



**IMUGENE**

Developing Cancer  
Immunotherapies

ASX:IMU

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CHECKvacc  
Phase 1 study  
advances to  
cohort 3

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Imugene presents  
new PD1-Vaxx  
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2022 WCLC

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Successful  
A\$80M  
Institutional  
Placement



# IMUGENE FEATURED AT THE J.P. MORGAN HEALTHCARE CONFERENCE



February 2023

# CALENDAR 2022 SAW US TAKE LARGE STRIDES RIGHT ACROSS THE BUSINESS

Leslie Chong  
Imugene CEO and Managing Director



## CEO UPDATE

A happy new year to our shareholders and interested parties as we bring you our latest shareholder newsletter following a big start to 2023, where for the first time we presented at the renowned JP Morgan Healthcare Conference. With biotechnology and pharmaceutical executives and investment professionals from all around the world on the ground in San Francisco for a range of events, meetings and networking, we take great pride in being invited to present the Imugene story at the headline conference this year.

**Watch Imugene CEO Leslie Chong's presentation at the J.P. Morgan Healthcare Conference in San Francisco: [bit.ly/IMU\\_JPM](https://bit.ly/IMU_JPM)**

Calendar 2022 saw us take large strides right across the business, and I wanted to take the opportunity to look back on the key developments and how this has the company so strongly positioned moving forward.

### Advancing our assets and technologies

While the entire portfolio has seen important progress throughout 2022, our CF33 Oncolytic Virus platform has delivered an abundance of news flow. The Phase 1 clinical trial of CHECKvacc targeting triple negative breast cancer has reached cohort 3, while the VAXINIA Phase 1 MAST study has reached cohort 2 in both the intravenous and intratumoral arms of the trial.

After being put on show in three abstracts at the Society for Immunotherapy of Cancer (SITC) Annual Meeting during November, our onCARlytics technology will receive FDA IND and will advance toward the clinic, with the first patient expected in 2023.

We were pleased to announce our final HER-Vaxx Phase 2 overall survival results in Advanced Gastric Cancer (HERIZON), which strengthened the foundation for this platform as the Phase 2 nextHERIZON trial commenced in September with the Phase 2 neoHERIZON trial to follow.

See further on in the newsletter for the value inflection points we expect to manifest from these assets and programs during 2023.

### Collaboration with high calibre partners

We now have the opportunity to collaborate and partner with some outstanding names in the biotechnology sector globally. Early in 2022 we added Roche to the list after announcing a supply agreement to evaluate PD1-Vaxx in combination with Roche's atezolizumab (Tecentriq®). This is in addition to our supply agreement with Merck KGaA and Pfizer for HER-Vaxx to be evaluated in combination with avelumab (BAVENCIO®).

We've also recently added to our scientific collaborators whereby we combine our onCARlytics technology with CD19 targeting therapies – with fellow ASX-listed biotech Arovella Therapeutics the latest such partner. Along with Celularity® and Eureka Therapeutics®, we're pushing to produce a therapy that can obliterate solid tumours in a fashion never seen before.

### Bolstering our team and financial position

We're particularly proud of the people and culture we've built at Imugene, mixing top-shelf talent into a team-oriented, high-performing ethos that we continue to see delivering on our goals. Several key appointments have been announced in the last six months, including CMO Dr Giovanni Selvaggi, CFO Mike Tonroe and Vice President CMC Paul Wright, while the board has been strengthened with the addition of Dr Jakob Dupont. Read on in the newsletter for more on these quality individuals.

In a year of uncertainty in the biotech sector, we were thrilled to be able to reinforce our balance sheet with an institutional placement to raise \$80m, giving the company an enviable cash runway of \$164m as reported in our September quarterly report. This allows us to progress our variety of clinical programs unimpeded, providing Imugene with a strong foundation for success.

We continue to spruik our achievements and updates at the various medical and investment conferences both locally and abroad – in the last 12 months, this has included J.P. Morgan, ASCO, WCLC, ESMO, SITC, ASX Connect and the Bioshares Summit.

We're also amplifying all of our activity using traditional media and the various electronic channels available to us to enable Imugene to reach a wider audience. In 2022, this resulted in a combined 399 social media posts, 31,700 views on the company's YouTube channel and 232,000 page views on the Imugene website.

