Biotech Daily

Friday October 25, 2024

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: CLARITY UP 7%; MICRO-X DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: CYCLOPHARM**

*** RESMED Q1 RECORD REVENUE UP 11% TO $1.85b, PROFIT UP 35% TO $491m**

*** ORTHOCELL $17m PLACEMENT**

*** BTC: AUSTRALIA APPROVES INFUSION PUMPS**

*** NEURIZON (PHARMAUST) PHASE I MONEPANTEL MND RESULTS**

*** AROVELLA RECEIVES $3m FEDERAL R&D TAX INCENTIVE**

*** ORTHOCELL $1.3m M-D, CFO RIGHTS AGM**

*** RADIOPHARM 107m BOARD OPTIONS AGM**

*** SYNTARA 2.8m M-D PERFORMANCE RIGHTS AGM**

*** INOVIQ 1m DIRECTOR OPTIONS AGM**

*** JENCAY TAKES 5.4% OF MEDICAL DEVELOPMENTS**

*** MTP CONNECT: 3 COMPANIES JOIN A.I. MEDTECH ACCELERATOR**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Friday October 25, 2024, with the ASX200 up 5.0 points to 8,211.3 points. Fourteen of the Biotech Daily Top 40 companies were up, 20 fell and six traded unchanged. All three Big Caps were up.

Clarity was the best, up 46 cents or 6.9 percent to $7.16, with 1.8 million shares traded. Resmed climbed 5.9 percent; Atomo was up 4.55 percent; Compumedics and Universal Biosensors were up more than three percent; Clinuvel, Dimerix, Paradigm, Percheron and Syntara rose more than two percent; Cochlear, Medadvisor and Polynovo were up more than one percent; with Aroa, CSL, Nanosonics and Neuren up by less than one percent.

Micro-X led the falls, down 0.5 cents or 6.7 percent to seven cents, with 423,390 shares traded; followed by Genetic Signatures, down four cents or 6.2 percent to 60.5 cents with 62,213 shares traded. Cynata and Proteomics fell four percent or more; Alcidion, Amplia, Curvebeam, Medical Developments and Resonance lost more than three percent; Cyclopharm and Telix shed more than two percent; Avita, Mesoblast, Opthea, Prescient and Starpharma were down one percent or more; with Emvision, Orthocell, Pro Medicus and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: CYCLOPHARM

By TIM BOREHAM

ASX code: CYC

Share price: $1.515; **Shares on issue:** 111,136,850; **Market cap:** $168.4 million

Chief executive officer: James McBrayer

Board: David Heaney (chair), Mr McBrayer, Kevin Barrow, Dianne Argus, Prof Gregory King, John Wigglesworth

Financials (half year to June 30, 2024): revenue $13.3 million (down 19%), sales revenue $12.27 million (down 17%), loss of $7.51 million ($2.9 million deficit previously), cash balance $27.6 million (up 52.5%)

Identifiable major shareholders: Anglo Australian Christian and Charitable Fund 12.2%, Regal Funds Management 11.31%, Australian Ethical 9.2%, Chemical Overseas Ltd 8.49%, CVC Ltd 6.14%, Mr McBrayer 5.64%

Just over a year ago, Cyclopharm won US Food and Drug Administration (FDA) approval for its lung imaging tool, Technegas. Given the agency took 16 years to bestow its consent, the moment was a seminal one indeed for the company.

But as new drug or device market entrants quickly discover, the FDA seal of approval is but one step in the commercialization process. Gaining reimbursement, forging distribution channels and winning the hearts of crusty clinicians are just as important.

A year on, Cyclopharm has made headway - notably by winning full US public reimbursement and forging a deal with the expansive veteran's health network.

"We have now ticked all the boxes," says Cyclopharm CEO James McBrayer.

This month the company reported US sales-to-date of $250,000 from Technegas - a solid but hardly dial-moving start. From here-on-in, revenues should be more impressive.

