



Biotech Daily

Friday September 3, 2021

Daily news on ASX-listed biotechnology companies

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- * **SUDA APPOINTS DR JOHN MAHER SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market climbed 0.5 percent on Friday September 3, 2021, with the ASX200 up 37.2 points to 7,522.9 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell and five traded unchanged. All Big Caps were up.

Optiscan was the best, up 2.5 cents or 9.8 percent to 28 cents, with 729,507 shares traded. Neuren was up 7.6 percent; Clinuvel climbed 6.3 percent; Mesoblast and Volpara improved five percent or more; Actinogen, LBT and Paradigm were up more than four percent; Immutep and Impedimed improved more than three percent; Amplia, Cochlear and Proteomics rose more than two percent; Avita, Compumedics, Dimerix, Imugene and Next Science were up more than one percent; with CSL, Cynata, Nanosonics, Pro Medicus, Resmed and Starpharma up by less than one percent.

Uscom led the falls, down one cent or 6.7 percent to 14 cents, with 64,350 shares traded. Patrys fell 4.4 percent; Genetic Signatures and Nova Eye were down more than three percent; Alterity, Antisense, Oncosil and Prescient shed two percent or more; Medical Developments, Polynovo, Telix and Universal Biosensors were down more than one percent; with Cyclopharm and Kazia down by less than one percent.

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

By TIM BOREHAM

ASX Code: NAN

Share price: \$6.69; **Shares on issue:** 301,502,220; **Market cap:** \$2.02 billion

Chief executive officer: Michael Kavanagh

Board: Maurice Stang (chair), Steven Sargent (deputy chair), Mr Kavanagh, Dr David Fisher, Marie McDonald, Geoff Wilson, Dr Lisa McIntyre

Financials (year to June 30, 2021): revenue \$103.1 million (up 3%), net profit \$8.6 million (down 15%), earnings before interest, tax depreciation and amortization \$15.2 million (up 4%), cash of \$96 million (up 4.5%)

Major identifiable shareholders: FMR LLC (Fidelity) 9.6%, Maurie Stang 6.2%, Bernard Stang 5.4%, Steve Kritzler 2.5%, Michael Kavanagh 0.34%.

Who said that the share behavior of ASX-listed biotech stocks was non-volatile, linear and totally unpredictable?

Certainly not Warren Buffett.

Just when we thought that investors had kyboshed one of the Australian medical device sector's greatest success stories, Nanosonics shares gained a powerful head of steam after the company's August 24 full-year earnings result.

In essence, sales of the company's mainstay Trophon medical probe sterilization devices are rebounding from the pandemic faster than expected.

The reported profit, though subdued, was roughly double what the market expected and the company returned to double-digit revenue growth in the six months to June 30. Management also expects 20 percent-plus sales growth this year.

Perhaps most importantly, management finally revealed its mystery extension product, called Coris, for sterilizing flexible endoscopes.

"We expect the uptake of the new platform technology might be faster than with the Trophon," chief executive Michael Kavanagh says. "The underlying fundamentals are stronger compared to what they were when Trophon was launched."

The 22 percent post-results share price hike contrasts with the market reaction afforded to the company in early July after it announced the release of Audit Pro, an equipment use tracking application.

Over the next four days, the shares lost 14 percent of their value, because Audit Pro wasn't the exciting product the company had promised.

Now that we know about what broker Wilsons dubs Nanosonics' "dirty little secret", investors have regained their love for the stock even if the brokers haven't (see below).

About Nanosonics

About the size of a microwave, Trophons are units that sanitize probes to certified high level disinfectant (HLD) standards. This is at a time when there's a heightened awareness of bugs such as drug-resistant bacteria, fungi, blood-borne viruses and venereal diseases.

The company has now launched a tizzed-up version called - you guessed it - Trophon 2.

And seeing you asked, severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) falls under the category of 'enveloped viruses', against which the Trophons have proven to be highly effective. But the machines have not been tested directly against the dreaded virus and so management makes no Covid-busting claims.

Based on hydrogen peroxide, the Trophon process takes seven minutes and produces harmless water and oxygen as a byproduct.

It's sober to ponder - especially before a colonoscopy - that past sterilization standards have ranged from a quick 'once-over' with a cloth to a procedure involving an isolating room with dangerous chemicals.

Formed in 2001 and listed since mid-2007, Nanosonics swiftly obtained regulatory approvals and has been selling worldwide over the last decade, notably in the US.