We're incredibly eager and committed to seeing Imugene reach new heights in 2023. We're aggressively developing a broad portfolio of high-quality assets, which is being overseen by a world-class team supported by an outstanding financial position. This is what gives myself and the team such confidence as we enter another important year for your company.



# Q&A WITH DR DUPONT



**Imugene was pleased to add Dr Dupont to our Board as a Non-Executive Director on 7 September 2022, after a distinguished 20-year career as an industry and academic drug development expert, specialising in oncology and other therapeutic areas.**

He has made major contributions to the development and approval of ten oncology drugs and has orchestrated successful development programs for numerous drugs.

Dr Dupont is currently the Global Head of Research and Development at NASDAQ-listed Atara Biotherapeutics (NASDAQ: ATRA), where he oversees all research and development including three clinical-stage programs spanning Phase 1 through to Phase 3, and numerous preclinical programs. He also oversees key collaborations with academic and pharma partners, holds leadership and guidance roles for various teams within the business and acts as a spokesperson to investors and the Board of Directors.

**We would like to formally welcome Dr Dunport to Imugene with a few questions:**

**What gets you most excited about what you do?**

I love working, as part of a great team, to develop new therapies to help patients with serious diseases. I feel so privileged to work in biotechnology where we innovate amazing new science for the betterment of humankind.

**Why join Imugene and why now?**

I think it is a great company with interesting technology, cutting edge platforms, and promising therapeutics. I find the platforms at Imugene to be so interesting because of the focus on oncolytic viruses (which is a platform that I have worked on and been interested in since my academic days); the novel concept of combining an oncolytic virus platform with CART really excites me (as someone who has a long history of working in cell

therapy); and the B-cell platform directed against important targets like HER2 and PD1 is fascinating and holds great promise.

I also think the Imugene team is terrific. Leslie and I have worked together in the past at Genentech, and I think she is great. I believe the company is at an exciting inflection point. There is clear evidence of clinical benefit with the platforms and the next phase of the company will be incredibly exciting.

**How is Imugene progressing towards bringing novel therapies in the immunotherapeutic landscape?**

I think the company is making great progress. The company has made a lot of good decisions to strategically build the pipeline and the Imugene therapeutic platforms. The platforms are also complementary to one another which yields exciting value creation opportunities—for patients and for the company. I also compliment the company on executions. My favorite part of our work is to conduct a clinical trial and to find out if the grand experiment worked to help patients. I really compliment the team at Imugene for effectively designing trials, initiating the trials and then enrolling the trials. Without this operational execution we can't know if the treatments will truly help patients in great need. I also think the company has done a tremendous job raising money to do all the cutting edge experiments and clinical trials. This is notable in these challenging times for biotech. The company deserves a lot of credit.

**What excites you about immunotherapy cancer treatments?**

This in many ways is my life's work. I worked in my first cancer immunology laboratory in 9th grade in high school. Since that time I have spent many years working on many types of cancer immunotherapy from cell therapy – such as CART, to cancer vaccines, to cytokine therapy, to checkpoint inhibitors, and even oncolytic viruses. I have endless fascination with cancer and its ability to escape a patient's immune response. And I have even more fascination in how we can harness the immune system to fight cancer.

**What is unique about the immunotherapies developed by Imugene and which area will they have the greatest benefit?**

I think Imugene really has a differentiated approach to cancer immunotherapy. There are so many companies out there that do checkpoint inhibitors, cell therapy, cytokines, etc. But the platforms and pipeline that Imugene have is really unique. I love the idea of infecting cancer cells with a virus that 'forces' the cancer cell to become visible to the immune system (by inserting a tumour antigen like CD19) and then chasing this with a CART (directed against CD19). I also think the B cell platform targeting PD1 and HER2 and other antigens holds great promise. Finally, the oncolytic virus is really an underappreciated platform in these days of more mature approaches to cancer immunotherapy. I think there are opportunities to re-visit this platform and make the most of this to help patients. Imugene is clearly a leader here.

