Biotech Daily

Friday August 12, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 13%; AVITA DOWN 16%**

*** DR BOREHAM'S CRUCIBLE: RHINOMED**

*** RESMED REVENUE UP 12% TO $5b, PROFIT UP 8% TO $1.5b**

*** AVITA H1 REVENUE DOWN 17% TO $22.3m; LOSS UP 47% TO $22.1m**

*** AVITA RECELL 'REDUCES GRAFTS, MISSES HEALING ENDPOINT'**

*** WOKE, QIMR TRIAL PSILOCYBIN FOR 'PROLONGED GRIEF'**

*** CYNATA CLOSES MEND STEM CELL COVID-19, RESPIRATORY TRIAL**

*** HYDRIX REQUESTS 'ANGELMED GUARDIAN' TRADING HALT**

*** NOVA EYE TO RELEASE 1.7m VOLUNTARY ESCROW SHARES**

*** STARFISH, PERPETUAL, HV LODGE, MANTRA DILUTED TO 12% DORSAVI**

MARKET REPORT

The Australian stock market fell 0.54 percent on Friday August 12, 2022, with the ASX200 down 38.5 points to 7,032.5 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Actinogen was the best, up one cent or 12.8 percent to 8.8 cents, with 3.7 million shares traded. Antisense climbed 10 percent; Nova Eye was up 9.1 percent; both Pharmaxis and Resonance rose four percent; Alcidion and Orthocell were up more than three percent; Cynata and Volpara improved more than two percent; with Amplia up by one percent.

Avita led the falls, down 35.5 cents or 15.6 percent to $1.915, with 2.3 million shares traded.

Dimerix lost 8.8 percent; Telix fell 7.7 percent; Nanosonics was down 6.4 percent; Mesoblast fell 4.35 percent; Clinuvel, Genetic Signatures, Micro-X, Oncosil, Polynovo, Resmed and Universal Biosensors were down more than three percent; Impedimed and Prescient shed more than two percent; Atomo, Cochlear, Next Science, Pro Medicus and Uscom were down more than one percent; with CSL, Neuren and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: RHINOMED

By TIM BOREHAM

ASX code: RNO

Share price: 17 cents; **Shares on issue:** 285,719,694; **Market cap:** $48.6 million

Financials (June quarter 2022): revenue $2.32 million, cash burn $2.83 million, cash on hand $2.03 million, quarters of available funding 1.6

Full year to June 30, 2022: revenue $9.1 million (up 134%), cash burn $6.01 million

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 39.2%, John McBain 18.5%, Ron Dewhurst 6.9%.

Did you know that the nasal anatomy of a four-year-old kid is very different to that of 12-year-old - which is different again to that of a fully-fledged adult?

We didn't - but now we nose.

For Rhinomed, this information is more than a fun fact: it guides the company's move from a developer of nasal inserts to improve athletic performance to an industrial-scale provider of swab testing devices for rapid antigen tests (RATs).

Looking somewhat like a mini padlock when inserted around the septum, the so-called Rhinoswabs obviate the need for the infamously uncomfortable long-handled swabs inserted at the back of the nasal cavity.

The 'brain stab' is bad enough for adults, but according to Melbourne's Royal Children's Hospital, 80 percent of parents of four-year-olds are reluctant to bring their kids in for Covid-19 tests because of the perceived discomfort. About 30 percent of the parents of 12-year-olds are similarly inclined, which is a pity because kids get colds twice as much as adults and could do with a quick 'Covid or not Covid' verdict.

"That's a real issue from a public health perspective, you do want parents to bring kids forward for testing if they have Covid-19 or any other respiratory disease," says Rhinomed chief executive Michael Johnson.

Rhinomed's answer is Rhinoswab Junior, a modified version of the adult swabs.

"We know that testing children can be traumatic and difficult. This new test kit changes the paradigm and getting it into every Australian home is our priority."

Merci beaucoup, Jean Leonard

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

Approved in the US, Australia and Europe as a class-one device, Rhinoswabs are plastic clip-like, flock-lined objects. When gently inserted into the nose, they collect the requisite snotty material to enable a reliable RAT assay.

The devices evolved from the Turbine, Rhinomed's original product which expands the nostrils to potentially provide more oxygen for enhanced athletic performance.

The company's motto: "We'll supply the air. You supply the guts."

The Mute - a low-cost treatment for snoring - followed next.

The company's motto? "50 percent of men snore. The other 50 percent are liars."

Derided by the ignorant as merely a bit of plastic, the Turbines deployed Poiseuille's law, a rule of physics that determines flow rates based on factors such as viscosity, temperature, pressure gradient, length and diameter of the tubing.

So, the company owes a huge 'merci' to 19th century French psychist Jean Léonard Marie Poiseuille - who we suspect didn't have as active a social life as he should have.

