



Biotech Daily

Friday June 21, 2019

Daily news on ASX-listed biotechnology companies

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- * **MORGAN STANLEY BELOW 5% IN TOTAL BRAIN**

MARKET REPORT

The Australian stock market fell 0.55 percent on Friday June 21, 2019, with the ASX200 down 36.6 points to 6,650.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and four were untraded.

Actinogen was the best, up 0.1 cents or 11.1 percent to one cent, with 13.9 million shares traded.

Ellex and Optiscan climbed more than six percent; Neuren improved 4.2 percent; Opthea was up 3.3 percent; Osprey, Starpharma and Universal Biosensors rose more than two percent; Avita, Benitec and Mesoblast were up more than one percent; with Clinuvel, Cynata, Nanosonics and Resmed up by less than one percent.

Proteomics led the falls, down 1.5 cents or 4.05 percent to 35.5 cents, with 94,000 shares traded.

Alterity (Prana), CSL, LBT, Medical Developments and Oncosil lost more than three percent; Cochlear, Paradigm and Pharmaxis shed more than two percent; Compumedics, Dimerix, Genetic Signatures and Pro Medicus were down by more than one percent; with Telix down 0.8 percent.

DR BOREHAM'S CRUCIBLE: NEXT SCIENCE

By TIM BOREHAM

ASX Code: NXS

Share price: \$3.92

Shares on issue: 179,164,575 shares (74,280,322 not quoted on the ASX)

Market cap: \$702.3 million

Chief executive officer: Judith Mitchell

Board: George Savvides (chairman), Judith Mitchell, Bruce Hancox, Dan Spira, Aileen Stockburger, Mark Compton

Financials (calendar 2018): revenue of \$US2,844,502 (\$A4,106,773), net loss of \$US13,997,234 (\$A20,207,819)

Major shareholders: Auckland Trust Co (Lang Walker) 25.96%, Walker Group Holdings 16.46%, Dr Matthew Myntti (founder and chief technology officer) 11.53%, Judith Mitchell 2.64%

In the never-ending battle against bacteria, Next Science has adopted a 'take no prisoners' approach in eradicating the bodily bolt holes in which these pathogens congregate and quietly multiply.

With a suite of four approved products, the recently-listed Next Science is opening up more battle fronts than the early years of World War II. Current targets include open surgery, chronic wounds and acne, with other theatres of war in the offing.

Unlike your usual weapons of war, they're all non-toxic and will only hurt the malevolent bugs.

According to CEO Judith Mitchell, the ingredients such as sodium citrate and citric acid are present in most kitchens. "It's just that people haven't put them together," she says. "We manipulate them in such a way that we take advantage of nature."

Ms Mitchell notes that chronic wounds kill more people annually than cardiac issues, with half of the patients undergoing amputations not surviving another year.

The problem

Next Science tackles bodily biofilms, which sneakily house 90 percent of all bacteria (the remainder is planktonic, or floating).

Within these lattice structures - described as “slimy tangles of protective fibres linked with metallic bonds” - germs survive out of reach of antibiotics. The lurgies not only survive: they co-operate with other species to help them proliferate. It’s called ‘quorum sensing’, but has nothing to do with a stacked ALP branch meeting.

Where do these biofilms reside? Start at the head and go down to the toes.

Infections can stem from devices: anything from humble contact lenses to breast implants, cardiac valves, urinary catheters and cardiac implants. Alternatively, the biofilm can harbor tissue related infections stemming from common disorders such as acne, bacterial vaginosis, kidney stones and common wounds.

The mouth and nasal cavities are a hotbed of infection. “The mouth is a festival of germs,” says Ms Mitchell, noting that plaque is a form of biofilm.

The story to date

Next Science was founded in 2012 by Dr Matthew Myntti, who was principal scientist at Medtronic Surgical Technologies where he led the biomaterials group.

At Medtronic, Dr Myntti developed ear, nose and throat (ENT) and neurological products. However, Medtronic didn’t share Dr Myntti’s interest in chronic wounds and happily handed over the relevant patents.

Dr Myntti then went in search of a backer, which led him to the portals of property developer Lang Walker. Mr Walker, who has also invested in the ASX-listed Neuren Pharmaceuticals and the unlisted AIDS test developer Atomo Diagnostics, funded most of the initial backing of \$66 million.

