standard item.

Mr McLellan cites the set-up cost to a client as between $US30,000 to $US50,000, for the software and the readers (customers might also opt for a box reader that can scan hundreds of samples at once). Typically, a customer would do thousands of samples a month, but a big one might do 15 million samples.

Mr McLellan says two to three years ago customers were wary about the cost of adopting Bluechiip’s tracking, but “now that we are selling the solution and not just the consumables, we don’t get any pushback at all,” he says.

He notes Bluechiip can eliminate “dual witnessing”: the need for two people to confirm a sample’s identification.

He adds that in the heavily regulated market the company targets, Bluechiip’s systems increasingly are being built into standard operating procedures.

Beyond human bio samples

While Bluechiip specializes in those really cold conditions - no, not Melbourne this unseasonal Summer - other opportunities beckon in the cold-chain logistics sector.

This refers to food, drink and other consumer goods, typically stored at a balmy minus 20 degrees. One challenge in this sector is knowing whether an item such as a bag of peas has been stored at above optimal temperature for any length of time.

“We are currently focused on on-premises storage, but we think we can work across the whole cold chain,” Mr McLellan says. “While there’s a massive market in life science, we are also seeing opportunities in crop science (seed banks), veterinary, industrial and defence.”

Finances and performance

In the December 2022 quarter, Bluechiip chalked up record customer sales of $280,000, with money through the door (receipts) of $527,000. But after recording outflows of $988,000, Bluechiip’s cash position was tighter than a Tupperware seal.

The end-of-December cash balance was $575,000, enough to fund just over a quarter of expenditure when a $57,000 unused facility is included. On those numbers, Bluechiip should be in the corporate deep freeze by now. But Mr McLellan says the picture is not so dire, given the expected receivables and a $825,000 Federal Research and Development Tax Incentive received after the December balance date.

In December, the company also received the first $173,000 of an $825,000 grant from the Federal Government’s Supply Chain Resilience Initiative (included in the ‘receipts’ total). We hadn’t heard of that one either, but suffice to say the company was one of only 18 successful applicants.

Mr McLellan says the company expects revenue to increase this quarter, given it signed up a “very large” customer in the December quarter. This client is expected to use Bluechiip in only one laboratory initially, expanding to between five and eight.

“Our pipeline continues to grow and we expect the number of accounts in our pipeline and conversions to accelerate in the current and future quarters,” he says.

Bluechiip expects a further $1 million Federal Research and Development Tax Incentive payment this current year. If it needs to, the company can access a financing arrangement allowing for an advance on this payment.

Outflows are expected to remain at around $1 million per quarter, as the company builds its sales capacity. In the mid-term, the company expects to invest in automation.

Bluechiip shares have ranged between two cents in September 2016 to 27 cents in July 2012. At the current 2.7 cents per share, Bluechiip is valued at a mere $16 million, with the shares losing one-third of their value over the last 12 months.

Covid radio silence

For the two years of the pandemic, management couldn't travel overseas to talk to clients and partners face-to-face.

"Big pharma checked out the product in 2019, but then there was radio silence until the start of 2022," Mr McLellan says.

"While there are a lot of samples going around, most of them were for Covid."

But the company seized the chance to expedite product development and nail the boring-but-important stuff, such as International Standards Organisation certification.

Mr McLellan says an upside to the pandemic was the populace's heightened appreciation of medical science: "Two years ago, you would never have seen a liquid nitrogen tank on a TV news article and then we went through a period where we saw it every night."

Dr Boreham's diagnosis:

When we last covered Bluechiip in October 2017 - and it's been a long time between frozen slushies - we opined that the company looked to be on the cusp of serious revenues and great fame and fortune after a protracted development period.

As is almost inevitably the case with biotechs, reaching this point of transition has proved elusive. But dare we say, Bluechiip now looks to be on the cusp of serious revenues and great fame and fortune after a protracted development period.

Mr McLellan says customers long have been frustrated by the travails of deep-freeze identification, but with the absence of any product in the market there hasn't been much clamoring for a solution.

"We're going in there and communicating that we are available."

Mr McLellan says biotechnology is a "follow-the-leader market, in that if you get the early adopters, the rest of the world will follow".

Not surprisingly, Bluechiip intends to be the leader and - for the time being at least - the company looks to have the market to itself.

Given there are thousands of labs handling more than 300 million samples a year "We are only scratching the surface."

But this enviable monopoly status will amount to nought if Bluechiip doesn't have enough funds to keep the lights on and the freezers running.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was thought to be on the cusp of great fame and fortune, but this has proved elusive.