As of June 30, 2021, 26,750 Trophons had been installed, compared with a tad over 14,100 five years ago. As well as selling (or leasing) the units, Nanosonics also makes money from servicing and consumables. The latter consists mainly of the hydrogen peroxide canisters that are used in the procedure (rather like a dishwasher powder tablet).

Join in the Coris

Coris stems from a concerted research and development push that saw the company spend \$17.2 million in the laboratory last year.

Flexible endoscopes are commonly used in procedures such as gastroscopies, enteroscopies, endoscopic ultrasounds and bronchoscopies. And because endoscopes are so complex, they're very hard to clean - even well beyond the scope of the Trophons.

As a guide, up to 200 manual actions are required (such as brushing and flushing) to clean the instruments. Because the channels can be one millimetre in diameter, "extensive biofilms" - that is, gunk - remain after cleaning.

Ew!

The company says 60 million endoscopic procedures are done each year in the US, Europe and Australia, with use growing at six percent a year.

As stockbroker Wilsons notes, hospitals had been pivoting to single-use endoscopes, especially for duodenoscopies.

But the availability of a top-class sterilization method means government funders and insurers are likely to steer back to the less expensive multiple-use instruments.

Nanosonics is coy about likely revenues but Wilsons estimates that Coris could generate “incremental Ebitda” of \$20 million to \$25 million in the three to five years after launch, which is expected in 2023.

All go for Audit Pro

Audit Pro is a cloud-based software application that allows medicos to track and trace reusable medical instruments (such as probes) which have the potential to transmit infections. It's Nanosonics' first internet cloud-connected 'internet-of-things' offering.

Used in conjunction with the Trophon 2, Audit Pro collects data with a bedside hand-held scanner, via a Bluetooth connection.

Initially, the company is tackling the ultrasound market, which isn't a bad idea given there are 650 million procedures annually (and not all for pregnancy monitoring).

Unlike the Trophons, Audit Pro works on a subscription model, which means the hospitals do not have to outlay up-front capital.

Stockbroker Bell Potter estimates a US “serviceable market” of \$US37 million (\$A51 million) a year for Audit Pro, based on 150,000 ultrasound consoles across 5,000 hospitals and specialist clinics.

Finances and performance

Nanosonics' full year numbers showed the benefit of the company's sales reps once more being able to access hospital decision makers, especially in the US.

Having declined 11 percent to \$43 million in the first (December) half, full-year turnover climbed three percent to \$103 million. The full-year net profit of \$8.6 million was 15 percent lower on the year, but well up on the first half tally of \$1.5 million.

Earnings before interest tax depreciation and amortization (Ebitda) edged up four percent to \$15.2 million.

At the depths of the pandemic, hospital access was crimped by 40 percent.

“With limited hospital access we have adjusted quite well to remote interaction,” Mr Kavanagh says.

The global installed base of Trophons rose 13 percent to 26,750 units, with US installations gaining 12 percent to 23,480.

Capital revenue sales - that is, Trophon units - fell 11 percent to \$26.7 million, the result of distributor GE Healthcare freezing orders in the pandemic-afflicted first (September 2020) quarter. But consumables/service revenue bounded nine percent to \$76.4 million.

As of the June 30 balance date, Nanosonics had \$96 million of cash - a handsome kitty for potential acquisitions and new product development.

In the last 12 months, Nanosonics shares have gamboled between \$5.05 (November 2 2020) and \$7.18 on August 24. Historically, the stock has traded as low as 17 cents, in December 2008.

What the finance experts think

Despite the improved sales outlook, the broking cognoscenti retain a cautious view on Nanosonics, if only because of the stock's lofty valuation.

Finance house Citi retains a sell call, but increases its 'target price' from \$4.40 to \$5.00 a share.

Wilson's upgraded its call on the stock from sell to "market weight" or hold, ascribing a \$7.18 valuation - a meaty upgrade from \$3.58, previously.

Bell Potter had also adjudged the stock a 'sell'. Like Margaret Thatcher, the firm's not for turning but upgrades its valuation of the stock from \$4.50 to \$6.35. "The absence of meaningful earnings growth is a significant driver of the ongoing sell recommendation," the firm says.

In July this year, Goldman Sachs downgraded its recommendation on the stock from 'neutral' to a sell call, with a \$4.93 valuation.

Morgans is more generous and ascribes a hold call to the stock, with a valuation of \$7.26 per share.

