

Biotech Daily

Friday March 15, 2024

Daily news on ASX-listed biotechnology companies

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- * NANOSONICS TO LOSE INVENTOR, CTO DR STEVEN FARRUGIA

MARKET REPORT

The Australian stock market was down 0.56 percent on Friday March 15, 2024, with the ASX200 down 43.3 points to 7,670.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell and 10 traded unchanged.

Syntara (Pharmaxis) was the best, up 0.2 cents or 10 percent to 2.2 cents, with 79,186 shares traded. 4D Medical climbed 5.6 percent; Resonance and Telix rose more than four percent; Atomo, Clinuvel and Universal Biosensors were up three percent or more; Alcidion and Neuren improved more than two percent; Percheron (Antisense) was up 1.05 percent; with Emvision, Polynovo and Resmed up by less than one percent.

Impedimed led the falls, down 0.5 cents or 4.8 percent to 10 cents, with 878,543 shares traded; followed by Immutep, Imugene and Mesoblast all down by four percent or more. Genetic Signatures and Opthea lost more than three percent; Amplia, Clarity, Curvebeam, Cynata, Nanosonics, Nova Eye, Paradigm and Pro Medicus shed more than two percent; Cochlear, Cyclopharm and SDI were down more than one percent; with Avita, CSL and Proteomics down by less than one percent.

DR BOREHAM'S CRUCIBLE: VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

By TIM BOREHAM

ASX Code: VIT

Share price: 14.5 cents; Shares on issue: 575,873,788; Market cap: \$83.5 million

Chief executive officer: Rodney Cocks

Board: Robert Iervasi (chair), Dr Marcia Walker, Mr Cocks, Guy Headley, Janelle Frewen (Mr Iervasi replaced Dr Walker as non-executive chair in February 2024. Dr Simone Scovell was appointed to the board in September 2022 but resigned in September 2023)

Financials (half year to December 2023): revenue \$59.97 million (up 4%), net profit \$3.3 million (down 57%), cash \$13.0 million (down 31%), bank debt \$6.21 million (up 100%)

Key identifiable shareholders: Dr Ben Jansen 20.71%, Dr Matua Hasyo Charles Jansen 8.55%, Cronos Global 10%, Regal Funds Management 5.8%.

While the use of medicinal cannabis in Australia soars, the benefits are not being felt by the ASX-listed pot stock sector which is struggling to maintain investor interest.

Late last year BOD Science ceded to financial reality and called in the administrators, while the ASX-suspended Cann Group is in a world of pain.

In a paddock of weeds - metaphorically and literally speaking - Vitura is the tall poppy with its model of matching patients, prescribers and suppliers on the one platform.

Formerly known as Cronos Australia, Vitura is in the rare position of producing revenues, profits ... and dividends. And no - we are not smoking anything!

The company has now expanded into the burgeoning tele-health field, having acquired the private Doctors on Demand platform last October.

"Tele-health was really only used [for remote communities] but during Covid the behavior changed in terms of clinicians and patients and we are seeing a rapid uptake," says Vitura CEO Rodney Cocks.

Despite the positives, Vitura's recent performance (and share price) has been weighed down by intensifying competition. A failed board challenge led by former director – and biggest shareholder – Dr Ben Jansen hasn't helped, either (see below).

About Vitura

Vitura's core Canview platform links more than 1,400 authorised marijuana prescribers (mainly general practitioners), 4,200-plus dispensing pharmacies and more than 11,000 regular patients. The platform sources 350 products from 40 local and Canadian suppliers.

Cronos Australia was a 50-50 venture between Canadian medical cannabis giant Cronos Group and a private equity fund owned by Mr Cocks - listing on the ASX in late 2019, having raised \$20 million at 50 cents apiece.

Cronos planned to build a cannabis manufacturing facility, but in September 2021 it merged with CDA Health Pty Ltd – founded by Dr Jansen - in a cash-scrip deal. CDA – as in Cannabis Doctors Australia - operates under a full tele-health model nationally.

In February 2023, the company became Vitura Health, to emphasise the move to a digital platform and away from a cannabis pure-play.

If Mr Cocks' name sounds familiar, you're right: he was awarded Victoria's Australian of the Year gong in 2005, for tending to injured bombing victims in Bali and Baghdad's UN Headquarters. He has held roles at Linfox and Boston Consulting Group.