TRUSCREEN GROUP

Truscreen says it has “firm commitments” for a $600,000 placement at 3.00 New Zealand cents (2.77 Australia cents).

In February, Truscreen said it would offer a one-for-five, pro-rata, renounceable rights issue to raise up to $NZ2.2 million ($A2.0 million) at 3.0 NZ cents (BD: Feb 17, 2023).

At that time, the company said eligible shareholders who elected to take up all of their rights would have an opportunity to apply for additional shares, at an issue price to be determined through an over-subscription book-build facility, which could be more than the issue price, but could not be less.

Truscreen said that the rights offer opened on February 28 and would close on March 15, 2023.

Today, the company said that the placement was in addition to the oversubscription bookbuild which would take place on March 15 and 16, 2023.

Truscreen was up 0.2 cents or eight percent to 2.7 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it will acquire 100 percent of the New York-based Pharma15 Corporation for $US4 million ($A5.9 million), half in cash and half in scrip.

Radiopharm said Pharma15 was a private venture developing therapeutic radio-pharmaceuticals for prostate cancer “which seek to overcome resistance to prostate-specific membrane antigen (PSMA) targeting cancer therapies”.

The company said that Pharma15 technologies had “highly specific targeting of receptors expressed on cancer cells, but not in healthy tissues … [which] may further limit toxicity in the new approaches to targeted radiotherapy in prostate cancer”.

Radiopharm said it would pay 50 percent in cash and 50 percent in shares, split into two equal instalments, the first scheduled for March 3, 2023, and the second on the anniversary of completion.

Radiopharm said it would issue 10.4 million shares in the first instalment, at the seven-day volume-weighted average price (VWAP) of 14.31 cents, with the second instalment of shares to be at the seven-day VWAP at that time.

The company said that the agreement set out contingent consideration of $US2.3 million in shares, subject to gaining “the significant value-adding clinical milestone of an investigational new drug application with the US Food and Drug Administration for Pharma15’s product” but said the milestone was “unlikely to be achieved before 2025”.

Radiopharm said Pharma15’s co-founder Prof David Ulmert and Prof Ken Herrmann would join its scientific advisory board.

Radiopharm managing-director Riccardo Canevari said that targeted radio-pharmaceutical therapies in PSMA-expressing tumor in prostate cancer was “a major innovation and [Pharma15 is] transforming the clinical approach”.

“With this agreement, we are looking at the potential next generation of radio-pharmaceuticals in prostate cancer to go beyond PSMA and to continue innovation for patients suffering from this disease,” Mr Canevari said.

“We are in early pre-clinical stage with these technologies, but we wanted to secure them in our pipeline, before other competitors may have, and we are excited by the underlying potential of going after those two new targets,” Mr Canevari said.

“Additionally, we will benefit from gaining access to the Pharma15 team of experienced scientists, clinicians and radiochemists and their deep experience in preclinical and translational [targeted radio-pharmaceutical therapies] development,” Mr Canevari said.

Radiopharm was unchanged at 13 cents.

IMUGENE

Imugene says it has dosed the first Vaxinia and pembrolizumab combination patients in its phase I study of CF33-hNIS for metastatic advanced solid tumors (Mast).
In February, Imugene said its phase I Mast study of Vaxinia, was ready for combination with pembrolizumab (BD: Feb 2, 2023).
At that time, the company said that both of the second cohorts of the intravenous and intra-tumoral arms of the monotherapy trial had been completed, showing acceptable safety, allowing progress to the combination dose and a higher dose of the Vaxinia as a monotherapy.
Today, Imugene said that three to six patients each were dosed in the first intra-venous and intra-tumoral cohorts of the combination dose escalation arm of the study, with the monotherapy dose escalation arm of the study continuing to the third intra-venous and intra-tumoral cohorts with three to six patients in each cohort.
Imugene managing-director Leslie Chong said that “having continued through the monotherapy dose escalation with safety and early positive signals, we’re eager to see Vaxinia used in combination with the well-known drug Pembrolizumab and see the potential benefit this could bring to patients”.
Ms Chong said the company was “setting an excellent pace with the trial”.
Imugene was unchanged at 13.5 cents with 10.2 million shares traded.