The second person to chip in with a million bucks or two was Judith Mitchell, who joined as CEO. Ms Mitchell was the president of De Puy Synthes Asia Pacific (the orthopaedics arm of Johnson & Johnson) and previously held senior roles at Cochlear and GE Medical.

Next Science listed in April this year, raising \$35 million at \$1 apiece.

The solution

Next Science’s products are based on its Xbio platform which erodes the existing protective structures by breaking down the ionic bonds that hold them together. These bonds are metallic, which means Mum was right when she told you to bathe a wound in metal-corroding salt.

Called cell lysis, the process whomps the bacteria and prevents decolonization.

“Unlike other agents that claim to destroy biofilms, there is no known evidence of bacterial resistance to the Xbio technology,” the company says.

Next Science's current product suite consists of:

- * Bactisure, a lavage to remove biofilms and bacteria in open surgery;
- * Surgx, a sterile gel to reduce surgical site infections;
- * Blastx, an antimicrobial wound gel for chronic wounds;
- * Torrentx, a wound wash for nurses, emergency departments and home care; and
- * Acne Gel, which is self-explanatory

Bactisure, Surgx and Blastx are approved by the US Food & Drug Administration as a 510(k) device, with European CE mark and local TGA approval expected this year.

Torrentx is approved as an over-the-counter product in the US, while the acne potion will be available in Australia this year as an over-the-counter cosmetics.

Where's the proof?

We hate to sound like Mrs Marsh from the Colgate ads, but university tests prove the efficacy of the approved products.

With Bactisure, Montana State University tests showed better results over 72 hours relative to the antiseptics Betadine and IriSept.

Ditto Torrentx over Prontosan and Vashe, or the Blastx gel relative to no dressing, gauze and the wound dressings Mepilex and Aquacel AG.

In the words of Mrs Marsh: "It does get in". For those who prefer pictorial evidence, there's plenty available in Next Science's latest investor prezzzo. Don't have lunch first, though.

Other scientific papers vouch for the efficacy of Next Science's biofilm disruption agents against *Candida auris*, a fungal superbug that is even more deadly than golden staph (*Staphylococcus aureus*).

Overall, the company has a data base of 80,000 patients to support its claims.

Then there are the off-label uses: a tonsillitis sufferer claims to have been cured of the ailment after imbibing Blastx, which is not exactly the intended method of delivery.

The size of the prize

The company claims vast addressable markets, such as the \$US50 billion chronic wound sector and the \$US4 billion market for prosthetic joint infections.

But there are surprises: the market for chronic sinusitis is estimated at up to \$US65 billion, while chronic otitis media (ear infections) costs \$US24 billion to treat. Even the relatively benign fungal nail infections cost \$US2.6 billion to treat.

To address these markets, the company has signed separate distribution agreements.

Zimmer Biomet takes care of Bactisure globally, while Minneapolis, Minnesota's 3M covers Blastx and Advanced Skin Technology 'does' acne.

Distribution agreements are in discussion for Torrentx and Surgx.

In early May, 3M acquired medical device maker Acelity Inc for \$US6.7 billion. The significance for Next Science is that Acelity's subsidiary KCI is the world's biggest player in wound vacuums, with an 80 percent market share.

Ms Mitchell says KCI will deliver Blastx to all areas of a hospital where scrubs are required.

"It's a long time since KCI had something to talk about," Ms Mitchell says. "It's a great opportunity to change profile of wound care."

Meanwhile, Grace Medical has been enlisted to sell the company's sinus lavage in key markets including the US and Europe.

Ms Mitchell cites sinus conditions, which account for five percent of western health budgets, as a particular opportunity.

"ENT (ear nose and throat) surgeons know what a biofilm is, you can see it looking down a microscope into the middle ear."

What's next?

The company expects to have lodged six approval applications to European regulators by the end of July, as well as three more to the FDA and three to the Australia's Therapeutic Goods Administration.

In terms of medical devices, Next Science is working towards a sinus wash (for chronic sinusitis), a lavage for minimal invasive surgery and a middle-ear wash.

On the pharmaceutical side, the company's box of tricks covers impetigo (school sores), atopic dermatitis, fungal nails, keloid prevention and bacterial vaginosis (look out, Starpharma!).

