

Biotech Daily

Friday August 20, 2021

Daily news on ASX-listed biotechnology companies

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- * CELLMID REVENUE DOWN 14% TO \$7m, LOSS DOWN 31% TO \$3m
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- * IMUGENE 'OVERSUBSCRIBED' SHARE PLAN RAISES \$5m; TOTAL \$95m
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- * EMYRIA APPOINTS DR MAT MARTIN-IVERSON MDMA ADVISOR

MARKET REPORT

The Australian stock market slipped 0.05 percent on Friday August 20, 2021, with the ASX200 down 3.7 points to 7,460.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell and five traded unchanged.

LBT was the best on no news, up 2.1 cents or 21.2 percent to 12 cents, with 2.8 million shares traded. Genetic Signatures and Uscom climbed more than three percent; Opthea and Universal Biosensors rose two percent or more; CSL, Dimerix, Next Science, Paradigm, Pro Medicus, Proteomics and Volpara were up one percent or more; with Cyclopharm, Nanosonics and Resmed up by less than one percent.

Patrys led the falls, down 0.3 cents or 7.9 percent to 3.5 cents, with 24.5 million shares traded. Cochlear and Resonance retreated more than seven percent; Antisense and Prescient were down more than five percent; Actinogen, Clinuvel and Pharmaxis fell more than four percent; Alterity, Cynata, Immutep, Imugene, Neuren and Polynovo were down more than three percent; Amplia, Avita, Nova Eye, Oncosil and Orthocell shed two percent or more; Starpharma lost 1.6 percent; with Medical Developments, Mesoblast and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: RHINOMED

By TIM BOREHAM

ASX code: RNO

Share price: 32 cents; Shares on issue: 253,809,132; Market cap: \$81.2 million

Financials (June quarter 2021): revenue \$951,000, cash burn \$1.52 million, cash \$2.4 million, quarters of available funding 3.2*

* Includes \$2.5 million working capital facility provided by two directors

Chief executive officer: Michael Johnson

Board: Ron Dewhurst (chair), Mr Johnson, Brent Scrimshaw, Prof John McBain, Dr Eric Knight

Identifiable major shareholders: W Whitney George 41%, John McBain 17.7%, Ron Dewhurst 5.2%.

We're learning more about the Covid-19 pandemic the more it hangs around - and some of the findings are startling indeed.

Take the recent studies by Colgate-Palmolive, which suggest that certain toothpastes and mouth washes can temporarily reduce the amount of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) - the virus that causes Covid-19 - in your mouth.

"We're working hard to figure out how this initial research translates into temporarily reduced virus levels in the mouth, and what this may mean for you," says Colgate's website.

The company (or its lawyers) hastily add that there's no evidence the products can treat or prevent Covid-19 or alleviate its symptoms.

But the findings DO imply that saliva-based Covid tests can be useless - at least in the case of those with decent oral hygiene.

So much for the Colgate ring of confidence.

A better way to test

Such testing deficiencies are music to the ears of nasal device maker Rhinomed, which has tweaked its existing products as a Covid testing swab, called Rhinoswab.

In its first commercial order, New South Wales Health has asked for one million of them to be delivered to the plague-stricken state.

"We are thrilled to have an Australian government support local innovation," says Rhinomed chief Michael Johnson - and he's polite enough not to add that that's a rare thing.

The Rhinoswabs are an alternative to the so-called long-handled 'brain stab' nasal and saliva swabs, used in the polymerase chain reaction (PCR) tests. These are the ones that need to go to the lab for analysis, with results taking between a few hours and a few days, depending on the workload.

The Rhinoswabs have regulatory clearance in the US, Australia and Europe as a classone device.

A nose for a good product

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

The devices are a clinical iteration of its original intra-nasal device called the Turbine, which expands the nostrils to potentially provide more oxygen for enhanced athletic performance. The Mute - a low-cost treatment for snoring - followed next.

Mr Johnson says the company had always been about developing a platform technology suited to diagnostics and drug delivery.

He was goaded into action when his father, who is in a Melbourne nursing home, complained of "being attacked by a nurse who stabbed me in the head with a straw".

Mr Johnson senior was, of course, referring to the standard Sars-Cov-2 test. "That gave me the idea," Mr Johnson junior says.

The company worked closely with its industrial design team and enlisted parties including the Doherty Institute for validation testing.

The Doherty 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".

New South Wales Health carried out its own comprehensive evaluation before placing the order.

