



# Biotech Daily

Friday January 28, 2022

*Daily news on ASX-listed biotechnology companies*

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- \* **REGENEUS APPOINTS DR SCOTT BRUDER ADVISER**

## MARKET REPORT

The Australian stock market rebounded 2.19 percent on Friday January 28, 2022, with the ASX200 up 149.8 points to 6,988.1 points. Twenty-three of the Biotech Daily Top 40 companies were up, 13 fell and four traded unchanged.

Imugene was the best, up three cents or 10.5 percent to 31.5 cents, with 69.6 million shares traded. Amplia climbed 10.3 percent; Polynovo was up 9.2 percent; Actinogen, Clinuvel, Medical Developments, Neuren and Volpara improved more than eight percent; Orthocell and Pro Medicus were up more than seven percent; Paradigm was up 6.6 percent; Prescient and Starpharma rose more than five percent; Dimerix, Nanosonics, Pharmaxis, Proteomics and Universal Biosensors were up more than four percent; Avita and CSL improved more than three percent; Alcidion, Immutep and Micro-X rose more than two percent; with Cochlear and Nova Eye up by less than one percent.

Compumedics led the falls, down four cents or 9.8 percent to 37 cents, with 11,250 shares traded. Genetic Signatures lost six percent; Atomo and Opthea fell more than four percent; Impeded, Mesoblast, Resonance and Telix were down three percent or more; Oncosil and Uscom shed more than two percent; Kazia was down 1.1 percent; with Emvision, Next Science and Resmed down by less than one percent.

## DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS

**By TIM BOREHAM**

**ASX Code:** MVP

**Share price:** \$4.40

**Shares on issue:** 71,280,057

**Market cap:** \$313.6 million

**Chief executive officer:** Brent MacGregor

**Board:** Gordon Naylor (chairman), David Williams, Max Johnston, Philip Powell, Christine Emmanuel, Mary Sontrop, Leon Hoare, Richard Betts

**Financials (year to June 30, 2021):** revenue \$25.27 million (down 12%), loss of \$12.56 million\* (previously a \$379,000 profit), cash of \$36.2 million (up 133%), debt nil

\* After \$8.95 million of asset impairments

**Major identifiable shareholders:** David Williams 13.3%, FIL Ltd (Fidelity) 5.7%.

Broadly speaking, the pandemic was neutral or beneficial for the ASX-listed life sciences sector - but not so for Medical Developments and its famous 'green whistle' painkiller.

Reduced ambulance call-outs in locked-down geographies and the cancellation of mass participation sports meant soft demand for the green whistles, which contain the inhaled analgesic methoxyflurane (Penthrox).

Medical Developments holds worldwide rights to the 46-year-old painkiller and is its only manufacturer.

The company also produces respiratory devices such as asthma spacers, but ironically was one of the few respiratory companies to be affected negatively by Covid-19.

As management laments, sales were depressed because of fewer cold and 'flu cases and "improved hygienic practices" - which doesn't sound too bad for the rest of us.

The poor conditions led to the company reporting its first loss in seven years and demotion from the ASX300 index.

The company also parted ways with its European and Australian distributor Mundipharma, which is owned by the litigation-mired US opioid drug maker Purdue Pharma.

“While there were some accomplishments during the period, for the most part we were left to pick up the pieces and move forward in a new direction,” chief executive Brent MacGregor told the company’s virtual AGM.

## **Whistle through the pain**

Medical Developments is all about re-inventing Pentrox, which was first used here in 1975.

Pentrox is also used as a veterinary drug, having been approved a decade ago in the US under the brand name Anafane.

Declaring ‘It’s Time’ for a fast-acting, non-addictive painkiller, prominent anaesthetist Dr David Komesaroff founded Medical Developments in 1972.

Pentrox was (and is) pitched as a rival product to nitrous oxide (laughing gas), morphine, Fentanyl (an opioid) and ketamine (better known as a horse tranquillizer).

