



# Biotech Daily

Friday September 29, 2023

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.34 percent on Friday September 29, 2023 with the ASX200 up 23.8 points to 7,048.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell and six traded unchanged.

Proteomics was the best, up 21 cents or 23.3 percent to \$1.11, with 1.3 million shares traded. Atomo and Next Science climbed more than eight percent; Emvision and Micro-X were up more than four percent; Opthea and Paradigm improved more than three percent; Amplia, Cyclopharm, Mesoblast, Nova Eye, Orthocell and Pro Medicus rose more than two percent; Medical Developments and Nanosonics were up more than one percent; with Avita and Cochlear up by less than one percent.

Cynata led the falls, down 1.5 cents or 10.3 percent to 13 cents, with 47,376 shares traded. Pharmaxis fell 8.3 percent; 4D Medical and Dimerix lost more than six percent; Alcidion fell 4.35 percent; Immutep, Prescient and Universal Biosensors were down more than three percent; Impedimed, Resmed, SDI and Starpharma shed more than two percent; Antisense, Clinuvel, Genetic Signatures, Neuren, Polynovo, Resonance and Telix were down more than one percent; with CSL down by 0.5 percent.

## [DR BOREHAM'S CRUCIBLE: NEXT SCIENCE](#)

**By TIM BOREHAM**

**ASX Code:** NXS

**Share price:** 43.5 cents

**Shares on issue:** 265,844,079 (post capital raising but not including 10,000,000 Walker Group convertible notes)

**Market cap:** \$115.6 million

**Chief executive officer:** Harry Thomas Hall IV

**Board:** Aileen Stockburger (chair), Mr Hall, Grant Hummel, Dan Spira

**Financials (six months to June 30, 2023):** revenue \$US10.1 million (up 87%), cash receipts \$US9.1 million (up 188%), reported loss \$US8.6 million (\$US7 million loss previously), cash of \$US3.5 million (down 32%\*)

**Major identifiable shareholders:** Lang Walker and associate interests 31.5% (ahead of exercise of convertible notes), Dr Matthew Myntti (founder and chief technology officer) 3.7%, Judith Mitchell 2.4%, Thorney Investments 5.74%.

With apologies to Charles Dickens, it's the best of times and the worst of times for the wound care house as it shapes itself up for a renewed market assault under a new CEO.

On the positive side of the ledger, the company raised \$12 million in a placement and then launched a share purchase plan (SPP) in search of another \$5 million.

Lo and behold, investors stormed the barricades and applied for \$9.6 million in the SPP, lured by the 35 percent discount on offer.

Management decided to accept \$8.5 million, raising a handy \$21.5 million in total.

The Next Science oversubscription is welcome news for the latest new CEO in the sector, Harry Thomas Hall IV (known as I.V.)

Next Science also achieved record revenue in the half year to June 2023.

The bad news? Despite the traction, Next Science shares are trawling record lows.

Mr Hall is unfazed.

"Our assessment is the market dynamics are moving in our favour," he told shareholders.

“There is significant support for our wound care offering that pairs the amazing properties of Blastx [one of the company’s key products] with collagen for diabetic foot ulcers and other chronic wounds.”

Ahead of the raising, Mr Hall said the company had “evolved its strategies to reflect the increasing opportunities” in the business.

“If we are going to take advantage of these opportunities, we need our shareholders to show us their support,” he said.

### **Another Myntti moment**

Next Science was founded in 2012 by Dr Matthew Myntti, who was principal scientist at Medtronic Surgical Technologies.

There, Dr Myntti developed ear, nose and throat and neurological products.

However, Medtronic didn’t share Dr Myntti’s interest in chronic wounds and happily handed over the relevant patents.

Next Science operates in the two key sectors of wound care and surgical infection control.

The former has a total addressable market of \$US3 billion (\$A4.68 billion) and the latter \$US10 billion.

In the US, 8.2 million people need wound healing annually. As for the surgical side, there are 48 million hospital-based procedures a year.