# RECAP OF RECENT NEWS

## CHECKVACC PHASE 1 STUDY ADVANCES TO COHORT 3

**We were informed by City of Hope® during August 2022 that the first patient had been dosed in cohort 3 of the Phase 1 clinical trial of oncolytic virotherapy candidate CHECKvacc. The trial is recruiting patients with triple negative breast cancer (TNBC).**

The purpose of the single centre, dose escalation study is to evaluate safety and initial evidence of efficacy using intratumoral administration of the drug.

During December new and first data from the trial was part of a poster presentation at the 2022 San Antonio Breast Cancer Symposium (SABC 2022). Dr Yuan Yuan from Cedars Sinai Medicine in Los Angeles, alongside Dr Jamie Rand from City of Hope®, outlined that CHECKvacc was safe and well tolerated at the dose levels tested, with highlights and results including:

### Key Findings

- 1 From October 2021 to June 2022, 6 patients were enrolled in this ongoing study and received at least 1 dose of CHECKvacc injection at dose level 1 ( $1 \times 10^5$  pfu) or dose level 2 ( $3 \times 10^5$  pfu).
- 2 No dose-limiting toxicities were observed. No treatment related adverse events were reported for 6 patients except 1 patient with injection site discoloration.
- 3  $^{99m}\text{Tc}$  SPECT imaging for virus tracking from virus induced replication of the human sodium iodide (hNIS) transgene shows enhancement in 4/6 (67%) patients in the first 2 dose levels. Enhancement was greater in patients with injection of nodal disease compared to dermal metastasis.
- 4 SPECT imaging of patient COH-004 (DL-2) on C1D8 showed significant enhancement of injected lymph node.
- 5 Baseline and on-treatment tumour biopsies of patient COH-004 using spatial immune profiling showed an increase in PD-L1 positive cells following treatment with CHECKvacc, demonstrating immune activation and tumour micro environment changes in association with response to therapy.

## VAXINIA MAST STUDY MARCHES ON

We've been pleased to be able to provide continuous updates on the progress of the Phase 1 MAST (Metastatic Advanced Solid Tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA).

In December, this included the announcement of the first patient being dosed as part of the intravenous (IV) cohort 2 of the trial. Meanwhile, the intratumoral cohort 2 has continued to progress after the first patient was enrolled in October, 2022.

The MAST trial delivers a low dose of VAXINIA to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment. The City of Hope®-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models.

In other developments related to VAXINIA, we welcomed receipt in September of the DIR licence required to expand the MAST trial within Australia. The Australian Government's Office of the Gene Technology Regulator (OGTR) requires this of organisations involved in the intentional release of genetically modified organisms into the environment. Using approximately 10 sites both within the US and Australia, we anticipate recruiting 100 patients for the MAST study.

During October we also secured our supply of VAXINIA by partnering with contract development and manufacturing organisation (CDMO) ABL, specialists in manufacturing solutions for biopharmaceuticals including oncolytic viruses and vaccine candidates. ABL will perform the manufacturing of VAXINIA for the MAST clinical studies and ensures Imugene's access to world-class CDMO services.



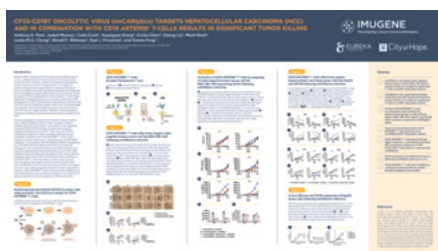
## RECAP OF RECENT NEWS

# ONCARLYTICS ON SHOW AT SITC

Being one of the most prestigious events in immunotherapy, our team was proud to have three abstracts related to the onCARlytics platform featured at the Society for Immunotherapy of Cancer (SITC) Annual Meeting held in Boston during November. Each poster was presented by Dr Anthony Park from Dr Saul Priceman’s lab at City of Hope®.

