Biotech Daily

Friday March 22, 2024

Daily news on ASX-listed biotechnology companies

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*** DR BOREHAM'S CRUCIBLE: HYDRIX**

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*** DARLA HUTTON REPLACES AROA DIRECTOR STEVEN ENGLE**

*** NEUROTECH APPOINTS ALESSANDRA GAUVIN CO CO-SEC**

MARKET REPORT

The Australian stock market fell 0.15 percent on Friday March 22, 2024, with the ASX200 down 11.4 points to 7,770.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 19 fell and four traded unchanged. All three Big Caps were up.

Yesterday's 6.7 percent worst, Actinogen, was today's best, up 0.4 cents or 14.3 percent to 3.2 cents, with 4.0 million shares traded. Resonance rose 11.1 percent; Opthea was up 9.6 percent; Cynata climbed 8.6 percent; Nova Eye was up 7.3 percent; Compumedics and Orthocell were up more than three percent; Avita, Immutep, Next Science and Percheron (Antisense) were up more than two percent; CSL, Cyclopharm, Genetic Signatures, Mesoblast and Resmed rose more than one percent; with Cochlear, Emvision, Proteomics and SDI up by less than one percent.

Dimerix led the falls, down two cents or 5.9 percent to 32 cents, with 5.6 million shares traded; followed by Impedimed and Telix down more than five percent. Imugene, Paradigm, Syntara (Pharmaxis) and Universal Biosensors fell more than four percent; 4D Medical, Atomo, Clarity, Polynovo and Prescient lost more than three percent; Clinuvel and Neuren shed more than two percent; Curvebeam, Medical Developments and Nanosonics were down more than one percent; with Pro Medicus and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: HYDRIX

By TIM BOREHAM

ASX code: HYD

Share price: 1.8 cents; **Shares on issue:** 254,218,847; **Market cap:** $4.6 million

Financials (December half 2023): revenue $5.97 million (down 17.5%), loss of $3.82 million ($1.96 million deficit previously), cash of $847,277 (down 73.5%)*****

***** After balance date the company entered a $1 million loan agreement with directors Paul Lewis and Julie King, which is undrawn.

Executive chair: Gavin Coote

Board: Mr Coote, Julie King, Paul Lewis, Paul Wright

Identifiable major shareholders: John W King Nominees 10.3%, Pusen Medical Tech Australia 4.72%, Invia Custodian (the Paj account) 4.23%, Invia Custodian (the Paj Lewis super fund) 3.26%, Roger Allen and Maggie Gray 2.05%, Indigenous Capital 2.05%

The reception area of Hydrix's south eastern Melbourne HQ proudly displays a 'museum' of gadgets the medical device company has developed.

These include Memphasys' Felix sperm-separation tool, Universal Biosensor's multi-layer test strip handheld device, Analytica Medical's Pericoach pelvic floor exerciser and Sunshine Heart's C-Pulse implantable heart-assist device.

There's even a Bluetooth-enabled controller for Cochlear implants.

If space allowed the company could also have showcased Nanosonics' Trophon disinfectors, LBT Innovation's culture plate automation devices and Micro-X's portable x-ray device.

Deeper within the bowels of the building, an army of 40 scientists and engineers are beavering away on an array of hush-hush, early-stage projects.

Given their potential to revolutionise healthcare - especially cardiac care - they won't remain anonymous forever.

Executive chair Gavin Coote says Hydrix's remit is to design class-three medical devices that are vital for sustaining life.

Put another way, if they malfunction, they "could have severe consequences, including loss of life".

He says: “We help clients to bring world first technologies to market - the hard stuff that hasn’t been done before.”

Hydrix endured some lean years during the pandemic, with the company’s shares losing three-quarters of their value over the last four years.

But Mr Coote says the company is enjoying a new lease of life after honing its strategy to focus on the cardiovascular sector.

Hyd-history

Hydrix began its listed life as Panorama Synergy, a tech tearaway that soared 4,000 percent in 2013 on the back of its micro-electromagnetic (MEMS) technologies.

In September 2017, the company acquired the private Hydrix Services, builder of the aforementioned medical devices as well as industrial and defence related systems.