The company says that chronic wounds kill more people annually than cardiac issues, with half of the patients undergoing amputations not surviving another year.

Early on, Dr Myntti won the backing of property developer and life sciences enthusiast Lang Walker, who funded most of the initial backing of \$66 million.

Mr Walker also invested in the wildly successful Neuren Pharmaceuticals, as well as the wildly underperforming Atomo Diagnostics.

Next Science listed in April 2019, raising \$35 million at \$1.00 apiece.

The company is based in Sydney, but its research and development is carried out in Jacksonville, Florida and its business is US centric.

### **Changes at the top**

When it comes to qualifications, I.V.is no drip.

Based in Jacksonville, Mr Hall had been an executive at Johnson & Johnson's orthopaedic device unit DePuy Synthes, responsible for a \$US3.2 billion platform.

He also completed the launch of the first surgical robot developed by DePuy Synthes.

He holds a Bachelor of Science and a Master of Science from South Carolina's Clemson University and a Master of Business Administration from Philadelphia's Pennsylvania State University.

Mr Hall says the Next Science portfolio "provides a unique and differentiated treatment to benefit patients, including those suffering biofilm-based infections".

The company's Australian-based CEO since November 2017, Judith Mitchell retired in July 2023.

Given the company's US emphasis, Ms Mitchell recognised the company's next CEO had to be on the other side of the Pacific.

## **The war on pathogens**

Next Science's products are based on its Xbio platform, which is all about eradicating the bodily bolt holes in which pathogens congregate and quietly multiply - out of reach of antibiotics.

Unlike your usual weapons of war, Next Science's armoury is non-toxic and will only hurt the malevolent bugs.

The base ingredients include sodium citrate and citric acid, which are present in most kitchens.

Xbio targets the biofilms that house 90 percent of all bacteria within lattice structures - described as "slimy tangles of protective fibres linked with metallic bonds".

The process removes the metal ions of the extracellular polymeric substance, which means the bacteria die and the biofilm matrix can't re-form.

It's the same mechanism of action as treating a wound in salt water.

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 Next Science armoury**

Next Science has split its business into surgical sales (for orthopaedics) and wound care (around the durable medical equipment or DME model).

Next Science's current product suite consists of:

- \* Blastx, an antimicrobial wound gel for chronic wounds;
- \* Bactisure, a lavage to remove biofilms and bacteria in open surgery;
- \* Surgx, a sterile gel to reduce surgical site infections;
- \* Torrentx, a wound wash for nurses, emergency departments and home care and Tridentx (the same product), for site preparation ahead of a tissue graft;
- \* Xperience, a surgical irrigation wash to prevent surgical site infections; and
- \* TBH - an over-the-counter acne gel (sold in Priceline chemists)

In 2022, Next Science products were used in 462,000 'episodes of care', 80 percent higher than the previous year.

## **DME status equals reimbursement**

Next Science last October won US accreditation as a durable medical equipment (DME) supplier, thus paving the way for Medicare and Medicaid reimbursement of its key wound care product, Blastx.

The DME structure is crucial because it allows the company to sell Blastx in combination with collagen for chronic wounds such as diabetic foot ulcers and pressure ulcers.

The body's natural healing protein, collagen, is the standard of care for 8.2 million patients and used by around 10,000 podiatrists and wound care clinics in the US.

Next Science says that case studies have shown that augmenting collagen treatment with Blastx can reduce time for closure in a stalled surgical wound or unhealed pressure ulcer from 12 to 16 weeks, to as little as two to four weeks.

Operating under the DME structure means the company doesn't have to tussle with a hospital's bean counters: the doctor writes the prescription; the company ships the product and puts in an insurance claim and is paid 15 days later.

## **Giving DFUs the boot**

Next Science's durable medical equipment status also allows reimbursement of the company's Foot Defender: "the first protective boot built from the ground up, to address diabetic foot ulcers".