Steered by then chairman and biggest shareholder David Williams, Medical Developments listed on the ASX in December 2003, after raising \$8.7 million at 25 cents apiece.

So far, more than seven million patients have administered Pentrox safely and effectively in multiple geographies.

In March 2020, CEO John Sharman departed, with board member Max Johnson acting as interim head before Mr MacGregor assumed command in November 2020.

Mr MacGregor was the head of commercial operations at Seqirus (CSL’s old influenza division) and formerly headed Novartis’s ‘flu arm.

The former chief financial officer for CSL and then head of Seqirus, Mr Naylor joined the Medical Developments board in October 2020 and a month later assumed the chairmanship from Mr Williams.

Naturally, Mr Naylor approached his old colleague Mr MacGregor, who was in the throes of leaving Seqirus.

“Frankly, I did it as a courtesy to Gordon when he first reached out to me, but one thing led to another,” says Mr MacGregor, who is Canadian-born but a US citizen domiciled in New Jersey.

## **Shaking the joint up**

Mr MacGregor wasted no time orchestrating a business improvement program to sharpen the company’s commercial direction and instil a culture of setting and meeting targets.

(Ironically, his predecessor Mr Sharman did the same at his next gig as head of Universal Biosensors).

Mr MacGregor notes that 80 percent of the Melbourne head office team is new, with global markets experience.

“We weren’t resting on our laurels, but expected bigger results which in hindsight were never going to be achieved,” he says.

A key message was just because Pentrox is registered in a country, it doesn’t mean the company will - or should - sell there.

Examples are Lithuania, Estonia Latvia, Macedonia and Montenegro

“We have actually relinquished market authorizations since I came on board,” he says.

“For our regulatory people it’s a dagger in the heart and I feel for them. But there’s a cost to maintaining a regulatory file.

“For example, if a testing lab changes address, you need to update that [with regulators]. It’s minutiae but there’s a cost associated with it.”

He adds that he is not criticizing his predecessors, who operated in different circumstances.

## **Revamping distribution**

In 2020, Medical Developments re-acquired the European Pentrox rights from Mundipharma, as well as the Australian franchise.

At the time, management described the parting of ways as “collegial and friendly”.

Medical Developments now distributes directly in France, Belgium, the Netherlands, Germany, Italy and Spain.

“In hindsight, Mundi were masters of opioids so they had their own products,” Mr MacGregor say, adding the sales reps weren’t going to “speak out of both sides of their mouths” by selling Pentrox as well.

“The elephant in the room is they’re going through the biggest litigation in the history of pharma, and they were preoccupied, to say the very least.”

In Canada, Medical Developments has also re-claimed the rights from Purdue Pharma.

The Northern Ireland-based Galen Pharmaceuticals continues to distribute in the UK and Ireland and won management plaudits by boosting sales by 41 percent last year. Supply deals with St Johns Ambulance and Scottish Ambulance have been extended for five years.

Another distributor, Medis has been engaged in five central European countries: the Czech Republic, Slovenia, Slovakia, Austria and Croatia.

In 2017, Tokyo's Daiichi Sankyo was hired to cover China, Thailand and Vietnam.

### **What about the US?**

The big gap in Medical Development's global repertoire is the US, where the US Food and Drug Administration remains to be convinced.

There's a bit of history here, in that methoxyflurane was used as an anaesthetic in the US, but not an especially good one and the agency withdrew approval.

Mr MacGregor argues the anaesthetic product of 25 years ago had 20 times the dosage than Pentrox's current usage, with a different patient population.

"But methoxyflurane is methoxyflurane and these folk [at the FDA] stay in their seats for a very long time," he says.

In any event, last August, the agency put a 'clinical hold' on the company, over kidney and liver toxicity concerns.

This means it can't yet sally forth with a proposed phase III trial in view of gaining approval.

The company lodged its clinical hold response with the FDA in December 2021 and is awaiting a response.

