

ASX RELEASE

6 November 2020

KAZIA ANNUAL GENERAL MEETING MATERIALS

Sydney, 6 November 2020 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide the Chairman's Address and CEO presentation which will be discussed at our Annual General Meeting at 9am this morning.

[ENDS]

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is paxalisib (formerly GDC-0084), a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib entered a phase II clinical trial in 2018. Interim data was reported most recently at AACR in June 2020, and further data is expected in 2H 2020. Five additional studies are in start-up or ongoing in other forms of brain cancer. Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells and is being developed to treat ovarian cancer. TRX-E-002-1 has completed a phase I clinical trial in Australia and the United States with the final data expected in the second half of calendar 2020. Interim data was presented most recently at the AACR conference in June 2020. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

For more information, please visit <u>www.kaziatherapeutics.com</u>.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.

KAZIA ANNUAL GENERAL MEETING 6 NOVEMBER 2020

CHAIRMAN'S ADDRESS

Ladies and Gentlemen,

It is my pleasure to welcome you to the Annual General Meeting for Kazia Therapeutics Limited. Due to the ongoing COVID-19 pandemic, our AGM this year is being conducted in a virtual format. I regret not having the opportunity to meet with shareholders in person on this occasion, but I very much hope that we will soon be able to return to some degree of normality.

Indeed, the virtual format is but one example of the fact that today's AGM takes place in the context of an extraordinary global environment. For each of us, 2020 has been a uniquely challenging year, and I expect that the impact of this period will continue to be felt for several years to come.

Given this backdrop, it is gratifying to report that 2020 has been Kazia's most successful year ever. In order to flourish, a biotech company must win on many fronts – it must secure investment, it must earn the trust of regulators, it must build productive partnerships, and it must generate positive clinical data. In each of those areas, Kazia has excelled this year, and I am proud to take this opportunity to talk to you about several of our key achievements.

At the ASCO annual meeting in June, we reported further interim data from the phase II study of paxalisib in glioblastoma. This suggested the potential for a survival benefit relative to the approved standard of care. If this finding is replicated in a pivotal study, it will represent a remarkable addition to the therapeutic armamentarium in this very challenging disease.

Consequently, that pivotal study has been an area of substantial focus for us in recent months. Perhaps the most significant landmark this year, indeed arguably the most significant landmark in Kazia's short history, has been the operational commencement of the GBM AGILE study. As shareholders will be aware, it is intended to serve as the pivotal study for registration of paxalisib in glioblastoma. In the past month, we have quietly become a 'phase III company', focused on what we believe to be one of the most exciting drug candidates in the global pipeline for brain cancer.

GBM AGILE encapsulates so much of what makes Kazia unique and innovative. It is a partnership, involving some of the leading experts in brain cancer and a number of leading US-based not-for-profit organisations. It is scientifically ground-breaking, using cutting-edge statistical techniques to efficiently evaluate several drugs simultaneously. It is strongly supported by regulators. And it is tremendously cost-effective, representing a demand on our cashflow that amounts to only a fraction of the cost of a comparable standalone study. In this, as in everything our company has done, we have found a way to accomplish more with the capital invested by our shareholders.

GBM AGILE is not the only new study this year. We were also proud to launch a phase II clinical trial in primary CNS lymphoma, in a new collaboration with Dana-Farber Cancer Institute. This will be the seventh clinical trial of paxalisib that Kazia has initiated. It has often been remarked that this broad portfolio of work would be the pride of a much larger organisation. For a company such as Kazia, the capital and resource efficiency with which these studies have been implemented is genuinely remarkable.

Looking forward, this broad program translates to one thing: data. Having seven clinical studies implies seven streams of new information about paxalisib over the next few years. As a very high-level generalisation, we expect new data from the paxalisib program to be reported approximately each quarter, on average, for the foreseeable future. Each of those read-outs will generate new opportunities for investors, partners, and regulators to evaluate the company's work and the potential of the drug.

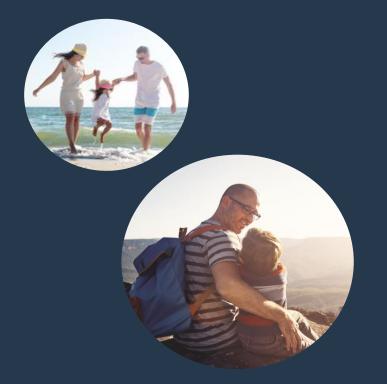
To be clear, not every study will be definitive. Despite all our scientific advances, drug development remains a process of trial and error. Some of these endeavours will no doubt prove more exciting than others. The beauty of the program that has been built, however, is that we don't need to win every time. In fact, if we were to see success in just one of these patient groups – be it glioblastoma, or DIPG, or primary CNS lymphoma, or brain metastases – we would have a very promising commercial opportunity on our hands. Conversely, we can only truly fail if every single study proves unsuccessful. In that sense, Kazia has not only succeeded in cultivating enormous economic potential, but also in substantially mitigating risk, which is always the flipside of any biotech investment. On the topic of investment, we have been grateful to welcome new shareholders to the register, and for the support of those existing shareholders who have participated in our two financing rounds this year. It is a measure of how far Kazia has come that the company's share register now includes several very high-quality, long-term and sector specialist institutional investors. We greatly appreciate the support of all our shareholders, large and small, recent and longstanding, and we never take it for granted.

