



# Biotech Daily

Monday September 18, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: STARPHARMA UP 25%; PATRYS DOWN 18%**
- \* **US FDA OKAYS GSK OJJAARA (CYTOPIA CYT387) FOR MYELOFIBROSIS**
- \* **BIOTECH DAILY EDITORIAL: IT'S A LONG WAY TO THE TOP**
- \* **BTC PAYS IZI \$720k FOR NEURO-SPINAL PRODUCT RIGHTS**
- \* **ADHERIUM: SENTA ADOPTS HAILIE ASTHMA MONITOR IN THE US**
- \* **TRUSCREEN: SAUDI ARABIA BUYS CERVICAL CANCER DIAGNOSTIC**
- \* **BCAL 'OVER-SUBSCRIBED' PLAN RAISES \$615k; TOTAL \$3m**
- \* **REPSIRI \$1.3m PLACEMENT TO PAYOUT \$410k US CONVERTIBLE NOTES**
- \* **VICTORIA: MODERNA mRNA VACCINE FACTORY 'AHEAD OF SCHEDULE'**
- \* **OSTEOPORE 'CLARIFIES' INNOVENTURES CHINA J-V**
- \* **PROTEOMICS TAKES 'TEST APPROVAL' HALT TO SUSPENSION**
- \* **AARON CHAN, JUSTIN MOUCHACCA REPLACE DORSAVI CFO, CO SEC**

## MARKET REPORT

The Australian stock market fell 0.67 percent on Monday September 18, 2023 with the ASX200 down 48.6 points to 7,230.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 23 fell, two traded unchanged and four were untraded. All three Big Caps fell.

Starpharma was the best, up 3.5 cents or 25 percent to 17.5 cents, with 3.05 million shares traded. Dimerix and Paradigm climbed more than nine percent; Next Science was up 7.95 percent; Resonance rose 6.15 percent; Micro-X improved 4.55 percent; Kazia and Orthocell were up more than two percent; Amplia and Pharmaxis were up more than one percent; with Emvision up by 0.9 percent.

PatrYS led the falls, down 0.15 cents or 17.65 percent to 0.7 cents, with 8.4 million shares traded. 4D Medical lost 9.7 percent; Volpara shed six percent; Actinogen, Opthea and Polynovo were down five percent or more; Alcidion, Antisense, Cyclopharm, Immutep and Mesoblast fell more than four percent; Imugene, Medical Developments and Pro Medicus were down more than three percent; Genetic Signatures, Impedimed, Nanosonics, Nova Eye and Prescient shed more than two percent; Avita, Clinuvel and Cochlear were down more than one percent; with CSL, Neuren, Resmed and Telix down less than one percent.

## [CYTOPIA, YM BIOSCIENCES, GILEAD, SIERRA ONCOLOGY, GLAXOSMITHKLINE](#)

Prof Andrew Wilks says that after 20 years of development, the US Food and Drug Administration has approved Ojjaara (Cytopia's CYT387) for myelofibrosis.

Prior to founding Cytopia, Prof Wilks and his team at Melbourne's Ludwig Institute for Cancer Research discovered and developed a suite of patents around JAK1 and JAK2 which were licenced by Cytopia, which he led with and Dr Chris Burns, now the chief executive officer of Amplia Therapeutics and Andrew Macdonald.

A media release from Prof Wilks said the JAK enzymes were the protein targets of Ojjaara, formerly known as momelotinib and CYT387.

The announcement said that Cytopia was founded in 1999 and listed on the ASX in 2004.

Prof Wilks said he was currently a managing-director at Synthesis Bioventures.

Dr Burns told Biotech Daily that "originally JAK was 'just another kinase' but it was formally named a Janus kinase for the Roman god of doorways".

"Like Janus, the kinase has two faces - binding to growth factors and cytokine receptors," Dr Burns said.

Dr Burns said that the "mel" in momelotinib was a reference to the Melbourne invention of the drug. Glaxosmithkline changed the name to Ojjaara.

In 2009, the then ASX-listed Cytopia said it would be acquired by the Toronto-based YM Biosciences for 16.59 cents a share or \$14 million (BD: Oct 6, 2009).

In 2011, YM Biosciences said that raised \$US46 million for Cytopia's CYT387, having acquired the company in January 2010 (BD: Mar 18, 2011).

YM said at that time that data suggested that CYT387 was able to significantly improve the symptoms of patients with myelofibrosis, a frequently fatal bone marrow disorder.

In 2012, Gilead Sciences said it would acquire YM Biosciences for \$US510 million, whose lead drug was the Melbourne-developed CYT387 (BD: Dec 13, 2012).

It has been widely reported that in 2018, Gilead sold the drug to Vancouver's Sierra Oncology for \$US3 million up-front; and last year Sierra sold CYT387 to Glaxosmithkline for \$US1.9 billion (\$A2.9 billion).