### **Take a deep breath**

Medical Developments also has a significant respiratory device business, with products such as Space Chamber and the Breath-A-Tech asthma device (acquired for \$2.5 million in 2016 from Avita Medical).

Breath-A-Tech products are stocked in 20,000 US pharmacies, while the company makes spacers for Walmart on a private label basis.

A collapsible breather is being stocked here by the Chemist Warehouse chain.

The company also has front-line oxygen therapy and resuscitation devices with names such as Oxi-Port and Oxi-Sok (therapy) and Oxi-Pro and Oxi-Life (resuscitation).

In cahoots with the esteemed Commonwealth Scientific and Industrial Research Organisation, the company is working on a manufacturing method based on its continuous flow platform.

Without knowing too much more, we can report the technique results in lower costs with a smaller carbon footprint than traditional batch processing.

The company is also working on the Selfie: a next generation, self-administered inhaler for pain relief.

## **Finances and performance**

“We won’t be profitable this year because we are investing a lot in the business,” Mr MacGregor says. “We hope to be sustainably profitable by 2023 but we are not giving guidance.”

The \$12.56 million bottom-line loss for the year to June 2021 was not as bad as it seemed, in that it resulted in two non-cash write downs. These pertained to the carrying value of the respiratory division (\$4.7 million) and capitalized costs of the CSIRO project (\$3.14 million).

The latter move recognizes the company is unlikely to derive revenue from these efforts in the foreseeable future.

The board refrained from declaring a dividend, having dispatched two cents a share in 2019-'20 and four cents a share in each of the previous four years.

Full-year revenue declined 12 percent to \$25.2 million. A key factor was the phasing-out of the Mundipharma tie-up, which created a supply gap as the distributor sold down its inventories.

The results show that Pentrox accounted for 77 percent of revenue, or \$19.5 million, with the devices accounting for the remainder except for \$380,000 from the veterinary device arm.

The geographic split shows a 33 percent bias to Australia, with the rest of the world accounting for the remaining two-thirds.

In the previous year, the split was more like 50:50.

The company is flush with funds, having raised \$36.7 million in December 2020 - \$24.9 million via a placement and \$11.8 million with a share purchase plan.

Over the last 12 months Medical Developments shares have traded between \$7.18 (January 21, 2021) and \$3.35 (September 6, 2021).

The stock peaked at \$11 on February 20, 2020, just before the spectacular but brief Great Covid Market Meltdown.

Despite the market gyrations, Medical Developments shares are pretty much where they were one year ago and five years ago.

## **What's next?**

Medical Developments can continue to make inroads into the ambulance and sports markets, which is the headline grabbing stuff.

But more fertile growth lies with expanding the use of Pentrox to emergency departments and minor surgeries.

Mr MacGregor says doctors have told him the drug is already being used off-label in these settings.

Medical Developments is also eyeing expanded uses for Pentrox, including as an item in home first-aid kits, for military purposes and for developing world aid programs.

In the short term at least, the respiratory side is expected to continue to account for about one-third of revenue.

“The US space chamber market is enormous but we have a very tiny share,” MacGregor says. “A lot is commoditized but we should be able to gain a better share than we have.”

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

When we last covered Medical Developments in June 2019, we pondered whether MVP could become the ASX-listed biotech sector's GOAT.

(For sports aficionados, this was a witty play on the company's share code MVP – most Valuable Player and Greatest of All Times.)

Given MVP's recent slip-ups, we're a bit sheepish about the GOAT prediction. Still, there's no reason the company can't vie for biotech hall of fame status.

Like a football player overcoming a dodgy knee, Medical Developments' comeback is gaining pace.

“Encouragingly, when restrictions eased in the [current half year] the company experienced a strong rebound in local Pentrox sales, with similar trends also observed in international Pentrox markets,” Mr Naylor told shareholders.