Sadly, a rigorous bicycle trial showed the Turbines were not effective.

More than kid's play

Ironically, little kids stick things up their nose all the time, as do some adults (insert Sydney or LA socialite quip here).

Mr Johnson says the key to developing Rhinoswab Junior was to harness this natural tendency, but to make the process fun.

For instance, the devices have moustaches, koalas and emojis attached to them.

"Clinically, what was really pleasing was it collected the equivalent of a combined nose and throat swab," Mr Johnson says.

The opening of the nose is an effective collection point, as it houses the highest amount of the receptors targeted by the virus.

"We capture as big a sample as possible because we are in the right area of the nose and because of the surface area and design of the swab," Mr Johnson says.

Big deal(s), really

Rhinomed's commercial path has been underpinned by four big deals.

Last year, the New South Wales Department of Health ordered a minimum on one million Rhinoswabs, to be used for its lab-based polymerase chain reaction (PCR) tests, which were all the vogue at the time.

Unlike RAT tests, PCR tests can use a minute amount of sample materials.

Victoria's health mandarins then followed suit, also for one million units.

In April this year Canada's BTNX ordered a minimum 22.5 million Rhinoswabs over two years. "We hope they order a lot more than that," Mr Johnson says.

BTNX is Canada's biggest rapid antigen test company and has performed about 390 million tests.

Then in July 2022, Surecreen Australia lobbed an order for 10 million tests over two years for its respiratory tests in Australia, New Zealand, Singapore and the South Pacific.

A significant but unquantified number are Rhinoswab Junior tests.

Surescreen is a subsidiary of the British based Surescreen Diagnostics.

Finances and performance

Rhinomed's June quarter results showed revenue of $2.32 million, 134 percent higher than the previous corresponding period. Full year revenue came in as $9.1 million as guided, a hearty 156 percent increase on the previous year.

Mr Johnson says demand for the Mutes "went gangbusters" during the pandemic, especially on the online Amazon platform. No doubt the incessant snores emanating from one's spouse was all the more irritating during lockdowns.

The Mutes cost about $20 for a pack of three and unlike the Rhinoswabs they can be re-used - albeit judiciously.

But "the lion's share of revenue in the next 36 to 48 months will certainly be driven by the diagnostic business".

Despite the market being flooded with "dodgy cheap" swabs, the company has maintained pricing at the upper end.

In May this year, the company raised $4.9 million in rights offer at 19 cents apiece, including a $455,000 placement to mop up the retail shortfall.

Mr Johnson says that with just over $2 million in the bank and a revenue surge to come, the company should not have to return with the begging bowl any time soon.

“Our target for the current year is that we will well-and-truly be cash-flow positive, with the ability not just to fund our existing programs but expand our diagnostic offerings.”

Naturally, the company is coy about pricing but Mr Johnson points to a 70 percent blended margin across all the products.

Over the last 12 months Rhinomed shares have traded as low as 10 cents (July 1 this year) and as high as 40 cents (August 11 last year).

Over time they’ve wavered between 69 cents (late 2013) and eight cents (mid 2020).

News from the factory floor

Now that it has its big boy’s pants on, Rhinomed will focus on scaling-up its manufacturing, currently based at a factory in the Melbourne suburb of Keysborough and supplemented by a Chinese supplier.

The recent Covid-related supply chain woes highlighted the importance of having facilities closer to the end market. For example, it took two weeks to get a shipment off a boat in New Jersey, which would fail even a Maritime Union of Australian performance metric.

Thus, the company is scouring for suitable sites in the US and Europe.

Mr Johnson laments that a container journey that costs $1,200 a year fetched as much as $18,000 at one point - and remains elevated.

Air freight? Don’t even think about it …

The company also expects to spend a few bob on upgrading the Keysborough facility, which already contains a clean room and injection molding, flocking, 3-D printing and drying facilities.

Making a difference

Mr Johnson says BTNX and Surescreen were enthused about how Rhinomed’s swabs could differentiate its products.

“Prior to the pandemic, everyone saw testing as a homogenous blob,” he says.

“But Covid has shown there are vulnerable populations that need to be tested more often and kids get twice as many upper respiratory infections than adults.”

Rhinomed is now working with BTNX and Surescreen on a product for the aged care sector, which has a similar problem with reluctant subjects for the traditional swabs.

“We’ll see what we need to do to adapt our existing adult swab, but already it can be self-administered,” he says.

Mr Johnson says that RATs are the future, not just for Covid but other upper respiratory diseases. He notes that Surescreen’s British parent company is developing a range of combination lateral flow tests tests, such as for influenza and covid but also monkeypox and respiratory syncytial virus (RSV).

Rhinomed is also looking at combining several lateral tests on the one swab.