Abolishing the Covid testing queue

Mr Johnson is "infuriated" when he sees a snaking queue at a Covid testing station because they are unnecessary - at least if Rhinomed has its way.

With Rhinoswab, one medical worker could overlook 10 or so patients at once, because the testees can put the device on themselves (the devices can only go on the snoz one way, so there's no room for error).

"The medical workers can observe, but don't need to go near the patient and it has telehealth applications as well," Mr Johnson says.

He says that within 15 seconds, the device yields a sample around 1.4 to 1.5 times greater than the standard swab. After two minutes it's 1.8 times more.

Test efficacy is more relevant for the rapid tests, because the PCR tests amplify the viruses present. "With rapid antigen testing there's a direct relationship with the size of the sample and the accuracy of the test," Mr Johnson says.

Rapid tests are not approved in Australia - not yet anyway - but are available over the counter in the US and the UK. In Germany, Aldi stocks them alongside the mince burgers and violins.

Don't forget the kids

One feature of the Delta variant is that children are not as immune from the virus as they were with the first iteration.

Rhinomed is looking at how its swab technology can be adapted for kids' noses, which differ to adult proboscises, physiologically speaking.

"Kids are undertested," Mr Johnson says. "They hate swabs and are potential super spreaders."

It's important to have an easy way of testing kids because they get colds on average twice as much as adults – six to eight times a year. The ability to call out runny noses as a standard snot attack rather than Covid will become increasingly important.

Meanwhile ...

Sales of Mute and Turbine are bubbling away, but in the US have been affected by a downturn in chemist patronage, with foot traffic falling in mid-2020 by as much as 70 percent.

"People were getting scripts but are not browsing," Mr Johnson says.

The company's US reach has been bolstered with an expansion through drugstore chain Rite Aid and grocery chain Giant Eagle. In early 2020, the company appointed a head of US business, John Ende, as well as a marketing manager, Kirk Hodgdon (former marketing director for nasal strip purveyor Breathe Rite).

"I thank my lucky stars we did it before the pandemic took off, because I haven't been back there since January last year," Mr Johnson says.

Locally, the company is getting good sales traction via Priceline and the Amazon electronic-commerce giant.

Finances and performance

Rhinomed chalked up \$3.9 million of revenue in the year to June 2021, 12 percent higher than the previous year.

June (fourth) quarter revenue rebounded 53 percent to \$915,000.

While Mute and Turbine volumes are recovering - especially in the lock-down free US - the swabs are expected to contribute significantly to future revenues.

The New South Wales Health deal is equivalent to 25 to 35 percent of Rhinomed's turnover last year.

Mr Johnson says Rhinomed aims to match the pricing of the standard swabs, of \$US1.00 to \$1.20 each. So, one doesn't have to be a financial guru to work out the NSW Health deal is worth \$1.4 million to \$1.64 million in revenue.

Meanwhile, Rhinomed shares traded at a low of 7.5 cents a year ago, but doubled to 40 cents after the New South Wales Health news on August 11 this year.

The company's ASX roots go back to 2013, when it morphed from the (now) unrelated Consegna Group (previously Helicon).

Join the Victor Kiam club

Rhinomed has developed quite a following from deep-pocketed parties who liked the product so much they bought (into) the company.

The latest is Glaswegian-born Prof John McBain, who founded the Melbourne IVF chain before selling it to private equity interests in 2008 for a reported \$200 million.

On a whim, Prof McBain bought a packet of Mutes at a chemist and the effect was evident after the first night.

Prof McBain was one of a handful of original investors in buy-now-pay-later provider Afterpay. At the time the shares were 20 cents; this month US fintech Square lobbed a \$126 per share offer.

Prof McBain has a 17 percent stake in Rhinomed.

He joins the high-profile New York based fund manager W Whitney George, with a 41 percent stake.

Rhinomed chairman and experienced financial services executive Ron Dewhurst accounts for a further five percent or so.

Mr Dewhurst and Prof McBain also kindly stumped up \$2.5 million for a working capital facility.

The clever country loses its smarts

With the New South Wales Health order in hand and presumably more to follow, Rhinomed's biggest issue becomes where to make the devices. Currently, they're produced in a factory at Keysborough, in Melbourne's southeast.

Rhinomed applied for Federal funding under the Modern Manufacturing Initiative (MMI), but no largesse was forthcoming for the expansion, costed at \$19 million over three years and creating 119 jobs.