The FDA's tardiness in approving the nuclear medicine device is a tad puzzling, in that Technegas is approved in 65 countries - including neighboring Canada - and has been administered 4.9 million times.

About Cyclopharm

Technegas was invented in the 1980s by Australian University bio-medical engineer Prof Bill Burch, who partnered with industrialist Ian Tetley to form Tetley Medical. Technegas was commercialized after being approved in Europe in 1988.

Cyclopharm was founded in 1991 and listed in January 2007, after raising $11 million at 30 cents apiece. Technegas was approved in Australia in 1986 - despite the Chernobyl meltdown that gave anything ‘nuclear’ a bad rap - and in Europe since the early 1990s.

A pharmacist and accomplished saxophonist, Mr McBrayer joined in June 2008, taking over from John Sharman who went on to head up Medical Developments and then Universal Biosensors. Mr McBrayer headed the nuclear medicine mob Syncor Australia, as well as Lipa Pharmaceuticals.

Cyclopharm took the unusual approach of tackling the rest of the world before the US, winning early approval in geographies including Europe and Canada. In June this year, the company won three-year reimbursement from the public US health insurers, which is just as important as FDA approval itself.

About Technegas

Technegas involves the patient breathing a superheated radioactive, gas-like substance, which sounds unhealthy but leads to better lung imaging.

The tool is currently used mainly to detected pulmonary embolisms - blood clots - but the FDA approval covers “visualization of pulmonary ventilation”. This includes common conditions including chronic obstructive pulmonary diseases (COPD), asthma and - lest we forget - long Covid.

Manufactured at the bedside, Technegas consists of dry-carbon nano-particles irradiated with the isotope technetium-99 (which, as nuclear scientist readers will know, is produced from decaying molybdenum-99).

The particles are 150 nano-metres and to put that in context a sheet of paper is about 100,000 nano-metres thick. The gas-like substance is freshly brewed by heating a carbon crucible to 2,700 degrees Celsius and inhaled by the patient via tubing. Only three to four breaths are required.

The gas works as an imaging agent, allowing three-dimensional viewing with a gamma or single photon emission computed tomography (CT) camera. The nanoparticles have a six-hour radioactive life, after which they are eventually dispersed through breathing. Technegas images the fine alveoli, where the oxygen and blood mix.

“If you can’t breathe, nothing else matters and we show where oxygen needs to go to get into the body,” Mr McBrayer says.

But what’s the problem?

Cyclopharm competes with the dominant CT and older two-dimensional nuclear techniques (see below). Currently, about 85 percent of patients are imaged with computed tomography pulmonary angiography, or CTPA. Nuclear imaging is confined to patients unsuited to CTPA, such as those who are pregnant, have poor kidney function or are allergic to the imaging agents.

Nuclear medicine diagnosis is done with an isotope called xenon-133, which requires a negatively-pressured room and a method to trap gases expelled by the patient.

Then there's another technetium-99 based liquid aerosol agent called DPTA, which is indicated for renal (kidney) imaging but has been deployed off-label for pulmonary embolisms. DPTA stands for diethylene-triamine-penta-acetate, seeing as you asked.

Cyclopharm claims Technegas surpasses CTPA and DPTA in terms of avoiding both false positives and false negatives.

Assaulting the vet market (no, not dogs and cats)

On October 8 the company announced a deal with the US Veterans Health Administration (VHA), which is expected to open the doors to other US Federal agencies. The US veterans' health market is a medical sector in itself - bigger than the entire Australian health system

"I was pleasantly surprised," Mr McBrayer says of the timing of the contract. "I thought we had a few more weeks to go until they would tell us one way or the other. Clinically and operationally, we ticked all the boxes but when you get into the contracting phase of any government entity, it can be challenging."

The interim deal will enable the company to access 120 VHA hospitals (those with nuclear medical medicine departments). The deal is also a springboard to accessing other Federal agencies, notably the Department of Defence and National Institutes of Health hospitals.