The company says Foot Defender alleviates average contact pressure by up to 50 percent "compared to other protective boots on the market".

In the US there are more than two million cases of diabetic foot ulcers annually and - on a grisly note - more than 100,000 amputations.

## **Tackling joint infections**

Since launching Xperience in April 2021, the company has been building a cache of research to prove the product's infection-preventing credentials. The biggest effort is a 7,600-patient pivotal trial using Xperience to treat periprosthetic joint infections (post hip or knee surgeries).

Based at the Ottawa Research Institute, the investigator-led study tests the efficacy of Xperience relative to diluted Betadine up to 90 days post-surgery. The first 88 patients have been enrolled in the first site.

In Canada, authorities approved Xperience for surgical irrigation, but according to former CEO Ms Mitchell said they first had to be convinced the product was "a medical device and not a form of cannabis".

Well, we are talking about joint healing ...

## **Finances and performance**

Next Science sales are growing strongly: with half-year revenue up 87 percent to \$US10.1 million.

One reason is management's emphasis on direct sales, which increased 226 percent, to \$US7.2 million. Faster and more profitable, direct sales now account for 72 percent of the company's sales, compared with 42 percent a year ago. Wound care sales (collagen/Blastx) climbed six-fold, while Xperience (surgical) sales rose 65 percent.

Next Science also struck its first group purchasing order (GPO) contract with Healthtrust, enabling access to 1,600 US hospitals.

The company reported a half-year deficit of just under \$US8.6 million compared with a \$US7 million shortfall previously.

Mr Hall said the company planned to be profitable in 2024.

Meanwhile, the \$12 million placement was struck at 42 cents per share. Mr Hall said \$2.9 million of the funds raised would be used to support the group purchasing order contract - with an expected payback of five to 10 times its investment.

Up to \$4 million will be earmarked for expanding the durable medical equipment business from private clinics to high-volume wound care centres, long-term acute care centres and skilled nursing facilities.

In an accompanying measure, the Walker Group has agreed to convert \$10 million of convertible notes into shares.

Over the last 12 months, Next Science peaked at 83 cents in mid-February 2023 and currently are trawling their lows. The stock hit an all-time high of \$1.97 in late May 2021.

Meanwhile, management has guided to revenue of between \$US16 million and \$US19 million for the current (second) half. Most pertinently, the company expects to be earnings before interest, taxation, depreciation and amortization (Ebitda) and cash flow positive and self-sustaining in 2024.

No doubt out of an abundance of caution, broker Wilsons plugs in a \$7.3 million Ebitda loss in 2024, abating to a \$2.7 million deficit in 2025.

### **Dr Boreham's diagnosis:**

Mr Hall says: "We have had a really strong six months which sets us up for the rest of the year. We are addressing a market with significant unmet needs, presenting significant commercial tailwinds for the business over the short and long term."

One potential headwind is that Next Science hasn't escaped the attention of rival wound care companies, who are keen to hose down the company's prospects. In the broad global wound care sector - and we're talking broad - the biggest players include Abbvie, 3M Co and Becton Dickinson and Co.

On the ASX, Next Science "competes" - for investor attention at least - with Polynovo, Aroa and Avita. Polynovo shares surged this week after a crowd-pleasing sales update.

Ahead of her departure, Ms Mitchell likened initial revenues from the durable medical equipment structure to a modest creek: "We are not quite a river, but a tributary."

Furthering the alluvial analogy, the company's sales momentum should have a cascading effect. While the company's current share performance is disappointing, investors ultimately should be awash with money as the company paddles hard to achieve its stated mission of "healing people and saving lives".

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. When he complains about his various war wounds to family and friends the response is "cry me a river".***

## [VALE DR WAYNE FINLAYSON 12.1.1956 – 26.9.2023](#)

Servatus says its executive director and chief executive officer Dr Wayne Finlayson died last Tuesday, September 26, 2023.