As has been the case for some years, gaining US approval remains the key to stepping to the next level.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is not the greatest of all time but is regularly called a goat anyway.***

## RESMED

Resmed says receipts from customers for the six months to December 31, 2021 was up 15.9 percent to \$US1,798,900,000 (\$A2,555,500,000) compared to the prior period.

Resmed said its record receipts were for its sleep and respiratory care products, as well as an increase of eight percent in its software-as-a-service business.

The company said that it had cash and equivalents of \$US194,476,000 at December 31, 2021 compared to \$US295,278,000 at December 31, 2020.

Resmed fell 15 cents or 0.5 percent to \$31.25 with 3.9 million shares traded.

## MEDADVISOR

Medadvisor says receipts from customers for the six months to December 31, 2021 was up 198.3 percent to \$42,345,000 compared to the prior corresponding period.

Medadvisor said its receipts from its Adheris medication adherence platform for the three months to December 31, 2021 was up 96.9 percent to \$21,111,000.

The company said it had a cash burn of \$2,569,000 for the three months to December 31, 2021, with cash of \$5,337,000 compared to \$21,208,000 at December 31, 2020.

Medadvisor was up half a cent or 1.35 percent to 37.5 cents.

## TOTAL BRAIN

Total Brain says receipts from customers for the six months to December 31, 2021 were up 185.6 percent to \$4,515,000 compared to the prior corresponding period.

Total Brain said its receipts from its brain health software-as-a-service products for the three months to December 31, 2021 were up 404.6 percent to \$3,961,000.

The company said that it was \$917,000 cashflow positive for the three months to December 31, 2021, with cash and equivalents of \$4,607,000 compared to \$3,708,000 at December 31, 2020.

Total Brain was up half a cent or 4.35 percent to 12 cents.

## CANN GROUP

Cann says receipts from customers for its marijuana products for the six months to December 31, 2021 was \$3,241,000 compared to \$192,000 in the prior period.

The company said that it had a cash burn of \$1,335,000 for the three months to December 31, 2021, with cash and equivalents of \$10,765,000 compared to \$27,736,000 at December 31, 2020.

Cann Group was up 0.75 cents or 2.7 percent to 28.25 cents.

## STARPHARMA

Starpharma says receipts from customers for the six months to December 31, 2021 was up 9.7-fold to \$2,458,000 compared to \$253,000 in the prior corresponding period.

Starpharma said receipts from customers for its Viralese nasal spray, Vivagel BV for bacterial vaginosis and condom coatings for the three months to December 31, 2021 was \$1,824,000 compared to \$189,000 in the prior corresponding period.

The company said it had a cash burn of \$4,230,000 for the three months to December 31, 2021, with cash and equivalents of \$51,254,000 compared to \$70,274,000 at December 31, 2020.

Starpharma was up 5.5 cents or 5.5 percent to \$1.05 with 1.9 million shares traded.

## UNIVERSAL BIOSENSORS

Universal Biosensors says receipts from customers for the 12 months to December 31, 2021 was up 412.0 percent to \$3,973,000 in the prior corresponding period.

Universal Biosensors said receipts from its Sentia wine testing platform and coagulation testing for the three months to December 31, 2021 was up 254.7 percent to \$1,270,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$483,000 for the three months to December 31, 2021, with cash and equivalents of \$18,099,000 compared to \$28,055,000 at December 31, 2020.

Universal Biosensors was up 3.5 cents or 4.2 percent to 87 cents.

## CONTROL BIONICS

Control Bionics says receipts from customers for the six months to December 31, 2021 was up 25.6 percent to \$1,894,000 compared to the prior corresponding period.

Control Bionics said its receipts from customers for its Neuronode technology for the conversion of thoughts into computerized actions for the three months to December 31, 2021 was up 25.5 percent to \$911,000.

In 2020, the company listed on the ASX after raising \$15 million at 60 cents a share to commercialize its Neuronode technology (BD: Dec 8, 2020).

Control Bionics said that it had a cash burn of \$1,619,000 for the three months to December 31, 2021, with cash and equivalents of \$8,527,000 compared to \$14,566,899 at December 31, 2020.