One reason for the expeditious approval - it took about nine months - was the company convinced the authorities to take a national approach, obviating the need for the company to deal with more than 20 regional offices.

Mr McBrayer says company does not expect all 120 sites to be up and running at once, given the need to train clinicians and source argon (an input in the process).

Finances and performance

In August, the company reported overall six-month Technegas revenue of a flat $7.46 million, with the US investment resulting in a loss of $7.48 million compared with a $2.66 million deficit previously. Total revenue of $13.3 million (down 19%), included $5.7 million from distributing third-party radio-pharmaceutical capital equipment and consumables.

This month, the company reported US Technegas sales of $250,000 in the 11 months post FDA approval.

"We will have a good second half," Mr McBrayer says. "We had to build inventory but now we have reimbursement we have gone up a gear."

Earlier this year the company raised $44 million, $40 million in a placement and $4 million in a share purchase plan, both at $1.42 a share (a 14% discount).

“I have been with the company for 16 years and I can count the number of capital raisings on one hand,” he says. “We have been very frugal.”

Mr McBrayer says the company expects to be cash-flow positive and profitable (on an annualized run rate) by the end of 2025.

Bell Potter forecasts calendar 2025 earnings before interest tax and depreciation of $1.1 million and a $1.7 million net loss, on revenue of $46.5 million (up 66%). 2026 is the year that delivers, with Ebitda of $1.1 million and a net profit of $11.1 million.

Quirkily, Cyclopharm paid a 0.5 cents dividend in 2023 and isn’t expected to pay one this year or in 2025, but Bell Potter forecasts a one cent payout in 2026.

Over the last 12 months Cyclopharm shares have scanned between $1.35 (August 30 this year and $2.45 (October 12 last year). They peaked at $2.98 in January 2021 and bottomed at 12 cents in March 2013.

The size of the prize

The US accounts for half of the world’s nuclear medicine market. In fact, the starred-and-striped nation always seems to account for 50 percent of any drug, device or diagnostic sector (and about 99 percent of the gun market).

Cyclopharm estimates a $US180 million US market for pulmonary embolism, with nuclear medicine accounting for 600,000 of the four million scans undertaken annually.

The company aims to double nuclear medicine’s 15 percent share of the market to 30 percent.

The company has a program called Beyond PE - as in pulmonary embolisms, not private equity or physical education - which seeks to expedite the company’s move into the aforementioned other lung diseases, notably COPD.

These indications would increase Cyclopharm’s addressable market to US$900 million.

Initially, the company is targeting about 2,000 of the 8,000 US nuclear medicine departments. “Through buying groups and the larger institutions, we have already engaged 830 sites with proposals in front of them,” Mr McBrayer says.

At the end of August six Technegas generators had been installed for US clients, with a further 11 contracts signed and 100 sites subject to contract or internal hospital committee review. Management has guided to 300 installed generators by December 2025.

The company cites actual and potential installations of 832, taking into account secondary sites contractually linked to the initial installation.

Mr McBrayer estimates the company has won an average 85 percent market share of nuclear medicine-based tests in other countries in which it operates.

Revenue model and reimbursement

In the US, Technegas is now subject to favorable 'transitional pass-through' rules.

This means the device is fully reimbursed, stand-alone, rather than part of a package including the cost of the radio-pharmacy and the procedure.

"We now have both the public and private sectors covered," Mr McBrayer says.

Clinicians are reimbursed at $US328 per test, whilst the company charges $US225 per test. This enables enough fat for the clinicians, the hospitals and the company to be happy.

Under the company's revenue model, it maintains ownerships of the machines (the Technegas generators) and charges rent of $US7000 a year.

There's also a one-off $US7,000 for installation and training for new clients, who also buy a starter kit of 50 tests at $US225 per test ($US11,250).

Taking the consumables into account, management expects average revenue of $US70,000 per year from the bigger sites.

"Our [product] is more expensive and rightly so because we are clinically better," chimes Mr McBrayer.

