



Biotech Daily

Friday April 27, 2018

Daily news on ASX-listed biotechnology companies

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- * **FEDERAL, VICTORIA \$1.75m FOR BURULI ULCER; NHMRC \$20m**
- * **RESMED Q3 REVENUE UP 15% TO \$783m, PROFIT UP 25% TO \$146m**
- * **UNIVERSAL BIO Q1 REVENUE DOWN 3% TO \$8m, PROFIT DOWN 97%**
- * **FDA CLEARS NANOSONICS TROPHON2 PROBE CLEANING SYSTEM**
- * **MICRO-X WINS \$133k UK DEFENCE CONTRACT**
- * **HONG KONG STAR BRIGHT 60% OF ADMEDUS VACCINES (CORIDON)**
- * **NUHEARA: ONE QUARTER CASH; RAMP UP, REVENUE UP, COSTS CUT**
- * **MMJ: DR SANJAY NIJHAWAN CANNABIS ACCESS MEDICAL DIRECTOR**

MARKET REPORT

The Australian stock market rose 0.72 percent on Friday April 27, 2018 with the ASX200 up 42.8 points to 5,953.6 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and three were untraded. All three Big Caps climbed.

Genetic Signatures was the best, up five cents or 17.9 percent to 33 cents with 69,057 shares traded. Eyepoint (Psivida) and Uscom climbed 10 percent or more; Nanosonics rose 8.4 percent; Admedus and LBT improved more than seven percent; Orthocell, Pharmaxis and Polynovo were up more than three percent; Clinuvel, Cochlear, CSL, Prana, Pro Medicus, Resmed and Universal Biosensors rose more than two percent; Ellex and Impedimed were up more than one percent; with Cyclopharm, Medical Developments, Mesoblast and Sirtex up less than one percent.

Osprey led the falls for the second day in a row, down 3.5 cents or 20 percent to 14 cents with 2.4 million shares traded. Compumedics lost 6.25 percent; Bionomics fell five percent; Immutep and Telix were down four percent or more; Actinogen, Optiscan and Starpharma shed more than two percent; Neuren and Opthea were down more than one percent; with Viralytics down 0.3 percent.

[DR BOREHAM'S CRUCIBLE: NUHEARA](#)

By TIM BOREHAM

ASX Code: NUH

Share price: 9.9 cents; **Shares on issue:** 828,315,828; **Market cap:** \$82.0 million

Interim chairman and chief executive officer: Justin Miller

Board: Justin Miller, David Cannington (executive director), Dr Michael Ottaviano, Kathryn Foster

Financials (December half): inaugural revenue \$1.96 million, interest income \$45,558, loss \$4.27 million (previous \$1.7 million loss), cash \$5.64 million * (previously \$4.2 million).

* Received R&D Tax Incentive of \$1.2 million in April

Identifiable shareholders: Wasagi Corp (Justin Miller) (7.91%), David Cannington (7.91%), Inkling Capital (Dr Mike Ottaviano) 3.1%

Watch out Cochlear! Here's an emerging company with world-leading hearing assistance technology, albeit for the moderately hearing challenged rather than the stone motherless deaf.

A player in the "augmented hearing" market, the Perth-based Nuheara has managed to get its Iqbuds on the shelves of 1,500 retailers globally since it launched the product in January last year.

Iqbuds are a Bluetooth-linked device to enable users to listen to music and answer phone calls, with a noise cancelling capacity as well.

Things get more interesting with Nuheara's second device, Iqbuds Boost, which are pitched as a hearing assistance device for people suffering mild hearing loss.

We're not talking about 95-year old Great Aunt Gladys with an ineffectual ear trumpet: about 75 percent of the populace are hearing impaired in some way, with the rot setting in at the ripe young age of 35.

From Silicon Valley to the ASX

Nuheara was co-founded by Silicon Valley entrepreneurs Justin Miller and David Cannington.

But they are no pony-tailed chancers: Miller founded and led the industrial and communication company Sensear Pty Ltd.

He also founded the ASX-listed cloud services provider Empired.

Cannington also worked for Sensear and has had marketing roles at Cadbury Schweppes, McCann Erickson and Exchange (data analytics).

The company is also backed by director Dr Mike Ottaviano, who leads the renewable energy play Carnegie Clean Energy.

Nuheara listed via the shell of Wild Acre in 2016, accompanied by a \$3.5 million raising at 2.5 cents apiece.

After attracting \$1 million of orders via the crowd-funding platform Indiegogo, the company began shipping Iqbuds in January 2017.

In February, the three-bloke board was supplemented with Kathryn Foster, a former Microsoft and Amazon exec who played a key role in building a distribution base for Xbox.