Dial-a-quack, not so big bill

Doctors on Demand was founded by Mt Isa pharmacists John Martin and John Neilson, to address the regional town's poor access to healthcare services. That was back in 2015, well before the Covid-era when the notion of dial-a-doc was a bit quackers.

Doctors on Demand facilitates around 300,000 consultations a year and derives revenue from services to companies such as remote miners and health insurers.

Currently, Doctors on Demand doesn't have a huge presence in cannabis: the nature of the consultations (and prescriptions) mirrors that of traditional clinics. The service also includes peripherals such as 'smoking cessation' (nicotine vaporizers) and medicated weight loss.

Doctor, doctor tell me the truth

... do I really need to see you in person?

Mr Cocks reckons 50 to 70 percent of general practitioner visits could be satisfied via telehealth - notably repeat scripts. He also questions why anyone would opt to spend time with diseased patients in a waiting room to see a doctor who invariably is running late.

"It can be a two-hour ordeal just to get a script and you can do that in a matter of minutes [online]."

For general practitioners - especially younger ones – tele-health offers Uber-style flexibility as they can work when and where they like (although the backdrop of a golf course or a strip club would not be a good look).

A little-known factor driving tele-health is a crack-down on 'sham' doctor contracts with the physical clinics, by which the doc works full-time but is deemed to be a contractor. Payroll tax has not applied in these cases, but the cash-strapped state governments are on to it ... big time.

The cannabis landscape

Australians have taken to medical marijuana (or medicinal cannabis) with aplomb: the industry grossed about \$244 million in revenue in 2022, with revenue increasing 41 percent from the first half of the year to the second. Anecdotal evidence suggests the illicit market is many times larger, and a recreational market opportunity.

In December, the Office of Drug Control said that Australian medical marijuana companies produced 24,900 kilograms of marijuana in 2022, up from 16,700kg in 2021.

(We thank Biotech Daily's cannabis correspondent Peter Olszewski – a.k.a. J.J. McRoach – for those insights).

On anonymized patient data, 80 percent of prescriptions were for chronic pain and as an alternative to opioids.

Mr Cocks says the typical patient is a female in her 50s who has never touched the devil's lettuce previously.

Of course, an unknown number of folk are accessing illegal dope for medicinal purposes (stay clear of Aunt Dora's hash brown cookies if you are driving).

Vitura reports most of the medication sold via the platform is whole flower bud (ground and vaporised), as opposed to extracted oils. Given the substances predominantly are used for pain, it's a fair bet that most of them contain the psychoactive ingredient tetrahydrocannabinol (THC).

Psychedelics, qu'est-ce que c'est?

With apologies to Talking Heads, Vitura isn't exactly running - fa-fa away - from the emerging opportunities in psychedelic medicine.

In May 2023, the company formed a joint venture called Cortexa, with Canada's Pharmala Biotech. Cortexa taps the strength of Vitura's distribution with Pharmala's drug manufacturing capabilities.

The initiative takes advantage of the recent liberalization of research-based psychedelic use, pertaining to MDMA (3,4-methelene-dioxy-meth-amphetamine, also known as Molly) and psylocibin (aka magic mushrooms).

Unlike 1960s hippy houses, the mind-bending substances are only dispensed under the watchful eye of a psychiatrist.

"Based on the research to date [psychedelics] have a lot to offer, for post-traumatic stress disorder and treatment-resistant depression especially," Mr Cocks says.

"But it is early days."

Finances and performance

Vitura recorded a sharp 59 percent profit decline in the half year to December 2023, to \$3.12 million. This was attributed to the industry-wide decline in the average selling price, gross margin pressures and costs related to the Doctors on Demand purchase.

"Competition has increased, the market has matured and we are seeing average prices decrease across the board," Mr Cocks says.

One manifestation of this is higher rebates paid to the pharmacy groups - especially the mega ones - as a reward for higher sales.

However, Vitura's key 'vital signs' were positive: record sales of 498,740 units, with the prescribing doctor base increasing by 423 to 1,401. Dispensing chemists on the platform grew by 531 to 4,244.

The company funded the \$25 million Doctors on Demand purchase via an equal combination of cash, equity, debt and vendor finance. The equity component was satisfied by the issue of \$6.25 million of shares to Regal Funds Management, installing the fundie as fourth biggest shareholder.