Dr Boreham's diagnosis:

Asked how much the company has expended to get to this juncture, Mr McBrayer quips: "in blood sweat and tears?"

On third-party estimates, Technegas has cost around $US80 million to develop.

Lest anyone get too carried away, the US Technegas rollout has been slower than expected.

But this should change as the transitional pass-through concession will spur interest from hospitals who can see a decent buck in it for themselves.

Put another way, management will have no excuses if US sales fail to launch.

Despite its US focus, Cyclopharm has no intention of leaving Australia, where it makes the Technegas generators at its Kingsgrove, Sydney site.

"We are happy to be part of the Australian community," Mr McBrayer says. "We are still an Australian invention that has been taken overseas."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he makes up for it in blood, sweat and tears.

RESMED

Resmed says record revenue for the three months to September 30, 2024 was up 11.1 percent to $US1,224,509,000 ($A1,846,979,000), with net profit after tax up 34.9 percent to $US325,358,000 ($A490,718,000).

Resmed said revenue was “driven by increased demand for our sleep devices and masks portfolio, as well as strong growth across our residential care software business”.

The company cited both US generally accepted accounting principles (GAAP) and non-GAAP data, saying it used non-GAAP information because it provided better insight when evaluating performance from core operations and provided consistent financial reporting. This report quotes the non-GAAP data.

Resmed said its increased profit was “due to manufacturing efficiencies and component cost improvements and an increase in average selling prices” with general and administrative expenses up seven percent due to employee-related expenses.

The company said it would pay shareholders an unfranked dividend of 5.3 US cents per share, up from 4.8 US cents per share in the prior corresponding period, with a record date of November 7 and a payment date of December 12, 2024.

Resmed said non-GAAP diluted earnings per share were up 34.1 percent to $US2.20, and that it had cash and cash equivalents of $426,361,000 at September 30, 2024 compared with $209,100,000 at September 30, 2023.

Resmed managing-director Mick Farrell said the results reflected “ongoing momentum and strong execution across all areas of our business,”.

“As we celebrate 35 years of growth and innovation, our recently launched 2030 strategy will further enable us to transform sleep health, breathing health, and healthcare technology at home,” Mr Farrell said.

“By building on our leadership in connected digital health, we are driving better care, simplifying the health journey, and improving access to our therapies globally so even more people worldwide are empowered to live healthier, higher-quality lives using products and services they love,” Mr Farrell said.

Resmed was up $2.11 or 5.9 percent to $37.73 with two million shares traded.

ORTHOCELL

Orthocell says it has “firm commitments” to raise $17 million in a non-underwritten institutional placement at 60 cents a share.

Orthocell said the issue price was a five percent premium to the 60-day volume weighted average price and a 12 percent discount to the 10-day volume weighted average price.

The company said the commitments were from “a significant number of new leading Australian and international institutional investors, alongside key existing institutional shareholders and life science funds”.

Orthocell said the funds would be used to fund commercialization of its Celgro collagen based Remplir for peripheral nerve repair in the US, Singapore, Southeast Asia, Canada, the EU and the UK, as well as scaling manufacturing infrastructure, automation projects to improve efficiency, sales force and marketing resources, working capital and the costs of the placement.

The company said chair John Van Der Wielen had subscribed for $100,000 in the placement, subject to shareholder approval.

Orthocell said it remained “on schedule to submit its Remplir US 510(k) market authorization application in 2024 with progression into US [Food and Drug Administration] approval and sales soon thereafter”.

Orthocell fell half a cent or 0.7 percent to 68.5 cents with 1.8 million shares traded.