Last week, Prof Wilks said that CYT387 or momelotinib "was the only asset of Sierra Oncology which was ultimately acquired by GSK in 2022 for US\$1.9 billion in an all-cash deal, making it the highest acquisition amount paid for a drug invented in Australia".

In June, Glaxosmithkline said that FDA Prescription Drug User Fee Amendments (PDUFA) date for momelotinib had been delayed by three months "to provide time to review recently submitted data" with a new date of September 16, 2023.

This week, the media release said that while Ojjaara was approved initially as a treatment for the bone cancer myelofibrosis, the molecule had "the potential to gain additional approvals for treating a number of inflammatory diseases".

Prof Wilks said that FDA approval for Ojjaara was "not only a personal victory but a triumph for the many scientists and clinicians with whom he worked across Australia".

"Australia punches above its weight in terms of life science discoveries," Prof Wilks said.

"And whilst government support drives the scientific sector, there needs to be a culture change for scientists to understand the commercial opportunities," Prof Wilks said.

"Despite Melbourne boasting one of the world's leading biomedical precincts in Parkville, Australian scientists often face a shortage of experience and capital required to maximize the value of their inventions," Prof Wilks said.

Prof Wilks said that Synthesis Bioventures was a fund focused on early-stage therapeutics, investing in projects from discovery through pre-clinical proof-of-concept and FDA investigational new drug application-enabling studies, investing in small molecule therapeutics, biologics, and cell and gene therapies for indications with unmet needs.

Biotech Daily editor David Langsam held shares in Cytopia at the time.

## [BIOTECH DAILY EDITORIAL: IT'S A LONG WAY TO THE TOP](#)

Accepting an award from the Victoria Governor many years ago, then CSL chief executive officer Dr Brian McNamee said: "In the glacial timelines of biotech, we have taken Gardasil from lab bench to blockbuster in 17 short years."

The approval of Glaxosmithkline's Ojjaara, formerly Cytopia's CYT387, raises the question, again, of why some Australian investors can't benefit from our drug know-how. I say some, because CSL is the exception to the rule, inventing drugs in Australia and returning dividends to investors.

On Friday afternoon in the US, the molecule first known as CYT387, which was sold to YM Biosciences for \$14 million, then to Gilead for \$US510 million, then to Sierra for \$US3 million upfront and finally to Glaxosmithkline for \$US1.9 billion, was finally approved - and may well become a blockbuster for myelofibrosis, and potentially other blood cancers.

The last Australian drug to be taken to US Food and Drug Administration approval was Neuren's trofinetide, now Acadia's Daybue. Giaconda's antibiotic combination Heliconda was bought by Israel's Redhill Biopharma in 2010, renamed RHB-105 and later Talicia, it earned \$US5.1 million in the six months to June 30, 2023.

Chemgenex took Omapro (Synribo) all the way through the regulatory process, apart from the final details shepherded by Cephalon-Teva. Like Clinuvel's Scenesse, although a great deal of development and regulatory progress was achieved by the Australian company, the original molecule was bought-in. Pharmaxis similarly won approvals for its mannitol-based Aridol and Bronchitol.

The only other drugs we can recall that have gone all the way were the Acrux combinations of generic oestrogen and testosterone in generic alcohol and generic sun cream and Hatchtech's Xeglyze for headlice and their eggs.

On the other hand, there are many devices and diagnostics with global approvals: Telix's Illucix, Sirtex Sir-Spheres, Nanosonics Trophon EPR, Cellestis Quantiferon-TB Gold, Compumedics brain diagnostics, Uscom's cardiac output monitor, Control Bionics Neuronode, Adherium's Hailie puffer monitor and Respiro's Wheezo asthma monitor.

But the FDA is finicky about drugs going into bodies and success has been few and far between.

While it is gratifying to know that Glaxosmithkline could take Cytopia's molecule all the way, how much better would it have been if the original team, including then chief executive officer Andrew Macdonald, Prof Andrew Wilks, Dr Chris Burns and the hundreds of investors – including this writer – could have had a share of the royalties.

The answer seems to be the need for much greater capital availability. Cytopia was sold to YM because it ran out of money and couldn't raise what it needed. The sector was very young back then and even if we did know then what we know now, there was never a guarantee that CYT387 would be successful, which is why we have large, randomized, controlled trials. And they aren't cheap.

**David Langsam, Editor**

## BTC HEALTH

BTC says it will pay IZI Medical Products \$720,000 to distribute its neuro-spinal tissue and bone biopsy needles in Australia and New Zealand.

BTC said its investee company BTC Specialty Health entered into the agreement with the Baltimore, Maryland-based IZI and its German subsidiary Ilumark GmbH to sell its disposable needle kits and radiological markers for neuro-spinal surgical procedures.