The Mutes and Turbines are made in China and the Rhinoswabs look like being made offshore as well.

"Government support would have enabled us to manufacture both the swab and consumer health products here in Australia," Mr Johnson says.

He notes that the private Queensland-based Ellume was awarded a \$300 million contract from the US Department of Defence to move the manufacturing of its rapid diagnostic test to the US.

Dr Boreham's diagnosis:

While it's dangerous to align a company's fortunes with a pandemic that eventually will abate, the demand for quick, ongoing testing is likely only to increase.

To date, two billion Covid tests have been carried out in the last 18 months, 26 million of them in Australia (roughly one for every man, woman and child).

Mr Johnson opines that just as the World Trade Centre attack two decades ago fundamentally changed airport security, the pandemic will instill regular testing at airports, workplaces and other venues for years to come.

He also expects the swabs will help drive the existing business and other muted sidelines, such as drug delivery.

Why?

"It socializes people to the concept of putting something up their nose."

Of course, some Sydney socialites are well familiar with that concept if you get the gist ...

Nonetheless we reckon Rhinomed's monied backers have sniffed out something promising.

As usual, it's a case of building sustained revenue while not running out of cash in the meantime.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. One could say he nose nothing.

COCHLEAR

Cochlear says revenue for the year to June 30, 2021 was up 10.4 percent to \$1,493,300,000 with net loss after tax turned to a profit of \$326,500,000.

Cochlear said underlying net profit, excluding patent litigation expenses of \$59,000,000 and innovation fund gains after tax of \$30,800,000, was up 53.9 percent to \$236,700,000. The company said "a more material disruption from Covid that significantly impacts sales or the supply chain remains a risk factor that does not form part of guidance".

"While we did see a moderation in demand at times of high hospitalization rates for Covid patients, the deployment of Covid vaccines and the recovery of surgeries that followed Covid surges gives us some confidence that any further surgery deferrals could also recover quickly," Cochlear said.

The company said revenue included \$898,600,000 from hearing implants, \$438,500,000 from its sound processor and remote services and \$156,200,000 from its acoustics. Cochlear said that 61 percent of its business came from cochlear implants, with 29 percent from services and 10 percent from acoustics.

The company said that 48 percent of its \$1.5 billion revenue came from the Americas, with 35 percent from Europe the Middle East and Africa, with 17 percent from the Asia-Pacific. Cochlear said its final dividend per share was \$1.40 with the record date of September 24 and payment on October 18, 2021.

The company said that last year's diluted loss per share of \$3.996, turned to an earnings per share of \$4.967 for the year to June 30, 2021.

Cochlear said that net tangible assets per share was up 30.9 percent from \$15.09 to \$19.756, and it had cash and cash equivalents of \$609.6 million at June 30, 2021 compared to \$930.0 million at June 30, 2020.

The company said that it expected net profit for the year 2021-'22 to be \$265 million to \$285 million, a 12 to 20 percent increase on underlying net profit for 2020-'21. Cochlear fell \$19.04 or 7.4 percent to \$237.05 with 330,771 shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the year to June 30, 2021 was up 21.2 percent to \$81,647,000, with net profit after tax up 111.0 percent to \$8,941,000.

SDI said revenue was "driven by strong sales in key product categories, new product releases and the normalizing of most dental markets" for its dental equipment and dental aesthetics, amalgam and whitening products.

The company said that sales in the Asia Pacific region were up 14.4 percent to \$16.2 million, Middle East and Africa sales fell 11.0 percent to \$6.1 million, North America was up 39.5 percent to \$20.4 million, South America fell 6.0 percent to \$7.6 million and Europe was up 32.5 percent to \$31.3 million.

SDI said the regional performances reflect the return to normal operating conditions, with the gradual easing of Government restrictions, but also the successful release of new products.

The company said the final fully-franked dividend was up 230 percent to 1.65 cents for a record date of September 6, to paid on September 20, 2021.

SDI said that diluted earnings per share were up 111.2 percent to 7.52 cents, with net tangible asset backing per share up 13 percent to 46.60 cents.

The company said that it had cash and cash equivalents of \$10,559,000 at June 30, 2021, compared to \$6,153,000 at June 30, 2020.

SDI was up 2.5 cents or 2.5 percent to \$1.025.

CELLMID

Cellmid says revenue for the year to June 30, 202,1 was down 14.36 percent to \$7,319,839, with net loss after tax down 30.99 percent to \$3,386,632.