BTC HEALTH

BTC says its Elasto-Q and Rhythmic Evolution drug infusion pumps have been included on the Australian Prescribed List of Medical Devices, from November 1, 2024.
BTC said inclusion on the Federal Government list provided “automatic reimbursement from private health insurers when private hospitals use the infusion pumps”.
The company said the reimbursement codes included “the Elasto-Q pump, the only soft-shell, variable flow rate single-use infusion pump available in the market, and the electronic Rhythmic Evolution pump, which is multi-functional and reusable”.
Last year, BTC said that it had approval from the Australian Therapeutic Goods Administration to market its Rhythmic Evolution electronic infusion pump for hospital and homecare (BD: Nov 21, 2023).
Today, BTC managing-director and executive chair Dr Richard Treagus said the company was “extremely pleased to have secured reimbursement for our products, and this provides certainty of access for our hospitals and their patients”.
“Our team can now actively switch our customers to these newer generation drug infusion products with complete confidence they will be reimbursed by private health insurance,” Dr Treagus said.
BTC was untraded at 6.5 cents.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says phase I study data for NUZ-001, formerly monepantel, shows the drug is safe and has a “statistically significant” benefit for amyotrophic lateral sclerosis.
Earlier this month, the then Pharmaust said its annual general meeting voted 99.5 percent in support of its name change to ‘Neurizon Therapeutics’ (BD: Oct 10, 2024).
Today, the company said its chief operating officer John Clark presented the results at the Boston-based Northeast Amyotrophic Lateral Sclerosis (Neals) Consortium meeting, held online from October 21 to 24, 2024.
Neurizon said the study met its primary endpoint of long-term safety and tolerability of NUZ-001 with no deaths or serious adverse events and demonstrated the therapy showed “promise as an innovative treatment for [amyotrophic lateral sclerosis]”.
In August, the then Pharmaust said that after four months, five of nine patients in its 12-month extension study of monepantel for motor neuron disease (MND) show “no functional decline” (BD: Aug 26, 2024).
Earlier this year, Pharmaust said it had dosed nine patients in its up-to 12-patient, open-label, phase I, 12-month extension study of monepantel for motor neuron disease (MND), or amyotrophic lateral sclerosis (ALS); and later, said it had approval to enrol the final three patients (BD: Feb 14, Apr 10, 2024)
Neurizon was up one cent or five percent to 21 cents.

AROVELLA THERAPEUTICS

Arovella says it has received $3.0 million from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Arovella said the incentive related to expenditure for the year to June 30, 2024, and that the funds would be used to progress ALA-101 to first-in-human clinical trials.
The company said it expected to receive a further $300,000 in the “coming months in relation to eligible expenditure covered by an advanced overseas finding”.
Arovella was unchanged at 17.5 cents with 5.4 million shares traded.

ORTHOCELL

Orthocell says its annual general meeting will vote to issue managing-director Paul Anderson and his spouse chief financial officer Nicole Telford about $1,327,587 in rights.
Orthocell said investors would vote to issue Mr Anderson $59,032 worth of short-term incentive rights and Ms Telford $30,099 in short-term incentive rights, with zero exercise price and expiring three years from the issue date.
The company said the meeting would vote to issue Mr Anderson and Ms Telford long-term incentive rights worth $344,353 and $234,103, each, respectively, exercisable within five years from the date of issue.
Orthocell said shareholders would vote to Mr Anderson an additional 1,200,000 retention rights at a face value of 55 cents each, exercisable at no cost within five years.
The company said the rights were in addition to Mr Anderson's $491,932 annual pay and Ms Telford's $334,432 yearly salary.
Orthocell said the meeting would vote to adopt the remuneration report, re-elect Prof Fiona Wood and Kim Beazley as directors, approve the additional 10 percent placement capacity, ratify the prior issue of placement shares and approve Mr Anderson's and Ms Telford's termination benefits.
The meeting will be held at Building 191, Murdoch University, South Street, Perth, on November 29, 2024 at 10am (AWST).