Hear! Hear! An affordable alternative to hearing aids

With a recommended retail price of \$649 per pair, Iqbud Boosts are marketed as an affordable alternative to hearing aids which can cost from \$6,000 to \$12,000 and require an audiologist to fit them.

As a result, most folk with mild hearing loss will settle for a cheaper four-word cure: “can you speak up?!!”

Or else they’re too vain to wear a hearing aid and risk getting placed on the outer table at weddings with Great Aunt Gladys.

Hearing gongs

The Iqbuds have won seven innovation gongs. Last year the consumer tech media company Mashable rated the buds the eighth best technical innovation of 2017, ahead of gizmos such as the Samsung Galaxy Note 8, Google Pixel 2 and Apple Watch 3.

But you can’t eat prestige.

Investors were more excited by the March announcement that Iqbuds Boost would qualify for inclusion under the Federal Government’s \$500 million Hearing Services Program (HSP).

The HSP subsidizes hearing assistance devices for pensioners and certain other concession card holders.

Investors were not deaf to the benefits, pushing the stock up from 5 cents to 14 cents on the day.

In the US, the Over-The-Counter Hearing Aid Act passed Congress last year. This fiat requires the Food and Drug Administration to approve a new category for mild to moderate hearing loss and – voila! – that includes Iqbud Boosts.

The upshot is that patients don't have to go to an audiologist to obtain a lower end device.

And did the Audiologists Union like that? Not one bit.

We hear the future

Nuheara plans a third entry-level, a \$249 bud called LiveIQ that still contains the basic features of its more expensive cousins.

At last count Nuheara had moved 20,000 Iqbuds, generating \$4.5 million of sales since last year's launch.

The devices are stocked at 1,500 brick-and-mortar outlets globally, as well as Amazon

Along the way, the company noticed that the Iqbuds were being used widely for the hearing augmentation aspect, rather than a nice way of listening to music.

Hence the evolution of Iqbuds Boost which incorporates a hearing test and automatically tunes the user's hearing profile.

The company this week said it had started shipping the buds from its Chinese supplier.

While much cheaper than hearing aids, the Boosts are also considerably more expensive than the \$399 Iqbuds.

Mr Miller says the Iqbuds Boost fit neatly into the 'general wellness' (health) category, which is "the new black in retailing".

So rather than being sold alongside a pair of Sennheiser headphones, the buds are more likely to be sold alongside Fitbits or a tin of probiotics.

Avoiding the tech money trap

Mr Miller says management is wary of falling into the tech start-up trap of aiming too high and burning cash too quickly.

The worrywarts at auditor Walker Wayland warn that Nuheara's status as a going concern depends on continued sales, the release of new products and controlling discretionary expenditure.

(Auditor, by the way, means "a listener" in Latin.)

The company recorded a December quarter cash burn of \$2.28 million on revenue of \$849,000, with a \$5.6 million end-of-quarter cash balance.

Nuheara hasn't been coy about passing the hat around in its short-listed life, having rustled up \$20 million to date. And the company banked a \$1.2 million Federal Tax Research and Development Incentive this month.

"With our cash and good inventory levels and sales continuing we are okay for the time being," Justin Miller says.

Nuheara is due to update investors on its sales at its August full-year results.

"It's very early days for us, so predicting sales is a risky proposition," Mr Miller says.

But given the uptick in the store coverage from 40 stores (as of July 2017) to 1,500, sales should be well north of the current number.

Dr Boreham's diagnosis:

Like being hard of hearing, the hearing market is hard.

On recent global experience, Nuheara will need to harness all its Silicon Valley smarts so as not to fall on its ear.

In August last year, a crowd-funded US mob called Kanoa foundered without selling one of its wireless headphones. The final straw was a savage Youtube clip in which the reviewer alleged the company tried to bribe him for positive coverage.

(Your columnist has never experienced this shocking practice, but is open to realistic offers.)

In November, Doppler Labs shut up shop, despite spending more than \$US50 million on developing its Here One 'augmented reality' ear buds.

"Six hearing aid companies have 90 percent of the business and the ears are a hard thing to get right," Mr Miller says.

"The hearables market is still in its infancy with players still muscling for position.

"Accordingly, all players must scale as the market scales. Too fast [and] you crash and burn too slow and you miss out," Mr Miller says.

Quite.

Despite these commercialization challenges, we are not deaf to Nuheara's appeal.

The Cochlears and hearing aid moguls of the world can rest easy for the time being, but they should hear the Iqbuds coming if Nuheara gains traction.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. What did you say??

FEDERAL GOVERNMENT, VICTORIA GOVERNMENT

The Federal and Victoria Governments say they will provide \$1.75 million for research into the spread and control of Buruli ulcer in Victoria.

In announcing \$20 million in National Health and Medical Research Council (NHMRC) grants, Federal Health Minister Greg Hunt said that a \$1.5 million grant would fund a two-year study led by the University of Melbourne's Prof Tim Stinear who found mosquitoes were a factor in spreading the bacteria to humans.