At December 31, 2023, Vitura had cash of just under \$13 million, having paid a one cent a share dividend (\$5.43 million in total) for the year to June 30, 2023, but no interim dividend. Mr Cocks says the board does not have a set dividend payment policy.

"We are not going to trade-off acquiring or investing in organic growth just to pay a dividend. It will all be done through the lens of creating shareholder value," he says.

Over the last 12 months Vitura shares have traded between 60 cents (early July 2023) and 14 cents (March 7 this year). They peaked at 90 cents in October 2022.

Little birdies in their nests disagree ...

At Vitura's November 2023 AGM, shareholders voted not to elect Dr Jansen and his running mates Nathan Hight and health sector "luminary" Shane Tanner.

As with the Voice, the 'no' vote came in at about 60 percent.

Dr Jansen and Mr Tanner were Vitura directors post the CDA purchase, after four original directors made way.

The company's chair, Mr Tanner stepped down in April 2022 and Dr Jansen quit in September of that year.

The Jansen's camp's concerns centred on the means (and effect) of issuing new shares and the terms of performance-based shares issued to Messrs Cocks and Headley (as well as their fixed remuneration).

The board hotly defends the arrangements.

While the challenge was rebuffed, the remuneration report was opposed by 57 percent of holders - presumably the Jansen camp. The rejection threshold for such motions is only 25 percent. If the company receives a second 'strike' at its next AGM, a mandatory board spill vote ensues.

"The [board] remuneration committee consists of independent directors, taking advice of two leading 'rem' experts," Mr Cocks says. "Was this really about rem, or attempting to take control of the board?"

Dr Boreham's diagnosis:

Vitura has a high falutin' strategy manifesto, but it boils down to increasing the doctor and patient numbers across the Doctors on Demand and Canview platforms, as well as adding services.

On a contentious note, one such add-on service is selling nicotine vapes under prescription, allegedly "to support patients on their journey to quit smoking and reduce their dependence on nicotine".

The highly opportunistic move hopes to take advantage of the Federal Government's crackdown on imported nicotine vapes to thwart rampant abuse of the devices among young people.

Management also has a weather eye on overseas markets, notably in the UK and Europe where medical marijuana is subject to similar regulation.

Currently, tele-health accounts for about three percent of the general practitioner market, so there's plenty of upside for Vitura in both the cannabis and traditional sectors. "But we like the Australian market and we think there is a large opportunity," Mr Cocks says.

On a relative valuation note, Vitura paid \$25 million for Doctors on Demand and Wesfarmers shelled out \$135 million for the rival Instantscripts.

So did Wesfarmers overpay, or did Vitura snare a bargain?

Mr Cocks is diplomatic - to a point.

"You will have to ask Wesfarmers that, but we bought well at one times revenue when they paid more like three times revenue."

Despite the depressed share price, Vitura is smouldering along nicely but the company risks being crimped by the ongoing brooding presence of the Jansen camp on the resister.

It's a problem that needs to be resolved, sooner or later.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is diplomatic – to a point

NOVA EYE MEDICAL

Nova Eye says its underwritten, one-for-eight retail rights offer at 21 cents a share raised \$2.9 million, taking the total raised to \$8.0 million.

Last month, Nova Eye said it hoped to raise \$8.0 million, having raised \$3 million in a placement and \$5 million in an institutional rights offer (BD: Feb 12, 14, 2024). Today, the company said the funds would be used to advance "near-term growth opportunities" in its glaucoma business, including expanding Itrack Advance's sales in the US and Europe, and broadening its product portfolio of glaucoma surgical devices. Nova Eye said E&P Corporate Advisory was the sole bookrunner and was joint lead manager with MST Financial Services and Taylor Collision.

Nova Eye fell half a cent or 2.4 percent to 20.5 cents.

CARDIEX

Cardiex says it Niall Cairns and Craig Cooper's C2 Ventures Pty Ltd will underwrite the \$14 million capital raise to \$8,466,424, pending shareholder approval.

Last year, Cardiex said it had a \$7.5 million loan from C2 Ventures at 10 percent a year with shareholder approval or 15 percent without approval (BD: Nov 9, 2023).

Today, the company said the \$1 million increase "ensures that Cardiex completes the previously announced \$14 million fund-raising package", pending investor approval. Last year, Cardiex said that it had raised \$4.0 million in a placement; and later, said its one-for-2.87 entitlement offer at eight cents a share had raised \$4 million, taking the total to \$8 million (BD: Dec 19, 2023 and Feb 7, 2024).