Panorama changed its name to Hydrix - and its code from PSY to HYD - in November 2018.

A corporate wheeler and dealer, Mr Coote spent 12 years in the US and then returned to his native Australia, where he executed small business turnarounds for a Melbourne-based family office. Mr Coote became a Hydrix director in 2017 and then executive chair in January 2020.

While Hydrix Services remains the core revenue business for the business, Hydrix has also created Hydrix Medical to distribute disruptive cardiac devices.

Its third arm, Hydrix Ventures, invests in high-potential medical technology ventures for which the company has developed products.

Hydrix Medical

The medical division has three market-ready products with distribution rights:

In 2022-’23, the company signed agreements with two companies – France’s Implicity and the ASX-listed Echo IQ - pertaining to cardiovascular health.

The Implicity product is an artificial intelligence (A.I.)-based remote patient monitoring and cardiac data management platform, enabling cardiology practices to keep tabs on devices including pacemakers, defibrillators, loop recorders and cardiac resynchronisers.

Because heart device makers such as Abbott and Medtronic have their own platforms, managing patients across different device brands is complex.

Unlike old Renaults, Implicity actually works.

Echo IQ's internet cloud-based Echosolv platform analyzes electro-cardiogram measurements, to improve the detection and diagnosis of structural heart diseases including aortic stenosis.

On a deeply pragmatic note, it helps clinicians to avoid litigation because of missed diagnoses.

The third product is Avertix (formerly Angel Medical) Guardian, the world's only real-time, implanted device to warn the wearer of an imminent heart attack (see below).

Hydrix Medical also plans to distribute a new outpatient ambulatory cardiac wearable patch device, which won local Therapeutic Goods Administration (TGA) approval last month.

While the medical division is in its infancy, management expects it to generate revenue within the next six to 12 months.

Keepin' it real

As a former systems engineering manager at Cochlear, Hydrix Services head Michael Trieu knows that novel devices will remain such if they are difficult to use.

For example, battery changing needs to be made easy for an 85-year-old user.

"It may be a great tech but if users can't use it adoption may never take off," he says. "Our … 'human factors' engineering and user experience design are capabilities we are very proud of."

While the services arm charges on an hourly fee basis, jobs are based on 'adaptive scoping'.

In other words, a project might last for five years or more so the company can't provide an up-front quote. Instead, the projects are costed over their various stages.

Hydrix has some likeness to the well-known, unlisted device developer Planet Innovation. A key difference is that Planet Innovation does contract manufacturing and does not focus on class-three devices.

Nothing Ventured, nothing gained …

Hydrix Ventures investments are:

***** 14 percent in Gyder Surgical (a surgical navigation tool for hip replacement surgery);
***** An approximate five percent stake in Cyban (non-invasive brain tissue continuous blood oxygen monitor); and
***** Avertix Guardian.

Mr Coote expects Cyban and Gyder to obtain US Food and Drug Administration approval within the next 12 months. Both companies also aspire to list on the ASX.

“We want to invest in products that can be commercialized in less than five years and we are on track with that,” he says.

Mr Coote says the division aims to help investee companies avoid the “valley of death” of a lack of seed funding.

“We are prepared to put our money where our mouths are and invest in them but we are also very selective about what we invest in,” he says.

“We don’t tend to do follow-on rounds, so there is a natural dilution. But we acquire at attractive valuations and are well placed to achieve returns of five times [on our investment] or more.”

Avertix Medical Guardian

Avertix Medical Guardian is the world’s only real-time, implanted device to warn the wearer of an imminent heart attack.

Like a pacemaker, the Guardian detects changes in the heart’s electrical conductivity. These patients have had a coronary episode already, or have co-morbidities such as diabetes or dodgy kidneys.

Mr Coote says the heart device can detect a pending episode 40 percent better than patient-recognized symptoms alone. Almost half of attacks have no discernible symptoms - as shown by the premature ‘dismissal’ of cricket legend Shane Warne.

In March 2020, Hydrix acquired the exclusive Asia Pacific rights to distribute Guardian, owned by New Jersey’s Avertix Medical (previously Angel Medical Systems).

Hydrix built the upgrades under a multi-million-dollar service agreement.