Cellmid said that revenue came predominantly from sales of its Advangen hair loss products, with revenue in Australia up four percent to \$1,242,123, revenue in the US down 27.9 percent to \$451,307 and revenue in Japan down 22.5 percent to \$4,348,206, caused by Covid-19-related trading disruptions with China.

The company said it sold its Lyramid midkine division for \$528,842.

The company said diluted loss per share was down 52.3 percent to 2.40 cents, net tangible assets per share fell 22.3 percent to 4.54 cents and it had cash and cash equivalents of \$6,727,764 at June 30, 2021 compared to \$6,970,967 at June 30, 2020. Cellmid was up 0.1 cents or 1.9 percent to 5.4 cents.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the six months to June 30, 2021 was up 52.9 percent to \$US3,111,000 (\$A4,354,551) with net loss after tax down 71.3 percent to \$US1,486,000 (\$A2,079,994).

Visioneering said revenue was from sales of its multifocal contact lenses and included \$US2,919,000 from North America and \$US192,000 from Europe and the Asia Pacific. The company said net tangible asset backing per share was up from nine US cents to 44 US cents, diluted loss per share was down 91.9 percent to eight US cents and it had cash and cash equivalents of \$US15,078,000 at June 30, 2020 compared to \$US4,035,000 at June 30, 2020.

Visioneering was up 2.5 cents or 2.4 percent to \$1.05.

IMUGENE

IMUGENE says its \$5 million share plan at 30 cents a share was "heavily oversubscribed" and it will be scaled back.

In July, Imugene said it had commitments for a \$90 million placement at 30 cents a share and hoped to raise \$5 million through a share plan (BD: Jul 29,2021).

Imagene fell one cent or 3.4 percent to 28.5 cents with 18.0 million shares traded.

IDT AUSTRALIA

IDT has told the ASX that being the subject of news reports about its capacity to manufacture messenger RNA (mRNA) may have pushed its price 48.6 percent. The ASX said IDT's share price rose 48.6 percent from 37 cents on August 17 to a high of 55 cents on August 19 and noted a "significant increase" in the volume of shares traded. IDT said it had "a number of current discussions and activities which are well developed and reflected in ... past announcements".

The company said it believed the recent share price movement reflected "press comment over the last 24 to 48 hours on sovereign vaccine manufacturing alternatives in Australia" as well as vaccine manufacturing pharmaceutical companies reporting significant increases in profits and growing demand for new supplies of vaccines.

IDT said the Federal Government called for proposals for an onshore mRNA manufacturing capability and the company filed a submission, with "numerous media reports" covering the submissions.

IDT was up nine cents or 19.6 percent to 55 cents with 6.8 million shares traded.

FEDERAL GOVERNMENT, BRANDON CAPITAL, MTP CONNECT, REGENEUS

The Federal Government says it has provided \$79 million to three organizations to develop new medical devices, medicines, and digital health technologies,

A media release from the federal Minister for Health Greg Hunt said that the Brandon Capital-managed Medical Research Commercialisation Fund would two tranches of \$19.75 million to support "preclinical medical research or medical innovation projects with commercial potential" and early clinical development of novel drugs, or novel uses for existing drugs, with commercial potential".

The media release said that MTP Connect's Medical Technologies and Pharmaceuticals-Industry Innovation Growth Centre (MTP-IIGC) would receive \$19.75 million "to support early clinical development of medical devices with commercial potential" with a further \$19.75 million going to Andhealth for "early-stage development of digital health technologies with commercial potential".

Mr Hunt said that the four companies had "established track records" in identifying and nurturing biotechnology ideas and would work with small and medium-sized businesses to progress commercial application of the research.

MRCF chief executive Dr Chris Nave said the company had helped commercialize "numerous great Australian research findings, using investment capital".

"For every 100 opportunities brought to us, only four pass the risk assessment for commercial investment," Dr Nave said.

"This doesn't mean the remaining 96 are bad ideas, and in many cases, it is simply because they are too early in their development and haven't yet generated key supporting data," Dr Nave said.

"This funding will allow us to support many more ideas, earlier and we will provide both capital and commercial expertise to guide them through to the point where they are ready to be translated into clinical development and commercialization, creating jobs and income and ultimately benefitting patients," Dr Nave said.

The media release said that New South Wales Health Pathology's Dr Ewan Millar and the Kolling Institute's Dr Cindy Chia-Fan Shu had been awarded fellowships under the Researcher Exchange and Development within Industry initiative.

