



Biotech Daily

Wednesday September 27, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: KAZIA, PATRYS UP 14%; PARADIGM DOWN 8%**
- * **PROF SARAH GILBERT CALLS FOR 'PANDEMIC PREPAREDNESS'**
- * **STARPHARMA DEP-IRINOTECAN, IO DRUG CANCER ACTIVITY, IN MICE**
- * **RACE: INDIA'S LAURUS LABS PRODUCES 3.25kg BISANTRENE**
- * **ORTHOCELL 8m DIRECTOR, CFO OPTIONS, 22% DIRECTORS PAY AGM**
- * **WALKER, AUCKLAND TRUST DILUTED TO 31.5% OF NEXT SCIENCE**
- * **BVF PARTNERS DILUTED TO 11% OF ACTINOGEN**
- * **IMPEDIMED APPOINTS DR STEVEN CHEN CMO**
- * **BIO-MELBOURNE NETWORK TO HOST EU ENTRY MASTERCLASS**

MARKET REPORT

The Australian stock market fell 0.11 percent on Wednesday September 27, 2023 with the ASX200 down 7.9 points to 7,030.3 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and one was untraded.

Kazia and Patrys were the equal best, both up 14.3 percent to 16 cents and 0.8 cents, respectively, with 75,306 shares and 463,549 shares traded, respectively.

Mesoblast and Starpharma climbed more than nine percent; Resonance rose 8.7 percent; Actinogen was up five percent; Alcidion, Micro-X and Resmed were up more than four percent; Clinuvel, Cyclopharm, Emvision and Neuren improved more than three percent; Avita, Imugene and Nova Eye rose more than two percent; Telix was up 1.15 percent; with Pro Medicus and SDI up by less than one percent.

Paradigm led the falls, down five cents or 8.3 percent to 55 cents, with 2.3 million shares traded. Cynata lost 6.9 percent; Compumedics and Immuteq were down five percent or more; Opthea fell 4.5 percent; Dimerix and Prescient lost more than three percent; Impedimed and Volpara shed more than two percent; 4D Medical, Amplia, Cochlear, CSL, Orthocell and Polynovo were down one percent or more; with Nanosonics down by 0.94 percent.

[THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY](#)

By JAMIE MILLER, DEPUTY EDITOR

Oxford University professor of vaccinology and co-developer of the Astrazeneca Covid-19 vaccine Prof Sarah Gilbert says we need to be more prepared for a future pandemic.

At a Doherty Institute talk on vaccine production, Prof Gilbert said of the 2020 severe-acute respiratory syndrome coronavirus 2 (Sars-Cov-2) outbreak, that the “question we should be asking around the world is: ‘how do we make sure we don’t get into this situation again?’”

The discussion was led by Doherty director Prof Sharon Lewin with a panel of three researchers who had each helped develop a separate Covid-19 vaccine; Prof Gilbert, the University of Melbourne’s head of vaccine and immunization research Prof Terry Nolan and the University of Queensland professor of virology Prof Paul Young.

In her book ‘Vaxxers’ co-authored with fellow Astrazeneca vaccine researcher Dr Catherine Green, Prof Gilbert said developing the Covid-19 vaccine was additional to her work “developing vaccines against five other diseases”.

Prof Gilbert said the Astrazeneca Covid-19 vaccine came from “more than 25 years of vaccine research” including prior vaccine manufacturing and 12 clinical trials of the same type of vaccine prior to April 2020 when the Covid-19 vaccine trials began.

Prof Gilbert said even though much of the preparatory work had been done “getting funding was a huge challenge”.

Prof Gilbert said that in 2019 she had tried to start a project on accelerating developing vaccines by working “in a different way” from the academic model of studying, publishing peer-reviewed results and fund raising which was “very, very slow”.

“I wasn’t successful in getting that project funded, but at least it meant that we had done the thinking about what we would need to do to respond fast, if there was an outbreak of an unknown virus,” she said.

Prof Gilbert said the planning of how to develop a vaccine in an emergency response quickly was put into practice a year later with the outbreak of an unknown respiratory virus, eventually called Sars-Cov-2 and its disease, known as Covid-19.

“I had a little bit of research funding that I could use to just kick-start the process in the lab, but once we get to manufacturing the vaccine for clinical trials, that is an expensive process and it was a constant problem through the Spring of 2020,” Prof Gilbert said.

“We formed a partnership with Astrazeneca, something negotiated by others in the University in the early months of 2020, and Astrazeneca agreed to work with us to take on the manufacturing of the vaccine which we had started for our first clinical trial, Prof Gilbert said. “But we were going to need a lot more of it for the full clinical development and commercial supply after that.”