Cardiex was unchanged at 8.1 cents.

RADIOPHARM THERANOSTICS

Radiopharm says three data sets supporting the use of its RAD301 and RAD302 for diagnosing and treating various cancers will be presented this week.

Radiopharm said the first presentation, titled 'Efficient reduction of renal uptake of $\alpha\nu\beta6$ -integrin targeted Ga-68 PET diagnostics and Lu-177 therapeutics' included data from a lung cancer mouse model.

The company said the data showed reduced kidney uptake of alpha-v-beta-6 ($\alpha v \beta 6$)-integrin targeting therapeutics and diagnostics, like its RAD 301, was "much stronger" following the administration of succinylated gelatin, a blood plasma replacement, compared to the arginine-lysine amino acid combination standard-of-care.

Radiopharm said the second set of results, titled 'Preliminary results of a Phase 2 study: 68Ga-Trivehexin PET/CT of $\alpha\nu\beta6$ -integrin expression in HNSCC and PDAC and correlation with ITGB6 expression', included data from a 33-patient trial comparing current imaging standard of care with RAD301.

The company said the data showed RAD301 had superior tumor-to-background ratio in pancreatic ductal adenocarcinoma and head and neck squamous cell carcinoma. Radiopharm said the final presentation, titled 'Relevance of $\alpha\nu\beta$ 6-Integrin as a theranostic target: In-depth immunohistochemistry (IHC) analysis of membranous ITGB6 expression in various human cancers', included data from a 1,400-patient study showing that alpha-v-beta-integrin was a cellular marker for tumor invasion and metastatic growth that was "highly expressed across a variety of common cancers".

The company said the data would be presented at the Porto, Portugal's European Molecular Imaging Meeting from March 12 to 15, 2024. Radiopharm fell 0.3 cents or five percent to 5.7 cents.

CLARITY PHARMACEUTICALS

Clarity says it has dosed the six-patient third cohort in its up-to 44-patient phase I/IIa trial of copper-67 Sar-bis-prostate specific membrane antigen (PSMA) for prostate cancer. In 2022, Clarity said it had treated the first of up-to 30 patients in its 'Secure' phase I/II trial of its copper-64 diagnostic and copper-67 sarcophagine (Sar)-bis-PSMA therapy for prostate cancer (BD: Oct 7, 2022).

In 2023, the company said the first patient dosed with two cycles of copper-67 Sar-Bis-PSMA had shown "undetectable levels" of prostate specific antigen (BD: Nov 30, 2023). Today, Clarity said it had completed dosing its third cohort of patients who received copper-67 Sar-bis-PSMA at the highest single dose level of 12 gigabecquerels (GBq), with no dose limiting toxicities reported to date.

The company said a safety review of the first three cohorts showed a "favorable safety profile, with most adverse events being mild or moderate" and recommended the trial progress to cohort four, to be dosed at 12GBq, with recruitment open at US sites. Clarity said nine of 15 patients, or 60 percent, in all cohorts to date had shown reductions in prostate specific antigen levels of more than 35 percent from a single dose, with 27 percent of patients showing reduction greater than 80 percent.

The company said "almost 80 percent" of participants from cohorts two and three showed reductions in prostate specific antigen levels greater than 35 percent from a single dose, with 44 percent showing reductions in PSA levels of more than 80 percent.

Clarity chair Dr Alan Taylor said it was "remarkable to see these patients, who have failed so many lines of therapy in the past, now respond to treatment with copper-67 Sar-bis-PSMA and with such a favorable safety profile."

"Based on these promising results, we have just opened the multi-dosing phase at the highest dose of 12GBq and all slots for the first part of cohort 4 have now been allocated, aiming to have the first participant treated in this cohort within weeks," Dr Taylor said. Clarity fell eight cents or 2.9 percent to \$2.65 with 808,915 shares traded.

RECCE PHARMACEUTICALS

Recce says it has completed dosing its four-participant, 20-minute infusion rate cohort in its phase I/II trial of intravenous R327 for urinary tract infection (UTI) and, or urosepsis. Last year, Recce said it had dosed the first male and female subjects at a faster infusion rate of 15 minutes in its phase I/II clinical trial of R327 for urinary tract infection and urosepsis; and earlier this week had begun dosing the 20-minute having tested 15, 30, 45 and 60-minutes (BD: Nov 7, 2023; Mar 12, 2024).