The company is also seeking approval from the US Environmental Protection Agency for a hard-surface disinfectant to kill bugs such as the aforementioned candida aura.

A key limitation of Next Science's products is that they can't tackle blood-borne infections. "But we're working on it," Ms Mitchell says.

Financials and performance

Post IPO, Next Science has cash of about \$30 million - enough to last for three and a half years in the absence of any sales.

Otherwise the company's financial performance is modest relative to its chunky \$780 million market capitalization.

The company has yet to lodge a quarterly report, but the prospectus shows the company made income of \$US2.8 million in calendar 2018, for a loss of \$US14.0 million.

A subsequent investor prezzo shows Blastx generated revenue of just over \$US1.4 million in the calendar year to date, compared with \$US200,000 in the previous corresponding period.

Bactisure chalked up a little over \$US250,000, compared with \$US150,000 previously.

In its short-listed life, the company's shares have gyrated between \$1.24 and \$4.73 on June 19, after a run that prompted an ASX price query.

Dr Boreham's diagnosis

Clearly, Next Science has a talented board and management, which includes Lang Walker investment director Bruce Hancox.

Chairman George Savvides is synonymous with health insurer Medibank Private, having been CEO for 14 years (he steered the insurer through its privatization).

Dr Myntti remains as chief technology officer and director and owns around 11.5 percent of the company.

Meanwhile, property investor Lang Walker has the register tied up like pussy's bow with a circa 42 percent stake.

Next Science tells an impressive story, but it needs to justify its market cap with evidence of ongoing revenue and earnings momentum.

We await the upcoming June quarter and full year results with more than a frisson of anticipation.

But we gotta say, Next Science is more than a germ of an idea and holds much promise.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never imbibed Blastx, but like Mother, he swears by a salt gargle to cure all manner of upper respiratory infections.

CSL

CSL says it will take over importing albumin into China to remove its reliance on third parties and work directly with clinicians.

CSL said the transition would not impact the availability of albumin to Chinese patients but would have a one-off financial impact in 2019-'20, with albumin sales expected to be \$340 million to \$370 million, down from more than \$500 million, with a "profit effect in line with historical CSL Behring margins".

The company said that it estimated "a more modest impact on cashflow as [it] continued to collect outstanding receivables from existing distributors ... [and] the cash collection cycle will improve under the new model".

The company said it expected sales of albumin in China to normalize in 2020-'21.

CSL said it had exported albumin to China for more than 30 years and was China's largest supplier of imported human albumin.

CSL fell \$6.96 or 3.2 percent to \$212.50 with 1.5 million shares traded.

NUHEARA

Nuheara says its National Health Service Scotland contract will be managed by the Rochester, Kent, UK-based distributor Puretone (BD: Jun 20, 2019).

Nuheara said it would have a contract term of 36 months with two optional 12-month extensions.

Nuheara was unchanged at 7.3 cents with 1.8 million shares traded.

IMMUTEP

Immutep says the Australian Patent Office has granted it a patent for its immunotherapy candidate eftilagimod alpha or IMP321 and a chemotherapy agent.

Immutep said the patent, titled 'Combined Preparations for the Treatment of Cancer' would protect its intellectual property until December 19, 2034.

The company said that the chemotherapy agent was either a platinum-based anti-neoplastic agent, such as oxaliplatin or carboplatin, or a topoisomerase I inhibitor, such as topotecan.

Immutep was unchanged at 2.6 cents with 4.6 million shares traded.

ALTHEA GROUP

Althea says it has prescribed its first medical marijuana patient in the UK and received a planning permit from Frankston City Council for a cultivation facility.

Althea said the UK would be a "second distribution channel for Althea's current and future Australian manufactured, medicinal cannabis products".

The company said it had been granted the planning permit for a manufacturing and cultivation facility at Skye, near Frankston.

Althea was up seven cents or 8.2 percent to 92 cents with 2.2 million shares traded.

ALCHEMIA

Alchemia says it will acquire Australian Primary Hemp to be a hemp growing company but did not mention medical marijuana or medicinal cannabis.