Dr Boreham’s diagnosis:

Rhinomed’s vision is to provide a clearly different product when hundreds of RAT test providers compete on price alone. Using the ‘Intel inside’ principle, other point-of-care diagnostic providers could differentiate themselves by promoting their products as using the Rhinomed swabs.

Mr Johnson says it’s now clear that Covid will never be banished entirely.

With people now used to RATs, lateral flow tests will also become common for other upper respiratory disorders and allow for quicker diagnosis and treatment.

Despite Rhinomed’s languishing share price, the company remains unusually well backed by three large - but non-institutional holders.

For the record, they are New York based fund manager W Whitney George, local IVF pioneer John McBain and finance executive Ron Dewhurst.

“They are fantastic long-term supporters,” Mr Johnson says. “They understand what we are trying to achieve and it’s a longer-term play for them.”

Mr Johnson describes Rhinomed as a “10-year overnight success story” that has been guided by the keep-it-simple approach.

“People get excited by overly complex technology, but our guiding principle is not to overcomplicate things,” he says. “Medical devices also have to be designed for manufacture at scale and we are now very good at that.”

In the space of a decade, Mr Johnson indeed has transitioned Rhinomed from purveyor of a modest nasal dilator to a meaningful player in respiratory diagnostics - and that’s snot bad at all.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He also never snores but may tell the odd fib.

RESMED INC

Resmed says revenue for the 12 months to June 30, 2022, was up 11.93 percent to $US3,578,100,000 ($A5,037,095,000) with net profit after tax up 7.96 percent to $US1,072,900,000 ($A1,510,382,000).

Resmed said the revenue came from sales of its anti-snoring and sleep apnoea devices, as well as its ventilators, ventilation mask systems and remote ventilation monitoring and assistance software for Covid-19.

The company said it provided both US generally accepted accounting principles (GAAP) and non-GAAP data.

Resmed said it "uses non-GAAP information internally in planning, forecasting, and evaluating the results of operations in the current period and in comparing it to past periods ... [and] believes this information provides investors better insights".

This report quotes the non-GAAP data.

Resmed said it would pay a dividend up 4.8 percent to 44 US cents per US share for the three months to June 30, for the record date of August 18 and to be paid on September 22, 2022.

The company said that its non-GAAP diluted earnings per share was up 8.6 percent to $US5.79.

Resmed said that cash and cash equivalents at June 30, 2022 was $US273,710,000 compared to $US295,278,000 at June 30, 2021.

Resmed chief executive officer Mick Farrell said "Our fourth quarter and full-year fiscal year 2022 results demonstrate strong growth and Resmed's market leadership".

"During the quarter, we saw continued adoption of our most advanced platform innovation to date, the 100 percent cloud-connectable Airsense 11," Mr Farrell said.

"We launched this solution into several new countries in Europe while continuing to see strong sales in the US," Mr Farrell said.

"We also introduced our newest device to meet the needs of an industry crisis in [positive airway pressure] supply, the Airsense 10 card-to-cloud solution, during the quarter," Mr Farrell said.

"Both of these platforms, as well as our legacy, market-leading, 100 percent cloud-connected Airsense 10 device, will support solid growth throughout [the year to June 30, 2023]," Mr Farrell said.

Resmed fell $1.07 or 3.1 percent to $33.55 with 1.4 million shares traded.

AVITA MEDICAL

Avita says revenue for the six months to June 30, 2022 was down 16.75 percent to $US15,874,000 ($A22,309,000) with net loss after tax up 46.75 percent to $US15,724,000 ($A22,098,000).

The company said revenue from sales of its Recell system for the treatment of burns was up 64.0 percent to $US15,874,000 and other revenue included funding from the US Biomedical Research and Development Authority (BARDA) which was up 9.7 percent to $US338,000 compared to the previous corresponding period.

Avita chief executive officer Dr Mike Perry said that the company's commercial team "continued to drive further Recell utilization and penetration within burn centres, and our clinical team advanced our soft tissue reconstruction and vitiligo trials".

Avita said diluted loss per share was up 40.0 percent to 63 US cents, net tangible asset backing per share was down 20.2 percent to $US3.64, and it had cash of $34,737,000 at December 31, 2022 compared to $US55,511,000 at December 31, 2021.

Avita fell 35.5 cents or 15.6 percent to $1.915 with 2.3 million shares traded.

AVITA MEDICAL

Avita says that although Recell significantly improved “donor sparing” in skin grafts it failed to meet its co-primary endpoint of healing non-inferiority.

Avita did not provide trial data, but said that compared to conventional grafting for donor sparing Recell had “a superior ratio of treated injury area to donor site area ($p < 0.001$)”.

The company said “the healing endpoint did not reach pre-specified statistical non-inferiority” but observed values for healing with Recell were the same or slightly better than control.