Guardian has been approved by the US FDA and also can be sold in other jurisdictions including Singapore, Malaysia, and Thailand.

In the US, a 1,000-patient trial was carried out to support the application, while 200 implants have been done commercially in the last 18 months.

Eight implants have been done in the Lion City (Singapore) but lack of reimbursement is a hurdle. The devices sell in the US for about $US10,000 and then there’s $US10,000 to $US15,000 for the surgeon’s toil and hospital costs.

Last year the TGA knocked back the Hydrix Guardian device, saying it was not “convinced that the patient benefits sufficiently outweigh potential risks” - despite the FDA’s imprimatur.

Mr Coote says the TGAs stance is “incongruous with the rest of the world” but adds: “it is their jurisdiction and they can set the bar wherever they like.”

Hydrix has also invested $US1 million for a 4.6 percent stake in Avertix Medical, paid in a mix of cash and services.

In October, Avertix canned Nasdaq plans and will stay private for the near term.

What’s new?

The Hydrix HQ houses about a dozen projects being undertaken for fee-paying clients. While some of them look like improvised school projects, others are more advanced.

The Swedish-based Scandinavian Real Heart has contracted Hydrix to develop the control systems for a four-chamber artificial heart - a world first.

In December last year, Hydrix was also awarded a contract with a US based cardiac company to develop a next-gen version of their existing product.

Confidential projects include:

***** a connected, wearable medical device for a large European-based company that will “disrupt the market”;
***** hardware and software design for a unique robot-assisted surgical application (for a US start-up); and
***** a technology for controlling and driving a new type of intra-aortic ballon pump (for a European company)

Beyond cardiac medical technology, Hydrix is also involved in developing devices for orthopaedics, point-of-care diagnostics, drug delivery and traumatic brain injury monitoring.

Finances and performance

Hydrix’s December half results were off the pace because of wages and inflation pressure and cautious customers.

Revenue shrunk eight percent to $5.9 million and the loss expanded to $3.8 million from $1.96 million previously.

But Hydrix Services had an “increased level of customer activity, coupled with pricing and operational cost adjustments.”

The company has guided to revenue of $12 million to $12.5 million and cash breakeven status for the current year.

Overall, the company cites a record $300 million potential revenue pipeline across 200 “opportunities”, with “active discussions” accounting for $100 million.

More tangibly, the company expects $30 million of revenue from 14 clients already signed up.

“Two of Hydrix Ventures portfolio assets are making significant progress towards obtaining regulatory approvals, which could significantly increase net asset values in the 2024-’25 year,” management chirps.

At December’s end Hydrix had slender cash of $847,000.

Post balance date, kindly directors Paul Lewis and Julie King agreed to lend $500,000 each, at a 10-11 percent interest rate.

There’s also an available $1.1 million trade debt facility.

In late 2019, the company carried out a one-for-10 share consolidation.

Accounting for this, Hydrix shares have traded between 27 cents in November 2018 and its current lows.

Dr Boreham’s diagnosis:

Mr Coote says: “We are not just a ‘me-too’ design and engineering firm. Our track record and capability in technologies are globally recognised.”

He concurs that investors view Hydrix needing more funds - with the shares marked down accordingly.

It’s some discount given the three ventures investments have a net value of $5.1 million - more than the company’s $4.3 million market cap.

But Mr Coote promises a “tsunami” of revenue is imminent: “We are generating a sales pipeline that is larger than at any time in the company’s history.”

Meanwhile cardiovascular disease is the leading cause of death in the world – accounting for about one-third of deaths.

“It is a large addressable market and it is not going away any time soon,” he says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He hopes a tsunami of revenue will head his way but suspects it will be little more than a trickle, and hopes he’s not going away any time soon.