A media release from Mr Hunt's office said it would be one of the first investigations to study the transmission of the Buruli ulcer and followed a spike in cases of the infection. The media release said that the disease had been found in Far North Queensland as well as parts of coastal Victoria, including East Gippsland, Phillip Island, the Mornington Peninsula and the Bellarine Peninsula.

The Federal Government said it had previously provided \$2.4 million for research into the Buruli ulcer and the study would be supported by Mornington Peninsula Shire, Barwon Health and the Victorian Government.

A media release from Victoria Health Minister Jill Hennessy said the State Government would contribute \$250,000 for research into the transmission of the Buruli ulcer in Victoria. The media release said the Buruli ulcer was caused by the bacterium *Mycobacterium ulcerans*, which was found naturally in the environment, but it was not known how humans become infected, although mosquitoes were thought to have a role in transmission.

Mr Hunt said the NHMRC funding was one of 23 Partnership Project Grants.

A full list of NHMRC recipients is available at: <https://bit.ly/2FkCczG>.

RESMED

Resmed says that revenue for the three months to March 31, 2018 was up 15.1 percent to \$US591,634,000 (\$A783,293,834) with net profit after tax up 25.4 percent to \$US110,125,000 (\$A145,799,994).

Resmed said diluted earnings per share was 76 US cents for the three months and a dividend of 3.5 US cents would be paid on June 14 for shareholders at the record date of May 10, 2018.

The company said research and development expenditure for the quarter was up 6.6 percent to \$US37,434,000 or 6.3 percent of revenue.

Resmed was up 30 cents or 2.4 percent to \$12.95 with 3.8 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the three months to March 31, 2018 was down 3.1 percent to \$7,684,147, with net profit after tax down 96.6 percent to \$83,821.

Universal Biosensors said its reduction in net profit after tax was "mostly a result of the increased development expenditure" as it increased development tests for a new coagulation product.

The company said Lifescan quarterly service fees for its blood glucose test strips was up 1.5 percent to \$6.9 million, while revenue from the sale of its Xprecia Stride Coagulation Analyzer test strips fell 44.4 percent to \$500,000.

Universal Biosensors said research and development expenditure for the quarter was up 87.7 percent to \$3,865,924 or 50.3 percent of revenue.

The company said it had cash and cash equivalents of \$25,277,584 at March 31, 2018.

Universal Biosensors was up half a cent or 2.4 percent to 21.5 cents.

[NANOSONICS](#)

Nanosonics says it has US Food and Drug Administration 510 (k) clearance for its Trophon 2 ultrasound probe infection control system.

Nanosonics said that the new features of the Trophon2 included a redesigned chamber to facilitate existing and future probe designs as well as new functionality to optimize point of care use and clinical workflow, as well as a large, high-definition color touch screen for ease of installation, training and use, quiet operation and programable options.

Nanosonics chief executive officer Michael Kavanagh said that the approval was “excellent news delivering earlier than anticipated FDA clearance for our next generation Trophon device”.

“Further, it delivers the first regulatory approval of our targeted new infection prevention [products],” Mr Kavanagh said.

Mr Kavanagh said that the Trophon2 had “a completely new mechanical and software design” based on input and feedback from customers including infection prevention specialists on future trends and requirements for semi-critical device reprocessing.

“Central to the new design is a totally new software platform which delivers superior capabilities including the all-new Acutrace feature ... [which] delivers paperless traceability and documentation of disinfection cycles,” Mr Kavanagh said.

Mr Kavanagh said that the Trophon2 could store more than 100,000 disinfection records, providing more accurate and complete records for improved compliance with required standards.

He said that the Trophon2 had digital connectivity enabling it to be integrated with hospital information technology systems.

“We see strong potential for the Acutrace system to assist hospitals with their audit compliance, as well as providing them with a seamless and easily integrated system to store and retrieve disinfection cycle data,” Mr Kavanagh said.

“From a user’s perspective it means that at the touch of a button they can verify that any probe, at any moment in time, has been successfully disinfected, resulting in peace of mind for patients and their care providers,” Mr Kavanagh said.

He said that the Trophon2 was designed to meet specific European market requirements including the ability to monitor and report on all the process parameters including dosage, temperature and time for each disinfection cycle.

“This new functionality helps pave the way to establish Trophon2 as the new standard of care in Europe as new country specific guidelines requiring [high level disinfection] for all semi-critical ultrasound probes are introduced,” Mr Kavanagh said.

He said that a European regulatory submission was currently under review and the expected commercial release in the US would be by October 2018.

“The original Trophon EPR device will remain in the market as an entry level product however we anticipate a significant proportion of sales to shift from Trophon EPR to the new Trophon2 system,” Mr Kavanagh said.