The company said it would pay \$200,000 within seven business days, a further \$120,000 on the completion of specified transition conditions and up to \$400,000 over 36-months, subject to profit hurdles.

BTC said IZI's products were distributed in Australia by Point Blank Medical Pty Ltd, and that product registrations, inventory and customer service functions would transfer to BTC Speciality Health immediately and be integrated into the existing company infrastructure. The company said that Point Blank Medical would work with its subsidiary to provide sales, marketing and training services in support of the customers and the shared objectives for the business.

BTC said it would pay Point Blank for its services on a fully commissioned basis, with the amount of commission payable linked directly to monthly sales and gross profit.

BTC executive chair Dr Richard Treagus said the agreement was "a decisive step for us to establish a presence in the neuro-spinal medical product field".

"It creates diversification, scale, and contributes immediately to the bottom-line profitability of our business," Dr Treagus said.

"Importantly this transaction also delivers the crucial expertise and clinical relationships which we expect to leverage as we execute on our growth strategy with the introduction of additional spinal products," Dr Treagus said.

BTC was up 0.7 cents or 26.9 percent to 3.3 cents.

## ADHERIUM

Adherium says the Atlanta, Georgia-based Southern Ear, Nose, Throat and Allergy (Senta) will use its Hailie asthma adherence software for its patients.

Adherium said that Senta would use its Hailie Bluetooth-enabled asthma puffer sensor to improve adherence and inhaler technique for its patients, with emphasis on the latest generation of devices that monitor patient inspiratory flow.

The company said that Senta was "one of the largest and most prominent allergy and asthma practices in the US" with 48 locations in six states with 88 allergy, asthma and ear, nose and throat physicians, physician assistants and nurse practitioners.

Adherium did not disclose the commercial terms of the agreement, but said Hailie enabled doctors to bill for long-term remote patient management under established US reimbursement codes, and that it received payment for sensor sales and monthly, per patient fees for generating and transmitting respiratory data.

The company said it had prepared an implementation plan with Senta starting this month, with an initial roll-out in Georgia under director of a lead physician, practice administrator and nurse practitioner.

Adherium said expansion to additional clinics was planned to begin this year, and it was investing and building up its US implementation team including clinical applications, technical support and customer service staff to support Senta's rollout.

Adherium chief executive officer Rick Legleiter said the "important partnership marks another US commercialization milestone as we strive to rapidly build large-scale product roll-out".

Adherium was up 0.05 cents or 12.5 percent to 0.45 cents with 1.5 million shares traded.

## TRUSCREEN GROUP

Truscreen says the Riyadh-based Dr Sulaiman Al-Habib Medical Group has installed the first tranche of four cervical cancer screening devices for commercial use in Saudi Arabia. Truscreen said the adoption of its screening technology by the Dr Sulaiman Medical Group private hospitals would be important reference sites for further market access in neighboring Middle Eastern nations.

The company said the installation followed evaluation in Saudi Arabia of its “artificial intelligence-enabled device for detecting abnormalities in the cervical tissue ... through measurements of the low level of optical and electrical stimuli” (BD: Mar 14, 2023).

Truscreen was untraded at two cents.

## BCAL DIAGNOSTICS

Bcal says its over-subscribed share plan raised \$615,500 of a hoped-for \$500,000 at 10 cents a share, taking the total raised with the \$2.4 million placement to \$3,015,500.

Last month, Bcal said that it had raised \$2.4 million in an over-subscribed placement at 10 cents a share and hoped to raise \$500,000 in a non-underwritten share purchase plan (BD: Aug 28, 2023).

Today, the company said all of its directors had participated in the share plan, and subject to shareholder approval, would apply for a further \$50,000 under the placement.

Bcal said chief executive officer John Hurrell, who currently resided in the US and was therefore ineligible for the share purchase plan, had applied for \$20,000 under the raise, which would be issued under Listing Rule 7.1.

The company said with the about \$3 million in funds raised through the placement and share purchase plan, an expected research and development tax incentive of about \$2.7 million and existing cash on hand it was “well-funded” with more than \$6.5 million.

Bcal executive chair Jayne Shaw said the company was “well positioned to progress the proprietary Breastest which will be launched in 2024”.

Bcal was unchanged at 11.5 cents.

## RESPIRI

Respiri says it has raised \$1.3 million in a private placement and would use the funds to payout the \$410,000 settlement sum of its Obsidian convertible note facility.

In May, Respiri said it had an agreement with Obsidian Global Partners LLC to issue \$4.5 million in convertible notes in two tranches, to buy distributor Access Managed Services LLC and raise a further \$2 million in a share plan at 3.4 cents a share (BD: May 24, 2023).

Last month, the company said it had raised \$2,384,420 in a share plan and the shortfall raised \$614,580, for a total of \$3,000,000, and later that month said it had raised a further \$900,000 in a private placement at 3.4 cents a share, taking the total raised to \$3.9 million (BD: Aug 8, 2023).