To view each of the posters below, visit:

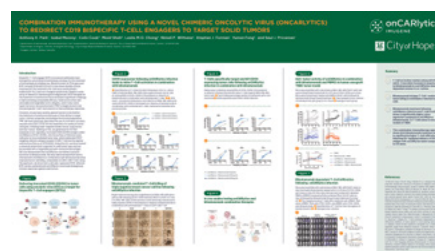
[bit.ly/IMU\\_PRESENTATIONS](https://bit.ly/IMU_PRESENTATIONS)



**CF33-CD19t oncolytic virus (onCARlytics) targets hepatocellular carcinoma (HCC) and in combination with CD19-Redirected ARTEMIS® T Cells results in significant tumour killing.**



**CF33-CD19t oncolytic virus (onCARlytics) in combination with off-the-shelf allogeneic CYCART-19 T-Cells targeting de novo CD19t expressing tumours.**



**Combination immunotherapy using a novel chimeric oncolytic virus (onCARlytics) to redirect CD19 bispecific T-Cell engagers to target solid tumours.**

## IMUGENE & AROVELLA JOIN FORCES TO EXPLORE POTENTIAL IN SOLID TUMOURS

We were excited to recently welcome yet another partner to test our onCARlytics technology in combination with novel cell therapy, as we announced a collaboration with ASX-listed Arovela Therapeutics (ALA) focused on seeking out and destroying solid tumours.

Arovela’s lead product, ALA-101, contains a Chimeric Antigen Receptor (CAR) that targets tumour cells producing CD19 on their surface, with CD19 expression commonly occurring on the cell surface of blood cancers. As Imugene’s onCARlytics enables solid tumour cancers to

express CD19 on their surface, creating the opportunity for ALA-101 to destroy the solid tumour cells.

Preclinical studies as part of this collaboration are well underway and a readout from this is expected in H1 CY23.

Advancements in treatment of solid tumours are an enormous market with a significant unmet need, representing 90% of diagnosed cancer cases, and as of 2021, the solid tumour market was said to be valued at US\$210 billion.

## nextHERIZON PHASE 2 TRIAL OPENS WITH FIRST PATIENT DOSED IN ADELAIDE

A key milestone in the second half of the year was the commencement of the nextHERIZON Phase 2 clinical trial that is investigating Imugene's HER-Vaxx in combination with chemotherapy or pembrolizumab for patients with HER-2+ gastric cancer. The first patient was dosed at Queen Elizabeth Hospital in Adelaide, Australia, overseen by Principal Investigator Professor, Tim Price. Further sites are expected to recruit patients in both Australia and the US, where FDA IND approval has been received.

The open-label, multi-centre, signal-generating, Phase 2 clinical trial is designed to assess the safety and efficacy of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER-2/neu over expressing gastric or gastroesophageal junction adenocarcinomas, who have previously progressed on trastuzumab. The study's primary endpoints are safety and response rate, while secondary endpoints include duration of response, progression-free survival, overall survival, and bio marker evaluation.

## IMUGENE PRESENTS NEW PD1-VAXX DATA AT THE 2022 WCLC

In August, we were pleased to present new PD1-Vaxx data from the Phase 1 IMPRINTER trial at the International Association for the Study of Lung Cancer 2022 World Conference on Lung Cancer (WCLC 2022). The conference was held from 6-9 August in Vienna, Austria and is the world's largest international gathering of clinicians, researchers and scientists in the field of lung cancer and thoracic oncology.

We were encouraged to see positive signals from the phase 1 trial, which was designed to look for safety, tolerability and early response signals to determine the optimal dose for further development. The results gave us the confidence to progress to Phase 1b combination studies in treatment naïve patients. A late-stage patient who had been in the trial for over 18 months had their tumour burden reduced to zero, without chemotherapy. It was very gratifying for us to see the potential for this treatment to improve the quality of life for patients.

Professor Michael Boyer M.D., MBBS, FRACP, PhD, Chris O'Brien from Lifehouse Hospital presented a poster named "Phase 1: IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer".

## ESMO ASIA PLAYS HOST TO POSITIVE NEW HER-VAXX HERIZON DATA

Positive new data on overall survival results in our HER-Vaxx HERIZON study was delivered to attendees as part of an oral presentation at the ESMO Asia Congress held in Singapore during December.

The trial's principal investigator Marina Maglakelidze presented the study design, information regarding demographics and characteristics of the 36 patients in the trial, and data covering safety and adverse events.