CLARITY PHARMACEUTICALS

Clarity says it has begun dosing the six-patient fourth and final cohort at two cycles of 12 (GBq) copper-67 Sar-bis-PSMA in its phase I/IIa treatment trial for prostate cancer.
Last week, Clarity said it had dosed the third cohort at one cycle of 12 giga-becquerels (GBq) in its up-to 44-patient phase I/IIa trial of copper-67 sarcophagine (Sar)-bis-prostate specific membrane antigen (PSMA) for prostate cancer (BD: Mar 15, 2024).
Today, the company said the final cohort would enrol three participants and administer two cycles of copper-67 Sar-bis-PSMA at the highest dose of 12 (GBq), with the potential to receive two additional doses, with three more pending safety committee approval.
Clarity said 15 patients had been treated at three different single-cycle dose levels of 4GBq, 8GBq and 12GBq, with no dose-limiting toxicities and a favorable safety profile reported.
The company said the final cohort would be followed by a 14-patient dose expansion phase of the trial “pending safety evaluation”.
Clarity said recruitment was ongoing at clinical sites in the US with all three patients in the first part of cohort four recruited and undergoing screening activities.
Clarity executive chair Dr Alan Taylor said that the "high pace of recruitment into the Secure trial reflects the high unmet need in the prostate cancer therapy space as well as clinicians’ excitement about our Sar-bis-PSMA product”.
“Results from the first three cohorts and the data from two patients who received additional doses of 67-Cu-Sar-bis-PSMA under the US expanded access program are outstanding,” Dr Taylor said.
“These two patients from the [program] received one or three additional doses of 67-Cu-Sar-bis-PSMA at 8GBq or 4GBq, respectively,” Dr Taylor said.
“They had failed multiple lines of therapy prior to being treated with 67-Cu-Sar-bis-PSMA and have had dramatic responses, 94 percent reduction in [prostate specific antigen] levels in one patient, and reduction to undetectable … levels in another, with only a few mild or moderate side effects from the treatment and excellent quality of life,” Dr Taylor said.
“This demonstrates great efficacy and a favorable safety profile of our product with the multi-dosing treatment,” Dr Taylor said.
“The data to date continues to reinforce our strong belief that we have a best-in-class radio-pharmaceutical therapy, with dramatic responses obtained in patients that had failed multiple treatments, including other radio-pharmaceutical therapies, as well as all other standard-of-care therapies and products in development,” Dr Taylor said.
“Coupled with the favorable safety profile, we believe we are well on our way to fulfilling our promise of improving treatment outcomes for people with cancer,” Dr Taylor said.
Clarity fell 10 cents or 3.4 percent to $2.85 with 705,257 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has raised $2.5 million at 15.0 cents a Chess depository interest (CDI) in a placement, with a $10 million one-for-3.46 rights offer to follow.
Earlier this month, Universal Biosensors said it hoped to raise $12.5 million through a $10 million rights offer and a $2.5 million placement (BD: Mar 1, 2024).
Today, the company said existing shareholder Viburnum Funds Pty Ltd was expected to fully-underwrite the rights offer, with all of its directors and its chief executive officer who were eligible shareholders expected to participate in the offer.
Universal Biosensors fell one cent or 4.55 percent to 21 cents.

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel says it expects revenue for the year to March 31, 2024 to be $NZ1.73 billion ($A1.59 billion), with net profit after tax between $NZ260 million ($A239.7 million) to $NZ265 million ($A244.3 million).

Fisher & Paykel said that it had updated its previous forecast of $NZ1.7 billion in revenue for the year to March 31, 2024, and between $250 million and $260 million in net profit after tax based on a change in the US to NZ exchange rates from 58 NZ cents to the $US1.00 to 61 NZ cents to $US1.00.

The company said it expected that higher interest rates would have an adverse impact on the valuation of its Karaka, Auckland property and it would therefore recognize any de-valuation as a non-cash accounting adjustment in its year to March 31, 2024 accounts, which would impact its reported profit for the year.

Fisher & Paykel was up $1.73 or 7.7 percent to $24.18 with 842,583 shares traded.

IMEX HEALTH SERVICES

Imex says it has renewed two Enterprise software contracts with Colsubsido and Clinica Medical, for a combined $1.0 million in yearly recurring revenue.

In 2022, Imex said it had a three-year expansion of its radiology services contract with the Bogota, Colombia-based hospital group Colsubsidio, which was expected to increase annual recurring revenue to about $7.2 million (BD: Jul 12, 2022).

Today, the company said its three-year contract with the Bogota, Colombia-based Colsubsido, or Caja Colombiana de Subsidio Familiar, would contribute $575,000 in annual recurring revenue, for a total contract value of about $1.725 million.