Today, Respiri said the additional funds would be used to further US working capital, to continue to drive patient acquisition with existing clients and to finalize and prepare for expected contracted clients which the company hoped to announce in the coming months.

Respiri chair Nicholas Smedley said the funds allowed the company “to remove the convertible note from our balance sheet, simplifying our capital structure, which is what our shareholders and the market wanted”.

“Now we continued to do what we have done, deliver [remote patient monitoring] patient numbers on existing contracts and secure significant new clients,” Mr Smedley said.

Respiri was up 0.1 cents or 3.1 percent to 3.3 cents with 1.4 million shares traded.

## VICTORIA GOVERNMENT, MODERNA AUSTRALIA

The Victoria Government says construction of Moderna's mRNA vaccine manufacturing factory has reached "the halfway mark, ahead of schedule".

A media release from the Victoria Minister for Industry and Innovation Ben Carroll said construction was on schedule to be completed in 2024, and the factory would have the capacity to produce 100 million vaccines a year for respiratory diseases.

The media release said the achievement was a "significant construction milestone for the facility, the first of its kind in the Southern Hemisphere".

The State Government said Moderna planned to manufacture various mRNA vaccines at the facility, including influenza, respiratory syncytial virus (RSV) and Covid-19.

The media release said the construction phase of the facility had employed 500 people, with up-to 500 additional employees needed for advanced manufacturing jobs once the facility was operational.

The State Government said the facility was a key component of Moderna's investment in Australia, complemented by the recent opening of its Regional Research Centre for Respiratory Medicines and Tropical Disease and Moderna Headquarters for Australia, New Zealand, South-East Asia and Oceania in Victoria (BD: Aug 15, 2023).

The State Government said Moderna was forming partnerships with Victoria's medical research institutes and clinical trial networks in the hope that Victorians would be among the first people to trial mRNA medicines for a range of health conditions.

Mr Carroll said Moderna's mRNA facility was "currently Australia's largest advanced manufacturing project".

"Today marks another important milestone in Victoria's partnership with the Commonwealth Government and Moderna, as we look to build Australia's mRNA industry, manufacture vaccines locally, create jobs and change lives for decades to come," Mr Carroll said.

## OSTEOPORE

Osteopore says it withdraws a previously announced investor relationship "as it is [too] early to confirm any details on the relationship and there is no agreement at this stage".

Last week, Osteopore said it had a joint venture agreement with the Shanghai-based Innoventures Inc to commercialize its orthopaedic products in China, saying that Innoventures had identified a prospective investor, a leading medical device and pharmaceuticals company in China, interested in the joint-venture (BD: Sep 12, 2023).

At that time, the company said it expected to launch the joint venture in Singapore, with Osteopore to provide Innoventures with an exclusive, royalty-free licence in return for 30 percent equity, with the high tibial osteotomy implant for knee joints to be the first product.

Today, the company said it had a memorandum of understanding with Innoventures for a joint venture to commercialize its products in China but regulatory approval and commercialization of its high tibial osteotomy implant would take about two-to-four years.

Osteopore said approval would be subject to the completeness of documentation and meeting regulatory requirements, so "the financial impact that the joint venture will have on the company cannot be assessed at this stage".

The company said that while the joint venture was "initially focused on orthopaedic applications of its products, the joint venture will have a right of first negotiation for Chinese rights for non-orthopaedic applications".

Osteopore said it would move toward executing a definitive agreement with Innoventures by November 30, 2023.

Osteopore fell 0.6 cents or 8.6 percent to 6.4 cents.

## [PROTEOMICS INTERNATIONAL LABORATORIES](#)

Proteomics has requested a suspension following Thursday's trading halt "regarding the application for regulatory approval of the Promarkerd test" (BD: Sep 14, 2023).

Trading will resume on the release of the announcement, which was expected by September 20, 2023.

Proteomics last traded at 90 cents.

## [DORSAVI](#)

Dorsavi says Aaron Chan will replace chief financial officer Troy Di Domenico and Justin Mouchacca will replace company secretary Brendan Case, effective from today.

Dorsavi said it had outsourced the role of chief financial officer to Mr Chan's consulting firm Upstart Advisory.

The company said Mr Chan was founder and director at Upstart and had previously worked as private client manager at Pricewaterhousecoopers (PWC) and as head of investment at Folk Capital.

Dorsavi said Mr Chan held a Bachelor of Commerce from the University of Melbourne.

Dorsavi said Mr Mouchacca was the principal of JM Corporate Services and was the company secretary and chief financial officer for a number of public companies.

According to his LinkedIn page, Mr Mouchacca held a Bachelor of Business from the Royal Melbourne Institute of Technology.

Dorsavi was untraded at 1.2 cents.