"[Astrazeneca] didn't fund us directly, we had funding from the UK Vaccines Task Force, but what they did was set up a fantastic manufacturing network ... [and] transferred [our vaccine] to 25 manufacturing sites worldwide ... including CSL," Prof Gilbert said.

Prof Gilbert said that it was the outbreak of the Ebola virus in 2014, and the world's "really quite poor response to dealing with that" that pushed thinking about outbreak pathogens that were known to have caused previous outbreaks and stimulated the puzzle of vaccine development for those pathogens before future outbreaks.

"We are nowhere close to completing that puzzle, we have hardly begun it and we really need to return to that," Prof Gilbert said.

"But it's not just about the vaccines, it's about the diagnostics ... and the social science studies of how people respond to these interventions," Prof Gilbert said.

Prof Gilbert said "unfortunately [the pandemic] ... has probably moved out of the public eye, but we need to keep it there as there is a lot more we need to do to keep countries protected in the future".

The University of Queensland's Prof Paul Young said that in Australia "we are getting more and broader engagement by industry in focus on potential pandemic type agents and the development of both vaccines and therapeutics to combat those, as a toolkit".

Prof Young said a future outbreak "will happen ... we can guarantee that, exactly whether it is a pandemic on the scale that we are currently seeing or a smaller epidemic is yet to be seen".

"What we need to be thinking about in Australia is not just developing capabilities in the manufacturing phase, but also upstream development phases," Prof Young said.

Prof Young said the biggest hurdle for most innovation coming out of research and development in Australia was whether a developing product could be translated into "actually going to phase I clinical trials".

"It is an extraordinarily complex process; you need a lot of expertise but you also need to be able to make that product in the early stages, and that's a very expensive prospect," Prof Young said.

In developing an alternate "molecular clamp vaccine technology" at the University of Queensland, Prof Young said eight years of prior research had gone into development before the pivotal moment of receiving \$15 million in funding, over three years.

With the funding, Prof Young said researchers "were able to reach out and support a wider team, that included people at Doherty ... and ultimately CSL, who agreed to partner with us in early 2020". Prof Young said "ultimately it is about scale".

"Research and development funding is sitting at 1.65 percent of [gross domestic product], which is in the bottom third of [Organisation for Economic Co-operation and Development] countries ... we need to be shifting that up to at least three percent," Prof Young said.

STARPHARMA HOLDINGS

Starpharma says dendrimer enhanced product (DEP)-irinotecan with immuno-oncology (IO) agents shows anti-tumor activity for colorectal and ovarian cancer, in mice.

Starpharma said that combined with data from human clinical trials and other pre-clinical work, DEP-irinotecan in combination with an immuno-oncology agent or a poly- adenosine diphosphate (ADP) ribose polymerase (PARP) inhibitor showed “superior anti-tumor activity and significant survival benefit when compared to these agents delivered alone in multiple [colorectal cancer] models”.

Earlier this month, the company said that early data from its phase I/II trial of DEP-irinotecan for colorectal and ovarian cancer showed “durable anti-tumor responses” (BD: Sep 13, 2023).

Starpharma said that treatment with DEP-irinotecan in combination with immuno-oncology agents, such as pembrolizumab, or Keytruda, showed “no immune-mediated adverse events”, which could occur with immune-oncology agents.

The company said that DEP-irinotecan in combination with AstraZeneca’s Olaparib, or Lynparza, was used to treat a colorectal cancer model resistant to olaparib alone and “increased anti-tumor effects” compared to DEP-irinotecan alone, and also prolonged survival.

Starpharma said it would present the data in three separate posters at the International Conference on Molecular Targets and Cancer Therapeutics in Boston on October 11 to 15, 2023.

The company said the three posters were titled:

‘A HER2 targeted polylysine dendrimer nanoparticle radiotheranostic demonstrates excellent tumor accumulation, rapid clearance from circulation, and promising performance in PET-CT imaging’;

‘A phase I/II study of dendrimer-enhanced (DEP) SN38 (SN38-SPL9111 / DEP irinotecan) in patients with advanced solid tumours’; and

‘An SN38 dendrimer nanoparticle, DEP irinotecan (SN38-SPL9111), demonstrates efficacy in mouse models of gastrointestinal cancer and augments anti-tumor effects of immune checkpoint blockade and PARP inhibition’.

Starpharma said that, given the results, it was engaged in discussions with potential commercial partners, including companies that sell immuno-oncology drugs.

Starpharma was up 1.5 cents or 9.4 percent to 17.5 cents.

RACE ONCOLOGY

Race says the Andhra Pradesh, India-based Laurus Labs has produced the first 3.25kg good manufacturing standard batch of bisantrene dihydrochloride.

Race said the batch was manufactured using an improved process that it considered scalable to commercial quantities.

The company said it had successfully transferred knowledge of the manufacturing process from the previous manufacturer to Laurus, with “significant” work undertaken on manufacturing process impurities.