Alchemia said the Geelong-based Australian Primary Hemp was “one of Australia’s leading hemp producers with a demonstrated execution capability and diversified business operations across the value chain, owning quality production assets in Victoria”.

The company said that Australian Primary Hemp had a network of growers who had procured more than 500 tonnes of hemp grain.

Alchemia said it would change its name to Australian Primary Hemp Limited on settlement, pending conditions.

The company said that the hemp-derived products were sold to wholesale parties who use either the raw hemp grain or processed products, including de-hulled hemp seed, milled powders, and cold pressed hemp oil as ingredients in their own products, such as muesli bars and breakfast cereals, and retail consumers of Australian Primary Hemp branded products including hemp seeds, milled fibre/protein powders and cold pressed hemp oil. Alchemia said it would issue 500,000,000 shares on settlement to the vendors and advisors of Australian Primary Hemp (APH) along with 183,268,743 options to the two founders and advisors of APH exercisable at 30 percent above the share price at re-compliance within three years.

The company said that if the conditions were not fulfilled or waived by March 29, 2020, then either party could terminate the agreement.

Alchemia said it had loaned APH \$600,000 at 6.0 percent per annum for general working capital and it had a number of agreements with Australian Primary Hemp chief executive officer Charles Mann and chief operating officer James Hood regarding the loan term interest, fees and costs.

Alchemia said the proposed acquisition would constitute a change in the nature and scale of activities from a life science business to a hemp growing and production business and ASX approval was required.

The company said it proposed to raise \$6,000,000 and conduct a 20-to-one consolidation. Alchemia said that all current directors other than Cameron Petricevic would resign and be replaced by Mr Mann and Mr Hood.

The company said it hoped to complete the acquisition by Friday September 13, 2019 and begin trading on the ASX on September 18, 2019.

Last year, told the ASX it was not aware of any information it has not announced which, if known, could explain recent trading in its securities after the ASX said the company’s share price rose 187.5 percent from 0.8 cents to 2.3 cents and noted an increase in the trading volume (BD: Oct 17, 2018).

In 2014, Alchemia’s share price fell as much as 86.1 percent from 62 cents to 8.6 cents on news that its 415-patient, phase III trial of HA-irinotecan for metastatic colorectal cancer failed to meet its phase III primary endpoint (BD: Oct 27, 2014).

In 2015, the company’s share price fell a further 51.8 percent from 8.3 cents to four cents on lower than expected revenue for its generic fondaparinux and a dispute with distribution partner Dr Reddy’s (BD: May 29, 2015).

In July 2015, Alchemia sold its versatile assembly on stable templates (VAST) drug discovery platform, for \$100,000 upfront and royalties to Vast Bioscience, a group led by former Queensland chief scientist Prof Peter Andrews who told Biotech Daily at that time that he was one of the patent holders on the VAST platform as well as a founder and former chairman of Alchemia (BD: Jul 3, 2015)

Alchemia was in an extended suspension for a change of activities and last traded at 1.1 cents (BD: Mar 29, 2019).

BOD AUSTRALIA

Bod says it has a distribution agreement with Burleigh Heads Cannabis and Cannabis Doctors Australia for its Medicabilis ECs315 medical marijuana product.

Bod said it would access Burleigh Heads' wholesale network and partner company Cannabis Doctors Australia medicinal cannabis education program network of specialists and physicians.

The company said that Cannabis Doctors Australia had commenced patient approvals for Medicabilis through its clinics and tele-health service.

Bod said it would work with Burleigh Heads to produce non-tetrahydrocannabinol (THC) cannabis prescription products.

Bod was unchanged at 25.5 cents.

TOTAL BRAIN

Morgan Stanley and subsidiaries say they have ceased their substantial shareholding in Total Brain.

Last month, the New York and Sydney-based Morgan Stanley said it became substantial in Total Brain with 52,754,460 shares or 6.78 percent and on May 27, 2019 held 39,309,787 shares or 5.05 percent (BD: May 21, 2019).

Today, Morgan Stanley said it sold 378,869 shares on May 28 for \$11,381 or three cents a share and 1,288,894 shares on June 18, 2019 for \$36,146 or 2.8 cents a share, implying a holding of 37,642,024 shares or 4.8 percent.

Total Brain fell 0.2 cents or 7.7 percent to 2.4 cents.