The Federal Government said that Dr Millar would undertake a 24-month, part-time project with the New York-based digital diagnostics company Paige, working with project teams in three continents to develop skills in application of artificial intelligence for breast cancer biomarker development to improve behavior predications and treatment response.

The media release said that Dr Shu would work with Regeneus for 12 months "to increase her skills in the translation of science".

The media release said that Dr Shu would focus on developing assays and models for pre-clinical trials for osteoarthritis treatments and progressing clinical trials and preparing regulatory submissions.

OSPREY MEDICAL

Osprey says an extraordinary general meeting will vote on a 100-to-one consolidation and issue 2,567,000 options over US shares to two directors.

Osprey said the meeting would vote on the issue of the options equivalent to 2,567,000 CDIs each to Steven Brandt and Martin Emerson, exercisable at the share price at the close on the day of issue within five years, and elect Mr Brandt and Mr Emerson as class II directors.

The meeting will be held online on September 3, 2021 at 10am (AEST).

Osprey was unchanged at 1.3 cents with 15.95 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says the US Food and Drug Administration has cleared its investigational new drug application for CHM1101 for patients with recurrent or relapsed glioblastoma. Chimeric said CHM1101 or chlorotoxin chimeric antigen receptor T-cell (CLTX CAR-T) was a cell therapy using scorpion chlorotoxin as its tumor targeting domain.

The company said CHM1101 had shown promising pre-clinical safety and efficacy and was currently in a single site phase I trial.

Chimeric chief operating officer Jennifer Chow said that the FDA clearance was "a critical milestone for Chimeric ... [and] our first step will be to open new phase I clinical trial sites under the current study protocol".

Chimeric was up 1.5 cents or 4.8 percent to 33 cents with 3.2 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says that 10,185,719 shares and the 2,045,500 options will be released from ASX escrow, with 2,524,998 shares to be released from voluntary escrow on August 29, 2021. According to the company's most recent Appendix 2A new share announcement after the release from escrow it would have 125,650,545 shares available for trading. Imricor was up 4.5 cents or 3.7 percent to \$1.25.

ANATARA LIFESCIENCES

Anatara says it has launched its irritable bowel syndrome with diarrhoea (IBS-D) clinical trial website.

In February, Anatara said it had ethics approval for a 200-patient trial of the pineapple stem bromelain-based complementary medicine (BD: Feb 8, 2021).

Today, the company said that the 12-week, phase I trial to determine the dose of its the gastrointestinal re-programming (Garp) product was expected to complete in March 2022. Anatara said the study targeted adults aged 18 to 65 years who had IBS-D and no history of inflammatory immune-mediated gastrointestinal disorder.

Anatara was untraded at 15 cents.

ALCIDION GROUP

Alcidion says it has appointed Victoria Weekes and Daniel Sharp as non-executive directors, effective from September 1, 2021 replacing Ray Blight and Nick Dignam. Alcidion said that Mr Dignam would resign at the November annual general meeting. The company said that Ms Weekes was the Sydney Local Health District Board's immediate, past, acting-chair of the and was an experienced non-executive director. Alcidion said that Ms Weekes held a Bachelor of Commerce and a Bachelor of Laws from the University of New South Wales.

The company said that Mr Sharp was an investment banker with more than 30 years' experience in capital markets, advising the boards of technology and healthcare-based organizations, with "a significant network of institutional and private wealth investors". Alcidion said that Mr Sharp was previously an executive director of Canaccord Genuity and held executive roles with Shaw and Partners and Lodge Partners.

The company said that Mr Sharp held a Bachelor of Economics and Bachelor of Laws from Melbourne's Monash University.

Alcidion was unchanged at 36 cents with 1.15 million shares traded.

EMYRIA

Emyria says it has appointed neuro-pharmacologist Dr Mar Martin-Iverson to advise on its 3,4-Methylene-dioxymeth-amphetamine analogue program.

Emyria said Dr Martin-Iverson was formerly the University of Western Australia's head of psycho-pharmacology and had more than 35 years' experience studying and researching the effects of amphetamines and other psychostimulants.

The company said Dr Martin-Iverson had authored more than 160 publications with a focus on dopamine-related effects including its role in drug addiction, schizophrenia, Parkinson's disease, attention and motivation.

Emyria fell one cent or 5.4 percent to 17.5 cents with 1.5 million shares traded.