Race executive director Dr Pete Smith the company had “sufficient active pharmaceutical ingredient for our RC220 ... drug product manufacturing program and near-term clinical trials”.

“As an unexpected bonus, there have been some discoveries made at Laurus during the manufacturing campaign that can add to our overall intellectual property position,” Dr Smith said.

Race was up eight cents or 9.4 percent to 93 cents.

ORTHOCELL

Orthocell says shareholders will vote to issue 8,000,000 options and 250,000 shares to directors and the chief financial officer and increase director remuneration 22 percent. Orthocell said its annual general meeting would vote to issue chair John Van Der Wielen 250,000 shares at 36.5 cents a share, as well as 4,000,000 options exercisable at 40.0 cents and expiring May 29, 2028.

The company said shareholders would vote to ratify the issue of 3,000,000 options exercisable at 40.0 cents and expiring March 8, 2028 to director Dr Ravi Thadhani. Orthocell said that it proposed to issue 500,000 plan options exercisable at 36 cents and expiring four years from date of issue under its incentive plan to both chief financial officer Nicole Telford and retiring director Prof Lars Lidgren.

Orthocell said that Ms Telford was the spouse of managing-director Paul Anderson. The company said shareholders would vote to ratify the issue of two tranches of 1,000,000 options exercisable at 60.0 cents by May 26, 2026 and 1,000,000 options exercisable at 80 cents by May 26, 2027, to the Veritas Securities' nominee Exertus Capital.

Orthocell said shareholders would vote to adopt the remuneration report, re-elect directors Dr Thadhani, Mr Van Der Wielen and Matthew Callahan, approve an additional 10 percent placement capacity and increase non-executive director fees by 22.2 percent from \$450,000 to \$550,000 and replace the constitution.

The meeting will be held at Building 191, Murdoch University, South Street, Perth on October 31, 2023 at 10am (AWST).

Orthocell fell half a cent or 1.3 percent to 37 cents.

NEXT SCIENCE

Walker Group and Auckland Trust Co say they have increased and been diluted in Next Science from 83,547,061 shares (38.90%) to 83,622,188 shares (31.46%).

In August, Next Science said it has raised \$8.5 million in an oversubscribed share plan at 42 cents a share and more than \$1 million from a US offer, taking the total with August's placement to \$21.5 million. (BD: Sep 22, 2023).

Today, the Sydney-based Lang Walker, as sole shareholder of Walker Group Holdings Pty Ltd, and Auckland Trust said that between July 1 and October 17, 2022 it bought shares, with the single largest purchase on July 1, 2022 of 26,333 shares for \$19,465 or 73.9 cents a share.

Next Science was unchanged at 41.5 cents.

ACTINOGEN MEDICAL

The San Francisco-based BVF Partners says its 247,334,680 share-holding in Actinogen has been diluted from 12.35 percent to 11.16 percent.

Earlier this month, Actinogen said it had raised \$10,001,449, with \$4,645,076 in subscriptions and \$5,356,373 in shortfall commitments through a rights issue at 2.5 cents a share (BD: Sep 7, 2023).

Actinogen was up 0.1 cents or five percent to 2.1 cents with 2.5 million shares traded.

IMPEDIMED

Impedimed says it has appointed Dr Steven Chen as its chief medical officer, effective from September 26, 2023.

Impedimed said Dr Chen was previously chief medical officer of Avelas Biosciences and the University of California, Davis chief of breast surgery, associate program director of the surgical oncology training program at the Los Angeles, California-based City of Hope National Medical Center, and was president of the American Society of Breast Surgeons. The company said Dr Chen was a surgeon in San Diego, California and the director of surgical oncology at the Southern California-based Oasis MD.

Impedimed said Dr Chen held a Doctor of Medicine and a Master of Business Administration from the University of Michigan.

Impedimed fell half a cent or 2.9 percent to 17 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will host a “masterclass” on how to enter European Union markets for long-term success, in November.

The Bio-Melbourne Network said the class, titled ‘Unlocking Europe: Operational Priorities for EU Market Entry’, was sponsored by the Victoria State Government and would include industry experts from Dublin’s Orphan Drug Consulting.

The Network said the class would guide participants on how to “prioritize operations, plan and budget for expansion, optimize product supply strategy, negotiate with investors and potential partners, or go it alone”.

The Bio-Melbourne Network said the program would include a forum at Allens law firm, 37th Floor, 101 Collins Street, Melbourne on November 14, 2023 from 4pm to 6:30pm (AEDT), a workshop at the Monash Conference Center, Level 7, 30 Collins St, Melbourne on November 15 from 8:30am to 5pm (AEDT), and a 30-minute individual session November 16 and 17, 2023.

For details and registration go to: <https://bit.ly/3ERtHgL>.