Today, the company said the data would support preparations for a phase II trial. Recce chief executive officer James Graham said that dosing the latest cohort marked "another milestone in our journey advancing R327 as a potential frontline treatment for [urinary tract infection and, or] urosepsis".

Recce was up two cents or 4.8 percent to 44 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

FIL Ltd (Fidelity Investment Management) says it has reduced its substantial holding in Medical Developments from 7,204,523 shares (8.35%) to 4,701,193 shares (5.45%). The Hong Kong-based FIL said that between February 5 and March 13, 2024 it bought shares at prices ranging from 82.16 cents to 93.95 cents each and sold shares between 65.00 cents and 77.00 cents.

Medical Developments was unchanged at 66.5 cents.

NANOSONICS

The Sydney-based Selector Funds Management says it has ceased its substantial shareholding in Nanosonics, with the disposal of 13,939,898 shares.

Selector said that between December 9, 2021 and March 12, 2024 it bought 5,693,958 shares, sold 731,343 shares and transferred 13,208,55 shares in specie, but did not disclose the consideration received for its purchases or sales, as required under the Corporations Act 2001.

In 2021, Selector said it held 20,566,564 Nanosonics shares or 6.82 percent of the company (BD: Dec 13, 2021).

According to its most recent filing, Nanosonics had 302,896,983 shares on issue, meaning that Selector held 12,320,624 shares or 4.01 percent of the company.

Nanosonics fell six cents or 2.1 percent to \$2.77 with 1.85 million shares traded.

VISIONEERING TECHNOLOGIES

Melbourne's Thorney, Thorney Investment Group Australia (Tiga) and related parties say their 25,209,832 shareholding was diluted from 48.13 percent to 46.04 percent. Last year, Visioneering said it raised \$2,370,961 of a hoped-for \$3.9 million in a five-fornine rights offer at 22 cents per Chess depository interest (CDI) and later said it raised a further \$238,665 of the \$1.5 million shortfall (BD: Nov 13, 2023 and Jan 21, 2024). Visioneering fell half a cent or 2.3 percent to 21.5 cents with 38 shares traded.

NYRADA, NOXOPHARM

Noxopharm says its 33,373,245 share-holding in Nyrada has been diluted from 21.39 percent to 18.60 percent due to the company's recent Chess depository interest offer. Earlier this month, Nyrada said it had "firm commitments" to place \$1,755,000 at 7.5 cents per Chess depository interest, with directors subscribing for \$210,000 more, subject to approval (BD: Mar 6, 2024).

Nyrada was up 1.5 cents or 15 percent to 11.5 cents with 11.6 million shares traded. Noxopharm was up 0.1 cents or 1.45 percent to seven cents.

NYRADA

Nyrada director and Exopharm chair Dr Ian Dixon says with Altnia Holdings and Helium Management his 10,114,033 shareholding was diluted from 6.48 percent to 5.64 percent. Nyrada said Dr Dixon and the related parties had been diluted following its recent offer of Chess depository interests (see above).

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

CSIRO says it has promoted the Australian Centre for Disease Preparedness deputy director Dr Debbie Eagles to director, effective immediately.

The CSIRO said Dr Eagles would lead its high-containment facility in Geelong, which helped protect Australian livestock and aquaculture industries as well as communities, from emerging infectious disease threats.

The Organisation said Dr Eagles was a veterinary epidemiologist with a background in vector-borne diseases, and had spent three years as research director for CSIRO's diagnosis, surveillance and response program, following eight years in its veterinary diagnostic team.

NANOSONICS

Nanosonics says Dr Steven Farrugia will retire as chief technology officer and continue as a consultant for 12 months.

Nanosonics said Dr Farrugia had decided to retire as the company submitted its US Food and Drug Administration regulatory application for its Coris endoscope cleaning device.

The company said that the submission filing "signifies the achievement of the key technical milestones of the product".

Nanosonics managing-director Michael Kavanagh said that Dr Farrugia had "played an integral role in the success of the company".

"He enters retirement having established a highly competent and capable [research and development] department and leadership team to continue our commitment to innovation in infection prevention," Mr Kavanagh said.

"In addition to the technical developments in our Trophon franchise, Steve has also overseen the development of our new Coris technology that will shortly be submitted for regulatory approval with the FDA," Mr Kavanagh said.

The company said it had begun the process of finding a replacement chief technology officer.