Servatus said the company was “very saddened to announce the passing of ... Dr Wayne Finlayson [and] the board extends its deepest sympathies and condolences to Wayne’s family, friends and colleagues”.

The company said that Dr Finlayson was “a well-respected and visionary scientist, who will leave a positive, resounding mark on the development of science and new medicines, both in Australia and globally”.

Servatus said that Dr Finlayson had been an executive director of the Nasdaq-listed Infergene and in 1990, founded Progen Pharmaceuticals and was its managing-director and chief executive officer; and later was a consultant and held various contract positions. According to his LinkedIn page, Dr Finlayson had been a director of the Coolum Beach, Queensland-based Australian Biotherapeutics since September 2018 and a director of Advanced Biotherapeutics Pty Ltd since July 2019.

LinkedIn said that Dr Finlayson was a director of agricultural company Terragen Biotech from May 2015 until November 2018 which later listed on the ASX; and was the general-manager of the Gold Coast, Queensland-based IMP Biotech from November 2010 until March 2013, developing and manufacturing agricultural biotechnology products.

Servatus said that Dr Finlayson held a Bachelor of Science and a Doctor of Philosophy in organic chemistry from Melbourne’s La Trobe University; and was a post-doctoral research fellow at the University of California, Berkeley.

The company said that with Dr Wolf Hanisch, Dr Finlayson founded Servatus in 2012 and established operations in 2013.

Servatus said that the two built a business with multiple operational areas, including “drug development, manufacturing and consumer products, leveraging their cutting-edge discoveries in the areas of live microbial bio-therapeutics and engineered proteins”.

The company said that Dr Finlayson would be sorely missed.

Servatus executive director and chief financial officer Mark Williams said: “We are all deeply saddened by Wayne’s sudden passing and offer our sincerest condolences to all those who knew him”.

“Servatus is the successful company it is today with an exciting future because of Wayne,” Mr Williams said.

“Wayne’s vision for Servatus will continue to inspire us as we carry forward his passion for excellence in bringing through new medicines and consumer products to solve today’s health challenges,” Mr Williams said.

Servatus is a public unlisted company.

## [RECCE PHARMACEUTICALS](#)

Recce says its entitlement offer has raised about \$2.7 million of a hoped-for \$3 million, at 44 cents a share, taking the total raised with the placement to \$10.7 million.

Earlier this month, Recce said it had commitments for an \$8 million placement at 44 cents a share, and hoped a one-for-26, non-renounceable entitlement would raise a further \$3 million (BD: Sep 11, 2023).

Today, the company said chief executive officer James Graham took-up his full \$102,700 entitlement, with other directors intending to take up about \$110,000 of the shortfall subject to shareholder approval at its upcoming annual general meeting.

Recce did not say whether it would place the remaining shortfall.

Recce was up four cents or nine percent to 48.5 cents.



## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarkerd diabetic kidney disease test will be reimbursed in the US at \$US391 (\$A606) per test, and the Australian regulator has refused its listing.

Proteomics said the US Centers for Medicare and Medicaid Services had listed its Promarkerd predictive blood test for national reimbursement, and the test would be distributed in the US by Sonic Healthcare.

In May, the company said it had an exclusive licence with the Austin, Texas-based Sonic Healthcare USA to distribute Promarkerd in the US (BD: May 10, 2023).

Proteomics said the Australian Therapeutic Goods Administration had decided not to include its Promarkerd test on the Australian Register of Therapeutic Goods “due primarily to [a] change of manufacturer”.

The company said the “TGA indicated that the submitted information did not contain adequate detail to enable the registration of the product that is intended for sale, and primarily that the clinical and analytical data needed to be predominately collected on the currently manufactured version of the test [the version manufactured in Europe]”.

Last year, Proteomics said it had filed a submission with the TGA to include Promarkerd on the Australian Register of Therapeutic Goods (BD: Jun 2, 2022).