Beyond Trophons

One overlooked aspect of the results is that management has doubled the size of the US addressable market for Trophons to 60,000 units. This means that rather than approaching saturation with a 78 percent share of the market, Nanosonics has a 39 percent share which implies plenty of growth.

Still, Nanosonics' ongoing prosperity revolves around new installations, upgrades and the smooth rollout of Coris.

Management estimates 5,000 to 6,000 of the original Trophons are five to seven years old and due for an upgrade to the Trophon 2.

"We will certainly be talking to those customers," Mr Kavanagh says.

Last November, Australia's I-Med Radiology Network said it would upgrade all of its Trophons to the Trophon 2 units.

By adding bells and whistles to Trophon 2, Audit Pro could hasten the redundancy of the first-generation Trophons.

As for new customers, Nanosonics estimates a total addressable market of 120,000 units, evenly split between North America, Europe/Middle East and the Asia Pacific.

The European market is relatively untapped, given some countries there were tardy in devising high level disinfecting guidelines.

Dr Boreham's diagnosis:

Your columnist refrains from hyperbolic comments such as "the next two years will be make-or-break for the company".

Having said that, the rollout of the "transformational" new products will be a salient test of whether Nanosonics warrants its \$2 billion-ish valuation.

A successful Coris launch would be something to sing about, but Mr Kavanagh adds that all the new stuff won't come on stream "at the flick of a switch".

Separately, management calls out the germ-conscious Japanese market as especially promising. The company has secured distributors there, but is waiting for official high level disinfectant guidelines to spur sales in earnest.

The company is also angling for regulatory approval in China, a market potentially worth ... a lot.

Without factoring in Coris, Nanosonics for the time-being looks fully-valued on an earnings multiple of 100 to 150 times this year's expected earnings.

As broker Citi says: "the current share price is implying little execution risk [for the new products] which is a little optimistic".

To its credit, Nanosonics has re-written the rules on disinfection control, with its units fast becoming the standard-of-care.

That means hospitals will be sued if they persevere with old and discredited anti-infective techniques for invasive medical equipment.

For patients about to 'go under' ahead of a colonoscopy, Nanosonics doesn't look overvalued at all.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He hopes that when the probing space aliens come for him, that have a Trophon in their ship.

BTC HEALTH

BTC Health says revenue for the year to June 30, 2021 for it and its subsidiaries was up 16.9 percent to \$7,115,150.

In a 'shareholder update' BTC said its loss before interest, taxes, depreciation and amortization was down 53.3 percent from the previous year to \$464,306.

BTC executive chair Dr Richard Treagus told Biotech Daily that because the company didn't have any taxation, depreciation or amortization that figure was "effectively the same as net profit after tax".

The company said it was a "pooled development fund" which owned subsidiaries Bio-Impact and BTC Specialty Health, and had the sale and distribution rights in Australia and New Zealand to Pharmaxis' Bronchitol for cystic fibrosis and the Aridol lung function test.

BTC said it had \$2,386,854 in cash at June 30, down from \$2,795,502 the prior year.

In its preliminary final report, BTC said revenue for the 12 months to June 30, 2021, fell 88.7 percent to \$19,190, with net loss after tax up 38.4 percent to \$391,686.

BTC Health was up 0.1 cents or 1.2 percent to 8.3 cents.

NEUREN PHARMACEUTICALS

Neuren says the US FDA has granted orphan drug designation to NNZ-2591 for the treatment of Prader-Willi Syndrome.

Neuren said that Prader Willi Syndrome was a rare, highly debilitating disorder related to defects on chromosome-15, which could lead to intellectual disabilities, sleep disturbances, morbid obesity and difficulty regulating emotions.

Neuren chief executive John Pilcher said the company was "delighted to receive orphan drug designation from the FDA following review of our rationale and data".

"This underpins the commercial opportunity and follows orphan drug designation already granted for Phelan-McDermid, Angelman and Pitt Hopkins syndromes."

The company said that orphan drug designation carried incentives, including seven years of marketing exclusivity to drug sponsors, plus six months if approved for paediatric use, as well as waiver of the prescription drug user fee for a marketing application.

Neuren was up 17 cents or 7.6 percent to \$2.42 with 563,642 shares traded.

BCAL DIAGNOSTICS

BCAL says the Sydney Breast Clinic will collect blood samples for its study to confirm the set of biomarkers for its blood test for breast cancer.