INCANNEX HEALTHCARE

Incannex says Catalent will develop and manufacture a psilocybin product for commercialization and use in its drug development program.
In 2021, Incannex said it would begin a 72-patient, phase IIa trial of psilocybin with psychotherapy for generalized anxiety disorder, with Monash University approving the triple-blind, placebo-controlled trial (BD: Oct 28, 2021).
In January, the company said 29 participants had completed treatment in psilocybin with psychotherapy for generalized anxiety disorder trial (BD: Jan 22, 2023).
Today, Incannex said that development and manufacture of its psilocybin followed interim data from its phase IIa trial, which it said would be released “soon”.
The company did not disclose the commercial terms of the arrangement with the Somerset, New Jersey-based Catalent, but said that the manufacturing process would be designed to be scalable to commercial supply.
Incannex managing-director Joel Latham said “having our own source of pharmaceutical grade psilocybin not only allows our company to freely undertake clinical trials, it also creates and assists with number of commercial opportunities which are currently at an advanced stage of investigation by the company, and will be announced in the coming weeks, following board appraisal and approval”.
Incannex was up one cent or 7.7 percent to 14 cents with 9.7 million shares traded.

RHYTHM BIOSCIENCES

The ASX says it has suspended Rhythm pending an announcement in relation to its Australian Therapeutic Goods Administration submission.
On Wednesday, Rhythm requested a trading halt in connection with its TGA submission, saying that trading would resume on March 3 (BD: Mar 1, 2023).
Last year, Rhythm said it had submitted the final TGA filing for its Colostat blood test for colorectal cancer screening (May 12, 2022).
Rhythm last traded at 96 cents.

PYC THERAPEUTICS

PYC has requested a trading halt pending an announcement regarding its “investigation new drug application with the US Food and Drug Administration”.
In February, PYC said it had filed an investigational new drug application to the FDA for VP-001 for retinitis pigmentosa type 11 (BD: Feb 2, 2023).
Today, the company said trading would resume on March 7, 2023 or on an earlier announcement.
PYC last traded at 8.6 cents.

OSTEOPORE

Osteopore says an extraordinary general meeting will vote to issue 11,100,000 performance rights to directors.
Osteopore said that the meeting would vote on the issue of 9,250,000 performance rights to executive chair Mark Leong, as well as 925,000 performance rights each to non-executive directors Prof Teoh Swee Hin and Daniel Ow.
The company said that the performance rights would be released to directors in five escalating tranches on meeting share price milestones of 25 to 55 cents a share, or market capitalization milestones of $32.5 million to $70 million, all expiring five years from the date of issue.
Osteopore said that shareholders would vote to approve an employee share incentive plan, potential termination benefits, and ratify the issue of shares and options in relation to prior placements and rights issues.
The meeting will be held at the Ground Floor, 16 Ord Street, West Perth, on March 31, 2023 at 11am (AWST).
Osteopore was unchanged at 12.5 cents.

MAYNE PHARMA

Lazard Asset Management says it has become a substantial shareholder in Mayne Pharma with 4,539,772 shares or 5.29 percent.
The Sydney-based Lazard said that it bought shares between November 2, 2022 and March 1, 2023, with the single largest purchase 7,035,854 shares for $1,586,202 or 22.5 cents a share, prior to the 20-to-one consolidation, equivalent to 351,793 shares at $4.509 a share.
Mayne fell 15 cents or 3.9 percent to $3.68 with 495,442 shares traded.

STARPHARMA HOLDINGS

Starpharma says it has appointed Justin Cahill as its chief financial officer and company secretary, effective from early April 2023.
Starpharma said Mr Cahill was most recently chief financial officer at Paradigm (see below) and previously Diver Foods and CSL Plasma US chief financial officer, as well as Costa Group’s finance manager.
The company said Mr Cahill held a Bachelor of Business and a Master of Accounting from Melbourne’s Swinburne University of Technology.
Starpharma fell 1.5 cents or 2.9 percent to 50 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed company secretary Abby Macnish Niven interim chief financial officer following the resignation of Justin Cahill, effective from March 3, 2023.
Paradigm said Ms Macnish Niven held a Bachelor of Science and Commerce from the University of Western Australia, and was the part-time chief financial officer and company secretary of two other ASX listed companies.
Paradigm fell 2.5 cents or 1.7 percent to $1.42.

RADIOPHARM THERANOSTICS

Radiopharm says it has appointed Dr Ken Herrmann to its scientific advisory board.
Radiopharm said Dr Herrmann had more than 18 years of experience in radio-ligand therapy, which included his current position as chair of the Department of Nuclear Medicine at Germany's Essen University of Medicine.
The company said Dr Herrmann held a Doctor of Medicine from Berlin University of Medicine, Masters of Business Administration from the University of Zurich.