At that time, Proteomics said it had requested Australian registration for its immunoassay version of the Promarkerd test which was originally manufactured in Australia, and had since been transferred to an ISO 13485 manufacturer in Europe.

Today, Proteomics said the TGA decision temporarily impacted its ability to sell its test in Australia but did not affect its activities in the US or Europe.

The company said it would consider its alternatives to address the items that the TGA raised.

Proteomics said that about 32 million adults had diabetes in the US, 61 million in Europe and 1.5 million in Australia.

Proteomics managing director Dr Richard Lipscombe said “the company's immediate focus is firmly on the major markets of the US and Europe”.

“The [Centers for Medicare and Medicaid Services] pricing of US\$390 per test in the US is testament to the clear value the Promarkerd test can deliver to the US health system, whilst our existing [Conformité Européenne] mark registration underpins our plans to access the European market,” Dr Lipscombe said.

Proteomics was up 21 cents or 23.3 percent to \$1.11 with 1.3 million shares traded.

## RESPIRI

Respiri says subsidiary Access has two additional US remote patient and therapeutic monitoring contracts, with recurring revenue of up-to \$US500,000 (\$A774,000).

Last month, Respiri said Access had remote patient monitoring contracts with US customers, worth about \$900,000 in annualized revenue (BD Aug 29, 2023).

Today, the company said that the first contract with the Tuscaloosa, Alabama’s Taylorville Family Medicine was with an initial 500 patients and worth up-to \$500,000 in recurring annual revenue.

Respiri said the second remote patient monitoring contract was with the O’ahu, Hawaii-based Kahuka Medical Center but that it had not finalized target patient numbers and could not determine the value the contract.

The company said with the Alabama and Hawaii contracts extended its US footprint and doubled its recurring revenue opportunity to more than \$US1.1 million.

Respiri was up 0.1 cents or three percent to 3.4 cents.

## BIONOMICS

Bionomics climbed 243.8 percent on the Nasdaq on news that its 212-patient trial of BNC210 had met its primary endpoint for post-traumatic stress disorder (PTSD). In August, Bionomics left the ASX to focus on its Nasdaq listing and last traded on the ASX at one cent (BD: Jul 25, Aug 28, 2023).

The company was attempting to develop drugs including BNC105 for cancer and BNC210 for anxiety and post-traumatic stress disorder but trials had not shown significant benefit (BD: Aug 3, 2011; Mar 19, 2014; Oct 2, 2018; Dec 19, 2022; Mar 9, 2023).

Last night in the US, Bionomics said the 'Attune' phase IIb trial "met its primary endpoint showing BNC210 treatment led to a statistically significant reduction in total PTSD symptom severity at 12 weeks ... [and] statistically significant secondary endpoints showed improvements in depressive symptoms and sleep".

Bionomics said BNC210 was "well-tolerated with a safety profile supporting chronic administration" with the most common adverse events headache, nausea and fatigue, consistent with previous BNC210 studies and there was a hepatic enzyme increase in 14 BNC210 patients (13.3%) compared to two placebo patients (0.19%), which in most cases were resolved without drug discontinuation.

The company said that the double-blind, placebo-controlled trial was conducted at 34 sites in the US and the UK, with the patients randomized to receive either twice daily 900mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks.

Bionomics said the trial met its primary endpoint of change in clinician-administered PTSD scale for the America Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders Fifth edition (DSM-5) (CAPS-5) total symptom severity score from baseline to week-12 ( $p = 0.048$ ), with a statistically significant change in CAPS-5 score observed at week-4 ( $p = 0.015$ ) and at week-8 ( $p = 0.014$ ).

The company said treatment with BNC210 showed statistically significant improvement in clinician-administered and patient self-reporting in two of the secondary endpoints.

Bionomics said BNC210 led to significant improvements at week-12 in depressive symptoms ( $p = 0.040$ ) and sleep ( $p = 0.041$ ) as measured by the Montgomery-Åsberg depression rating scale and insomnia severity index, respectively.