In 2020, Avita said it had enrolled the first patient in its up to 65-patient pivotal study of Recell spray-on skin for soft tissue reconstruction at the Arizona Burn Center and this year said it had completed patient enrolment (BD: Mar 3, 2020; Jan 16, 2022).

In March, Avita said the US Biomedical Advanced Research and Development Authority (BARDA) would support the trial and soft tissue reconstruction was of “particular concern” to BARDA as skin grafting, the current standard of care for soft tissue reconstruction, required the harvesting of donor skin which could result in an additional wound to the patient (BD: Mar 22, 2022).

The company said at that time that pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring were associated with donor site wounds.

Today, Avita said the pivotal, randomized, controlled trial evaluated the safety and effectiveness of Recell combined with meshed autograft for reduction of donor skin harvesting in soft tissue reconstruction, and that injuries included any full-thickness acute skin defect, such as degloving or peeled back skin injuries, road rash, surgical wounds and flesh-eating disease.

Avita chief executive officer Dr Mike Perry said the study showed “statistically superior donor sparing and comparable healing rates for Recell treatment of soft tissue injuries and we are confident in moving forward with our plan for a [pre-market approval] submission later this year”.

“The Recell system has been used to effectively treat serious burn injuries and we anticipate that the Recell system will be well-positioned to treat patients with soft-tissue injuries, pending [US Food and Drug Administration] review and approval,” Dr Perry said.

Avita said that it planned to submit detailed results from the trial for peer-reviewed publication, and if FDA approved, the existing reimbursement codes used for burn treatment with the Recell system would apply to this indication.

WOKE PHARMACEUTICALS

Woke says that with the Queensland Institute of Medical Research it will trial its novel WP002 psilocybin tablet in about 15 patients with prolonged grief disorder.

Woke said the Queensland Institute of Medical Research Berghofer’s Prof Vanessa Beesley would design and run the open-label trial, expected to begin in 2023, to show recruitment feasibility, intervention acceptability and proof-of-concept efficacy.

Prof Beesley said there was “an unmet need for novel approaches to treat prolonged grief particularly in cancer carers”.

“Psilocybin-assisted psychotherapy has shown to be beneficial in previous studies for the treatment of related mental health disorders and therefore I have put together a team of leading scientists from around Australia with expertise in psycho-oncology, psychiatry, and psychedelic medicine to design a new intervention to address this need,” Prof Beesley said. “As a secondary analysis of potential efficacy, we will also explore changes in grief scores.”

Woke is a private company.

CYNATA PHARMACEUTICALS

Cynata says it will close its 'Mend' trial of Cymerus mesenchymal stem cells for Covid-19 and respiratory failure in intensive care.
In 2021, Cynata said it enrolled the first of 24 patients for the trial (BD: May 24, 2021).
Today, the company said that although patient recruitment was strong at first, the changing nature the pandemic, and continuous pressure on healthcare systems delayed recruitment as hospitals "prioritized conventional standards of care over clinical trials".
Cynata said the introduction of new antiviral drugs and rapid uptake of vaccines meant fewer patients migrating to intensive care units, further reducing the pool of eligible patients.
The company said that despite initiatives to adapt to changing clinical circumstances, it had "become apparent that recruitment would remain unpredictable and behind target".
Cynata chief executive officer Dr Ross Macdonald said that "in a highly dynamic environment … the situation around the Mend clinical trial has certainly exhibited a fast-moving landscape".
"Our strategic portfolio review was intended to ensure that we focus the application of resources on only the most viable opportunities," Dr Macdonald said. "The decision allows us to refocus our resources on … our other promising clinical programs."
Cynata was up one cent or 2.35 percent to 43.5 cents.

HYDRIX

Hydrix has requested a trading halt pending an announcement "in relation to the Angelmed Guardian device".
Trading will resume on August 16, 2022.
Hydrix closed up 1.5 cents or 17.65 percent at 10 cents.

NOVA EYE

Nova Eye says it expects to release 1,736,653 voluntary escrow shares on August 24, 2022.
According to its most recent filing, Nova Eye had 145,579,791 shares on issue.
Nova Eye was up two cents or 9.1 percent to 24 cents.

DORSAVI

Starfish, Perpetual, HV Lodge and Mantra say their 48,763,230-share substantial holding in Dorsavi has been diluted from 13.78 percent to 12.30 percent.
In July, Dorsavi said it had commitments for a placement to raise $400,000 at one cent a share and would conduct a one-for-12 rights offer for $297,073 (BD: Jul 29, 2022).
Today, Melbourne's Starfish Technology Fund, Sydney's Perpetual Trustee, the Delaware-based HV Lodge; and the Luxemburg-based Mantra Secondary Opportunities said the reduction was due to the "allotment of 40,000,000 new ordinary shares on August 8, 2022 from the institutional share placement announced on July 29, 2022".
Dorsavi fell 0.1 cents or 7.1 percent to 1.3 cents.