### Key Conclusions

**HER-Vaxx + chemotherapy showed a statistically significant 42% overall survival benefit compared to chemotherapy alone (13.9 vs 8.3 months)**

**Duration of response is longer in the HER-Vaxx + chemotherapy arm over chemotherapy alone (30 vs 19 weeks)**

**Vaccination with HER-Vaxx induced persistent HER-2 specific antibodies which correlated with a clinical response as proof of concept for a first-in-class B-cell immunotherapy based on HER-2 peptides**

**No significant additive toxicity was seen when HER-Vaxx was administered in combination with chemotherapy.**

**The full presentation provided at ESMO can be viewed at:**

[bit.ly/IMU\\_PRESENTATIONS](https://bit.ly/IMU_PRESENTATIONS)



## RECAP OF RECENT NEWS

### IMUGENE FEATURED AT THE J.P. MORGAN HEALTHCARE CONFERENCE

**Imugene's CEO Leslie Chong had the pleasure of presenting at the prestigious 41st Annual J.P. Morgan Healthcare Conference, held 9-12 January 2023 at The Westin St. Francis in San Francisco, California, USA.**

The J.P. Morgan Healthcare Conference is one of the largest and most prestigious events on the healthcare and biotechnology industry calendar each year, with more than 8,000 attendees at the 2022 event.

This invite is an honour that is rarely extended to Australian biotechnology companies. It is an acknowledgment of our promising future by the investment community and was great opportunity to showcase our technology to a new global audience.



### INVESTOR ROADSHOW WITH PROFESSOR YUMAN FONG & DR SAUL PRICEMAN

We were thrilled to host a week-long roadshow for shareholders and prospective investors during November that included the co-inventors of Imugene's onCARlytics technology, Professor Yuman Fong and Dr Saul Priceman.

The week saw Professor Fong, Dr Priceman and members of Imugene's management team present at events and meetings across Australia with a combined ~300 investors attending the presentations.

We're planning the next such roadshow for March, 2023, and will be in contact via our email and social media channels with the full details in due course.

### SUCCESSFUL A\$80M INSTITUTIONAL PLACEMENT

In September 2022, we were excited to announce a placement of A\$80 million at \$0.20 per share, which was subscribed by two leading institutional investors with significant healthcare and biotechnology expertise. The high calibre of these institutional investors is a testament to our company, especially considering the recent volatility in the biotechnology indices.

The funds raised will strengthen our balance sheet and provide a long runway for the development of Imugene's deep pipeline of clinical programs. This may be further assisted by partnering and licensing opportunities and R&D rebates in the near future. In addition, the funds provides us with flexibility to add complementary assets should attractive opportunities present themselves.





# NEW APPOINTMENTS TO THE IMUGENE EXECUTIVE TEAM



## DR GIOVANNI SELVAGGI

Dr Selvaggi commenced his role as Chief Medical Officer (CMO) on 4 October 2022. Dr Selvaggi is a pulmonologist, trained in thoracic malignancies management with a focus on lung cancers and mesothelioma.

He brings over 10 years of experience in the pharmaceutical industry in clinical development focused roles with GlaxoSmithKline (GSK), Novartis Oncology and Bristol Myers Squibb. Most recently, he was with US oncology company Xcovery Holdings Inc where he was CEO and CMO early in 2021.

Dr Selvaggi was previously an attending physician of Thoracic Oncology at San Luigi Hospital in Turin, Italy. This included being an investigator on various oncology clinical trials.

He studied at the Medical School at the University of Torino in Italy, where he also completed his Residency in Respiratory Medicine at the Postgraduate Medical School.



## MIKE TONROE

Mr Tonroe commenced his role as Chief Financial Officer (CFO) in early September 2022. He has extensive experience as a CFO and Company Secretary within the biopharmaceutical industry across US, Canada, UK and Hong Kong, in addition to Australia.

Most recently, Mr Tonroe was CFO and Company Secretary at ASX and NASDAQ-listed Genetic Technologies Limited and Opthea Limited, and prior to that was in the same role for private business Australian Synchrotron Company Ltd. These tenures included management of the US IPO and NASDAQ listing of Opthea along with M&A, restructuring, capital raising and leading the finance function across these businesses.

Mr Tonroe graduated in Business Studies with Honours from Buckingham University UK, and is a Fellow of the Institute of Chartered Accountants in England & Wales. He is a member of the Australian Institute of Company Directors.