The company said that BNC210 showed signals and trends across visits in the other secondary endpoints.

Bionomics chief executive officer Dr Spyros Papapetropoulos said the company was "excited about the results of the Attune trial that delivered a positive dataset with treatment effects considerably higher than currently approved therapies".

"We believe these results will enable FDA discussions for the registrational path of BNC210 in PTSD," Dr Papapetropoulos said.

"These results, together with the results from earlier this year in social anxiety disorder, and the recently completed phase III-enabling end-of-phase II meeting with the FDA on social anxiety disorder, positions BNC210 as a compelling late-stage experimental therapeutic for multiple prevalent neuropsychiatric diseases with high unmet need," Dr Papapetropoulos said.

Last year, Bionomics said BNC210 did not meet the primary endpoints in its 151-patient, phase II study for social anxiety disorder but "exhibited trends towards improvements" (BD: Dec 19, 2022).

At the end of 2021, Bionomics said it raised about \$US20 million in an initial public offering of 1,622,000 ADS at \$US12.33 per ADS, on the Nasdaq (BD: Jan 16, 2022).

On the Nasdaq last night, Bionomics climbed \$US2.3899 or 243.84 percent to \$US3.370 (\$A5.218) with 125.15 million shares traded.

## IMRICOR

Imricor says it has drawn \$299,100 as a first tranche from its \$30 million security subscription facility with Luxembourg's Gem Global Yield LLC.

In July, Imricor said Gem Global would provide a \$30 million, three-year draw-down equity facility, with funds to be drawn in tranches for Chess depository interests (CDIs) with Gem Global paying the higher of 90 percent of the 15-day average closing bid price, or a fixed floor price nominated by Imricor in its notice (BD Jul 6, 7, 2023).

Today, the company said it would issue Gem Global 533,333 CDIs at 56.08 cents each and would also issue a further 74,983 fee CDIs to Gem Global at 59.83 cents each to settle the \$44,865 partial payment due in settlement of the facility fee.

The company said the funds would be used for sales and marketing activities, product development, clinical trials, regulatory compliance and other working capital needs.

Imricor fell five cents or nine percent to 50.5 cents.

## BIOTRON

Biotron has told the ASX that it is not aware of any information it has not announced, which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 118.75 percent from a low of 3.2 cents to a high of 7.0 cents, today, and noted a "significant increase" in the trading volume.

Biotron closed up 1.7 cents or 33.3 percent to 6.8 cents with 32.9 million shares traded.

## ALLEGRA ORTHOPAEDICS

Allegra Orthopaedics says its annual general meeting will vote to change its name to Allegra Medical Technologies, a special resolution requiring 75 percent votes.

Allegra said the change "more accurately reflects [its] proposed future operations" and would take effect when the Australian Securities Investment Commission approved it.

The company said shareholders would vote to adopt the remuneration report, re-elect director Peter Kazacos, approve its additional 10 percent placement capacity and approve the issue of up-to 10,000,000 shares under its employee incentive plan.

The meeting will be held online on November 1, 2023 at 9am (AEDT) at:

[https://us02web.zoom.us/webinar/register/WN\\_Gz4b\\_Qv3QHKXWiCZEKnplw#/registration](https://us02web.zoom.us/webinar/register/WN_Gz4b_Qv3QHKXWiCZEKnplw#/registration).

Allegra was untraded at 6.1 cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says director Andrew Likierman will resign in November, with chair Willem Blijdorp stepping down to non-executive director, from January 1, 2024.

Clinuvel said Mr Likierman had been with the company since April 2022 and was resigning to "focus on his various academic and consultancy activities".

The company said Mr Blijdorp had announced he would step down as chair pending his re-election as a non-executive director at its November annual general meeting.

Clinuvel said it had begun a review process, after which a new chair would be announced.

Clinuvel fell 19 cents or 1.3 percent to \$14.71 with 114,465 shares traded.