Imex said its two-year contract with the Los Angeles-based Clinica Medical would contribute $425,000 in annual recurring revenue, for a total contract value of $950,000.

The company said the Colsubsidio contract was renewed with improved terms and pricing and that the renewed Clinica Medical contract had improved pricing and a larger scope of services.

Imex chief executive officer Dr German Arango said the company was “very pleased with these two important renewals which show our strength in providing cutting edge medical imaging technology over many years”.

“This a testament to the sustainability of our [annualized recurring revenue],” Dr Arango said.

Imex was up 1.5 cents or 3.0 percent to 51.5 cents.

CANN GROUP

Cann says Sativite Pty Ltd has paid the final $1.9 million from the sale of its ‘Southern’ marijuana cultivation and manufacturing factory and related assets.

In 2022, Cann said Brisbane’s Sativite would buy its Melbourne ‘Southern’ growing and manufacturing facility for a total $5,480,000 (BD: Jan 21, 2023).

Today, the company said Sativite was granted a licence from the Office of Drug Control to operate the facility, which was the final condition of the sale agreement, triggering the $1.9 million payment.

Cann said it had “consolidated” its cultivation and manufacturing operations at its Mildura plant, and would continue its research and development work at its Bundoora facility.

Cann was in a suspension and last traded at 6.2 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has developed a comprehensive hereditary risk assessment test for cancers, cardio-vascular disease and type 2 diabetes.
Genetic Technologies said it had the “world’s most advanced comprehensive risk test revolutionizing personalized healthcare”.
The company said its saliva test included more than “200 high penetrant genes” that would test hereditary disease risk, building on its current multi-test used for common cancers, cardio-vascular disease and type 2 diabetes.
Genetic Technologies said the non-invasive sample test would identify patients “at risk of serious disease in nearly 70 percent of annual mortalities and morbidities”.
Genetic Technologies fell half a cent or 3.6 percent to 13.5 cents.

AROVELLA THERAPEUTICS

Arovella has requested a trading halt “pending the release of an announcement regarding a capital raise and subsequent issue of securities”.
Trading will resume on March 26, 2024, or on an earlier announcement.
Arovella last traded at 13 cents.

HEXIMA

Hexima says it has received $695,171 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Hexima said the rebate related to research and development expenditure for the year to June 30, 2023.
Hexima was untraded at 1.3 cents.

DIMERIX

Peter Meurs and Skiptan Pty Ltd say they have increased and been diluted in Dimerix from 69,375,992 shares (15.09%) to 75,304,506 shares (13.80%).
The Melbourne-based Mr Meurs and Skiptan as trustee for Meurs Family Trust said they exercised 5,928,514 options on March 20, 2024 for $746,993, or 12.6 cents each, and were diluted on the same date by an “institutional placement”.
Earlier that week, Dimerix said it had “commitments” for a $20 million placement at 30 cents a share to complete its phase III trial of DMX-200 for focal segmental glomerulosclerosis (BD: Mar 12, 2024).
Dimerix fell two cents or 5.9 percent to 32 cents with 5.6 million shares traded.

AROA BIOSURGERY

Aroa says it has appointed Darla Hutton as an independent non-executive director, effective from March 22, with director Steven Engle retiring on March 31, 2024.
Aroa said Ms Hutton was currently San Francisco’s Intuitive Surgical head of Asia commercial operations and marketing and previously worked for Boston Scientific and Glaxosmithkline, and according to her Linkedin profile, Ms Hutton held a Bachelor of Science and Master of Science from Florida’s University of Tampa.
Aroa chair Jim McLean thanked Mr Engle for his “significant contribution … over the past nine years”.
Aroa was up 3.5 cents or 6.5 percent to 57 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Alessandra Gauvin joint company secretary alongside existing company secretary Erlyn Dawson.

Neurotech said Ms Gauvin had more than six years of corporate governance experience in mining, technology, biotechnology and industrial.

According to her Linkedin profile, Ms Gauvin holds a Bachelor of Commerce from Perth's University of Western Australia.

Neurotech fell one cent or 9.1 percent to 10 cents with 3.7 million shares traded.