Control Bionics was unchanged at 38.5 cents.

## OSTEOPORE

Osteopore says receipts from customers for the 12 months to December 31, 2021 fell 27.9 percent to \$1,109,000 compared to the prior corresponding period.

Osteopore said its receipts from its cranial scaffold technology for the three months to December 31, 2021 was down 35.1 percent to \$287,000.

The company said it had a cash burn of \$1,077,000 for the three months to December 31, 2021, with cash of \$4,530,000 compared to \$9,027,000 at December 31, 2020.

Osteopore was unchanged at 23 cents.

## IMUGENE

Imugene says the Basel-based Roche will supply atezolizumab (Tecentriq) for up to five years for a phase I trial of Imugene's PD1-Vaxx for non-small cell lung cancer.

Imugene said the open-label, multi-center, dose escalation and expansion trial would assess the safety, efficacy, and optimal dose of its PD1-Vaxx as monotherapy or in combination with Roche's atezolizumab.

Imugene said that it would sponsor and fund the study, with Roche supplying the atezolizumab for its duration.

Imugene said it would own all data collected during the study, but that all rights to inventions from the study would be shared between the two companies.

Imugene was up three cents or 10.5 percent to 31.5 cents with 69.6 million shares traded.

## IMUGENE

Imugene says the European Patent Office has granted a patent for its HER-Vaxx immunotherapy for HER-2-positive gastric cancer.

Imugene said the patent, titled 'A Vaccine Composition and Uses Thereof' would protect its intellectual property until 2036.

## ANTEOTECH

Anteo says Australia's Therapeutic Goods Administration has requested more data for its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test.

Anteo said the request "primarily relates to collation of additional clinical data" but said that it expected a trial at Melbourne's Alfred Hospital and Burnet Institutes would provide any further data the TGA required.

The company said that hospital and staffing surges due to the most recent Omicron case load was impacting the timeline.

Anteo fell nine cents or 28.6 percent to 22.5 cents with 51.8 million shares traded.

## OVENTUS MEDICAL

Oventus says it has received \$416,674 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Oventus said the rebate related to research and development expenditure for the year to June 30, 2021.

Oventus fell 0.2 cents or 2.9 percent to 6.7 cents.

## ALTHEA

SG Hiscock says it has increased its substantial holding in Althea from 11,813,182 shares (5.06%) to 18,969,215 shares (6.07%).

SG Hiscock said that between July 1, 2021 and January 24, 2022 it bought and sold shares, with the largest acquisition 3,145,834 shares for \$755,000 or 24 cents a share.

Althea fell half a cent or 2.4 percent to 20 cents.

## PROBIOTEC

Probiotec says it has appointed Paul Santoro as a non-executive director, effective from February 1, 2022.

Probiotec said that Mr Santoro was currently the chief executive officer of Cygnett, co-owner of Forest Hill Medical Centre and was formerly Dorevitch Pathology's chief executive officer.

Probiotec fell four cents or 1.7 percent to \$2.26.

## IDT AUSTRALIA

IDT says it has appointed Dr Jane Ryan as an independent, non-executive director, effective immediately.

IDT said Dr Ryan had more than 30 years' experience in the pharmaceutical and biotechnology industries and was currently a director of Anantara and Bionomics.

IDT was up half a cent or 2.3 percent to 22 cents.

## REGENEUS

Regeneus says it has appointed Dr Scott Bruder as an advisor to the board, effective from February 1, 2022.

Regeneus said that Dr Bruder was the founder and current chief executive officer of New York's Bruder Consulting & Venture Group and was previously chief medical and scientific officer of the Kalamazoo, Michigan-based Stryker Group.

The company said that Dr Bruder had worked for Becton Dickinson & Co, Johnson & Johnson and Osiris Therapeutics.

Regeneus was up 0.4 cents or 4.9 percent to 8.5 cents.