The company said the Breast Clinic would collect blood from mammogram patients to validate and assess analytical performance of candidate biomarkers, optimize the algorithm and establish protocols suitable for transfer of the test to pathology laboratories.

BCAL said that stage one of the study would analyze blood from 1,000 participants.

BCAL was unchanged at 19.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says the Federal Department of Industry, Science, Energy and Resources has approved its Research and Development Tax Incentive off-shore claims.

Neuroscientific said that the approval, through Ausindustry, related to the development of Emtinb as a treatment for conditions that damage the optic nerve, and eligible research and development expenditure incurred over 2021, 2022, and 2023.

Neuroscientific was up 1.5 cents or 4.8 percent to 33 cents.

OSPREY MEDICAL

Osprey says its extraordinary general meeting has approved the proposed 100-to-1 consolidation of its Chess depository instruments (CDIs) and options.

Osprey said the record date for the consolidation would be September 16, and that trading would recommence on September 24, 2021.

Osprey was unchanged at 1.2 cents.

NOVA EYE

Nova Eye says it has bought back 388,334 shares at 31.5 cents a share in unmarketable parcels worth \$500 or less, held by 1,249 investors.

In July, Nova Eye said it had a buy-back facility for holders of unmarketable parcels of shares, based on the share value on July 8. of 31.5 cents a share (BD Jul 16, 2021).

Nova Eye fell 1.5 cents or 4.8 percent to 33 cents.

CSL

CSL says its annual general meeting will vote to grant up-to 31,640 performance share units worth \$US7,214,120 (\$A9,835,201) to chief executive officer Paul Perreault.

CSL said the proposed long-term incentive was equivalent to 400 percent of Mr Perreault's base salary of \$US1,803,530 (\$A2,435,065), to be paid in two tranches.

Last year, the company proposed to grant Mr Perreault a long-term incentive of \$9,524,069 in performance rights, which was opposed by 61,753,639 votes (23.65%) with 199,339,923 votes (76.35%) in favor (BD: Sep 4, 2020).

Today, CSL said investors would vote on the remuneration report and the election of directors Dr Brian McNamee, Prof Andrew Cuthbertson, Alison Watkins and Prof Duncan Maskell.

The meeting will be held online on October 12, 2021 at 10am (AEDT).

CSL was up 43 cents or 0.1 percent to \$303.87 with 633,116 shares traded.

MGC PHARMACEUTICALS

MGC says it that India has approved the import of its Cimetra herbal remedy for Covid-19. MGC said the import permit was "a final step towards obtaining emergency use authorization for the treatment of patients with Covid-19".

The company said Medopharm Private was managing the Cimetra emergency use authorization and had been appointed the should Cimetra be approved.

MGC said Cimetra was based on curcumin and Boswellia, while Artemic (Cimetra backwards) comprised artemisinin and curcumin.

MGC was up 0.7 cents or 14.9 percent to 5.4 cents with 51.7 million shares traded.

DIMERIX

Peter Meurs says he has increased his substantial holding in Dimerix and been diluted from 24,819,309 shares (12.55%) to 26,529,309 shares (10.68%).

The Melbourne-based Mr Meurs said he bought 1,710,000 shares on-market between July 23, 2020 and November 25, 2020 for 507,357 or 29.7 cents a share, and was diluted in the \$20 million placement (BD: Aug 16, 2021).

Dimerix was up half a cent or 1.45 percent to 35 cents with 1.1 million shares traded.

ALTHEA GROUP

Regal Funds Management says it has become a substantial shareholder in Althea with 22,946,369 shares (7.48%).

The Sydney-based Regal Funds Management said that the shares were acquired between May 3 and August 31, 2021, buying 64,876 shares for \$30,232 or 46.6 cents a share on May 3 and the largest acquisition on August 31 of 14,583,334 shares for \$3,500,000 or 24.0 cents a share.

Althea was up 1.5 cents or 5.9 percent to 27 cents with 1.2 million shares traded.

SUDA PHARMACEUTICALS

Suda says it had appointed Dr John Maher to its scientific advisory board to inform the development of its invariate natural killer T-cell therapy platform.

Suda said Dr Maher established chimeric antigen receptor-T-cell (Car-T) research at Kings College London, where he had led development of immunotherapy involving engineered T-cells.

The company said Dr Maher was the founder of Leucid Bio, a clinical stage cell therapy company.

Suda was up 0.2 cents or 3.6 percent to 5.7 cents with 2.7 million shares traded.