“As a result of the earlier than anticipated regulatory clearance, expectations are that the market and our distributor partners will now commence the transition to Trophon2 which means it is likely there will be a short-term impact on both inventory and trading volumes which will have a transitional impact on revenue recognition in the current quarter,” Mr Kavanagh said.

“However, it is expected that Trophon2 will continue to drive installed base growth as well as introduce the opportunity for an upgrade market and any impact on short term sales of Trophon EPR due to the imminent release of Trophon2 is anticipated to be made up after the full commercial release of Trophon2,” he said.

Nanosonics was up 19 cents or 8.4 percent to \$2.45 with 7.2 million shares traded.

MICRO-X

Micro-X says it has a GBP71,900 (\$A132,668) six-month research and development x-ray security contract with the UK Ministry of Defence.

Micro-X said the contract with the UK Defence Science and Technology Laboratory was for a lightweight x-ray imaging system for detecting explosives hidden in consumer electronic devices.

The company said that it would develop and test a system using a combination of x-ray backscatter and conventional projection x-ray imaging techniques "to provide a unique high-resolution image of consumer electronic devices which might be carried on board passenger aircraft".

Micro-X said it would collaborate on the project with Durham University's Prof Toby Breckon with existing automated target recognition algorithms to be applied to Micro-X's combined backscatter and projection x-ray images.

Micro-X managing-director Peter Rowland said the project "combines the technical successes we have had both in our lightweight medical projection imaging system and our Backscatter Imager which we demonstrated to the Australian Defence Force's counter-[improvised explosive device] task force last year".

"We conducted some imaging tests before submitting our bid for this project and were very pleased at the tiny amounts of explosive material which were easily detectable using this backscatter imaging technique," Mr Rowland said.

The company said that a follow-on second-phase would ready the technology for a future airport trial system planned.

Micro-X said it had provided indicative costs for a follow-on second phase which would ready the technology for a future airport trial system.

Micro-X was up two cents or 5.7 percent to 37 cents.

ADMEDUS

Admedus says Hong Kong's Star Bright Holding intends to take 60 percent of subsidiary Admedus Vaccines Pty Ltd for \$18 million.

Last year, Admedus said it was looking for alternative funding for the subsidiary, formerly known as Coridon, with research led by Gardasil inventor and head of the Brisbane-based Translational Research Institute Prof Ian Frazer (BD: Oct 30, 2017).

In 2011, the then Fortescue Metals-invested Allied Medical merged with Biomed to form Allied Healthcare Group with a stake in Coridon, which was developing DNA vaccines for the prevention and treatment of infectious diseases and cancers, including Epstein-Barr virus, or glandular fever (BD: Feb 15, Jun 14, Jul 20, 2011).

Today, Admedus said that the Star Bright letter of intent included a non-refundable break fee of \$500,000 securing a six-month exclusivity period to finalise an agreement and the aim was to provide Admedus Vaccines with alternative funding to continue its research.

Admedus chief executive officer and Admedus Vaccines chairman Wayne Paterson said that the "new funding opportunity for Admedus Vaccines ... would see it operate as a new entity with Admedus Limited maintaining an active stake".

"Once finalized, this will also deliver on our earlier commitment to secure an alternative funding source for the immunotherapies division which requires significant additional investment to fulfil its potential as the developer of ground-breaking vaccines," Mr Paterson said.

Prof Frazer said the arrangement would "greatly enhance our resources and allow myself, and the team, to accelerate our projects".

Admedus was up 2.5 cents or seven percent to 38 cents with 1.7 million shares traded.

[NUHEARA](#)

Nuheara says its net operating cash burn for the three months to March 31, 2018 was \$1,088,000 with cash at the end of the quarter of \$4,866,000.

In its Appendix 4C quarterly report, Nuheara it had received a \$1.2 million Federal Research and Development Tax Incentive after the end of the period and expected to spend \$4,350,000 in the three months to June 30, 2018.

Nuheara chief executive officer Justin Miller told Biotech Daily that the projected three months expenditure included a major ramp-up for manufacturing, including a third product. Mr Miller said the company expected significantly increased revenue, along with a much-reduced expenditure beyond the June quarter.

Nuheara was up 0.6 cents or 6.45 percent to 9.9 cents with 8.5 million shares traded.

[MMJ](#)

MMJ says medical cannabis portal Cannabis Access, has appointed Dr Sanjay Nijhawan as its medical director.

Earlier this month, MMJ said it had invested \$1 million for a 16.7 percent ownership in the Sydney-based Biologics Research Institute-owned Cannabis Access, which is said was an online portal for Australian healthcare professionals (BD: Apr 10, 2018).

MMJ was unchanged at 36.5 cents.