RADIOPHARM THERANOSTICS

Radiopharm says its annual general meeting will vote to issue 107,290,690 incentive and remuneration options to its managing-director, chair and directors.
Radiopharm said the meeting would vote to issue 55,250,286 incentive options to managing-director Riccardo Canevari and 4,040,404 incentive options to director Ian Turner, exercisable at 4.1 cents each until June 30, 2029.
The company said investors would vote to issue executive chair Paul Hopper, chief financial officer, joint company secretary and director Phillip Hains as well as non-executive directors Mr Turner, Noel Donnelly, Hester Larkin and Dr Leila Alland 8,000,000 remuneration options, each, exercisable at six cents each by September 30, 2029.
Radiopharm said the options were in addition to the recipients' respective salaries.
The company said the meeting would vote on the remuneration report, elect Mr Turner, Mr Hains and Mr Donnelly as directors, ratify the prior issue of shares, approve the 10 percent placement capacity and approve the issue of incentive plan securities.
The meeting will be held online and at Level 3, 62 Lygon Street, Carlton, on November 25, 2025 at 10am (AEDT).
Radiopharm fell 0.1 cents or 3.7 percent to 2.6 cents with 20.45 million shares traded.

SYNTARA

Syntara says its annual general meeting will vote to issue 2,771,000 performance rights to managing-director Gary Phillips.
Syntara said Mr Phillips' performance rights were zero grant and zero exercise price options, vesting in two equal tranches on June 30, 2026 and June 30, 2027, and exercisable within 10 years, in addition to his $475,730 annual base salary.
The company said investors would vote on the remuneration report, to re-elect director Dr Kathleen Metters, approve the employee incentive plan and appoint an auditor.
The meeting will be held online on November 28, 2024 at 10am (AEDT).
Syntara was up 0.1 cents or 2.2 percent to 4.7 cents with 2.9 million shares traded.

INOVIQ

Inoviq says its annual general meeting will vote to issue 250,000 options, each, to directors Robert Johnston, Philip Powell, Dr Geoff Cumming and Mary Harney.
Inoviq said shareholders would vote to issue the options as “competitive benefits” with the options in addition to each director’s $60,000 in annual fees and exercisable at $1.00 each by November 29, 2028.
The company said the meeting would vote to adopt the remuneration report, elect Mr Johnston, Mr Powell and Ms Harney as directors and approve the 10 percent placement capacity.
Inoviq fell one cent or 2.1 percent to 47 cents.

MEDICAL DEVELOPMENTS

Jencay Capital Pty Ltd says it has become substantial in Medical Developments with 6,056,704 shares, or 5.38 percent.
The Sydney-based Jencay said that between June 23 and October 23, 2024 it bought 2,212,672 shares for $895,620, or 40.5 cents each.
Medical Developments fell 1.5 cents or 3.2 percent to 45.5 cents.

MTP CONNECT

MTP Connect says it has opened an accelerator program for three Australian small and medium enterprises using artificial intelligence in medical technology products.
MTP Connect said the companies included Perth’s Cortical Dynamics Ltd and its brain anaesthesia response monitoring system, Brisbane’s Microbio, which was developing molecular pathogen diagnostics for sepsis, and Sydney’s Resonait Medical Technologies and its electro-encephalogram monitoring software for depression.
The Federally-funded industry organization said the program, called the Biomedical A.I. Sprints Accelerator, or BASA, was being conducted with the Advanced Robotics for Manufacturing (ARM) Hub.
MTP Connect said the program was designed to “address a lack of expertise in A.I. and big data management, in particular addressing critical skills shortages within Australia’s life sciences sector”.
The organization said following participation in the program, the companies would have “a tailored plan of how to scale their innovative A.I. applications and leverage data infrastructure to overcome A.I. adoption hurdles”.
MTP Connect said the companies would “harness their data and AI to revolutionize their products”, with the program designed to “enhance their medical products to become internationally competitive”.
MTP Connect chief executive officer Stuart Dignam said the organization was “delighted to be working with the team at the ARM Hub to make this A.I. accelerator a reality to support innovations in medical product discovery and to advance human health”.
“Providing support to these promising innovative companies means we are building sovereign A.I. capabilities in our medical science sector and that is a smart approach if we want to be globally competitive,” Mr Dignam said.