## PAUL WRIGHT

Mr Wright commenced his role as our Vice President CMC (Chemistry, Manufacturing and Controls) on 4 October 2022. His areas of expertise include monoclonal antibodies, bioconjugate vaccines, viral vectors, and oncolytic viruses, with experience spanning all phases of development.

Prior to joining Imugene, he spent 21 years at Pfizer holding positions of increasing responsibility within the Global Manufacturing and Vaccine Research and Development organisations. Most recently, he was Director of Bioprocess and Analytical and member of the Executive Leadership team within Cancer Vaccines and Immunotherapeutics.

His work included leading the successful process development, tech transfer, and clinical trial manufacture of Pfizer's vaccinia-based oncolytic virus (PF-07263689).

Mr Wright holds a Bachelor of Science with Honours, Cell and Molecular Biology from Anglia Ruskin University, Cambridge UK.



# FROM THE CHAIR

**As evidenced by the wide array of content in this newsletter, our team continues to operate with high intensity as we build the company and develop our world class technologies and clinical program.**

Just a month into calendar 2023 and our team has hit the ground running with presentations at the J.P. Morgan Healthcare Conference and ASCO GI, announcement of ethics approval for VAXINIA in Australia, as well as having held our annual strategy meeting.

It was overwhelming to see the response to our roadshow in November featuring Professor Yuman Fong and Dr Saul Priceman, and we thank shareholders who took the time out to attend the events throughout the week as well as our AGM. We anticipate hosting similar roadshow functions during 2023, including one during March that we'll be in contact on soon.

Having recently addressed shareholders in a detailed letter released to the ASX on 6 January 2023, I want to avoid revisiting old territory, but again emphasise

that despite what was a grim year in capital markets and valuations within the biotechnology sector, the opportunity in front of Imugene has only grown stronger.

I encourage those that have not read the Letter to Shareholders recently published to do so by visiting [bit.ly/IMU\\_LETTER](https://bit.ly/IMU_LETTER). Here you'll be able to read more on my thoughts about the strength of Imugene, a view on recent developments and the year ahead.

I'm as excited about 2023 as any year in Imugene's history, and the rest of the board, management and wider team shares this enthusiasm. We look forward to bringing you continued updates soon and throughout the year.

**Paul Hopper**  
**Executive Chairman**



**The Imugene team at its annual strategy meeting**  
January 2023





# IMUGENE

Developing Cancer Immunotherapies

ASX:IMU

## THE NEXT 12 MONTHS

Technology	Milestone
VAXINIA	MAST: IV Cohort 2 Cleared
VAXINIA	MAST: Combination EPI IT and /or IV
CHECKvacc	COHIST: IT Cohort 3 Cleared
onCARlytics	FDA IND
PD1-Vaxx	IMPRINTER: Combination FPI
CHECKvacc	COHIST: Optimal Biological Dose
CHECKvacc	Dominica: FDA IND
HER-Vaxx	neoHERIZON: CA Clearance
VAXINIA	MAST: Optimal Biological Dose (Monotherapy IV and/or IT)
HER-Vaxx	nextHERIZON: Interim Data Readout
HER-Vaxx	neOHERIZON: FPI
onCARlytics	FPI
VAXINIA	MAST: Combination OBD IV

### About

Imugene is a clinical stage immuno-oncology company developing a range of new treatments that seek to activate the immune system of cancer patients to identify and eradicate tumours.

### Contact

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### Connect



[imugene.com](http://imugene.com)

### Financial Snapshot as at 25 January 2023

ASX code	IMU
Market cap	\$963M
52 week high/low	\$0.345 / \$0.13
Cash balance at 31 Dec 22	\$162M
Industry	Biotechnology

Note: All figures are in Australian dollars. Market capitalisation calculations based on ordinary shares (6.422) only and excludes the dilutive impact of options outstanding (0.477b).

### Top 5 Shareholders

JP Morgan Nominees Australia Pty Limited	9.12%
HSBC Custody Nominees (Australia Limited)	5.77%
Paul Hopper	4.94%
Mann Family	4.60%
Citicorp Nominees Pty Limited	4.58%

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