I should comment briefly on our second asset, Cantrixil, which is in development for ovarian cancer. We presented positive data from the phase I study of Cantrixil at the AACR annual meeting earlier this year. As we have said previously, our aspiration for Cantrixil is to find a good quality partner for the asset, one who shares our belief in its potential, but also one which can bring the necessary expertise and resources to fulfil that potential. With final data nearly in hand, we expect those discussions to be a key priority in coming months.

This has been a terrific year for our company. We embark now on the most exciting part of our journey: the final chapter of paxalisib's development, which we hope will establish it as the first new drug treatment for glioblastoma in decades.

In closing, I want to commend our CEO, James Garner, and his management team, for all their determination and hard work throughout the year. On behalf of my colleagues on the Board, I also want to thank all our shareholders for their ongoing support of the company. Your faith in us is a substantial part of what motivates us to work hard every day to ensure the company's success. We look forward to continuing that journey with you as paxalisib moves closer towards becoming a commercial product.





Presentation to Annual General Meeting of Shareholders

Dr James Garner Chief Executive Officer

Sydney, NSW 6 November 2020

Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the "safeharbor" provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements, including changes from anticipated levels of customer acceptance of existing and new products and services and other factors. Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. The Company has no obligation to sales, future international, national or regional economic and competitive conditions, changes in relationships with customers, access to capital, difficulties in developing and marketing new products and services, marketing existing products and services update the forward-looking information contained in this presentation.



Investment Rationale

in Brain Cancer	

World-Class Asset

Clear Path to Commercialisation

- Paxalisib developed by Genentech, the world's most successful cancer drug company
- Well-proven mechanism of action, with unique differentiating factor of brain penetration
- Strong scientific rationale for development in brain cancer
- Encouraging clinical data emerging from US-based phase II study
- Potential best-in-class toxicity profile
- FDA-endorsed GBM AGILE study will serve as pivotal study for registration
- US\$ 1.5 billion pa commercial opportunity in glioblastoma, with potential upside in other cancers
- High unmet medical need existing standard of care ineffective in two-thirds of patients
- 5x additional clinical studies at top tier US hospitals provide multiple shots on goal
- Optimised regulatory position with Orphan, Fast Track, and Rare Paediatric Disease Designations

Strong Corporate Story

- Kazia is a late-clinical-stage company, funded for phase III, with one of the leading assets in the global glioblastoma pipeline, and the potential to address a \$1.5 billion market
- Highly-efficient operating model, with ~80% of expenditure applied directly to R&D
- Lean team of internationally-experienced drug developers
- Good potential for partnering and / or M&A during remaining development of paxalisib



Investment Rationale

Paxalisib is...

➔ In a pivotal study for registration

and

Well-funded

and

Diversified into other brain cancers

and

➡ Attractive for partnering



Agenda

- Operational Report
- Financial Report
- Looking Ahead



A broad-based clinical program is underway across multiple forms of brain cancer

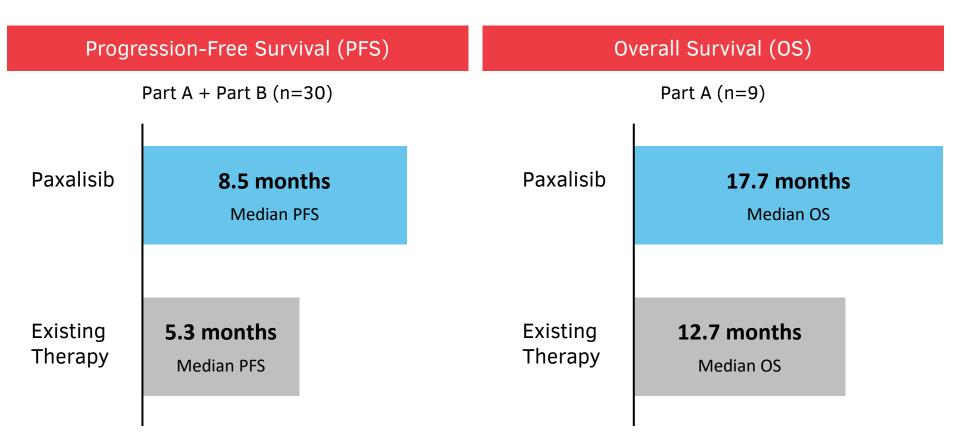
Paxalisib (GDC-0084)						
Primary Brain Cancer (brain cancer that begins in the brain)					ondary Brain Can at spreads from elsew	
Glioblastoma	Glioblastoma	DIPG	Primary CNS Lymphoma	Brain Metastases	Breast Cancer Brain Mets	Brain Metastases
Most common and most aggressive brain tumour	(planned pivotal study for approval [in set-up])	Highly aggressive childhood brain tumour	Treatment- resistant brain cancer	Cancer that has spread from any primary tumour	(combination with Herceptin®)	(combination with radiotherapy)
Phase II	Phase II / III	Phase I	Phase II	Phase II	Phase II	Phase I
NCT03522298	<u>NCT03970447</u>	NCT03696355	TBD	<u>NCT03994796</u>	NCT03765983	NCT04192981
KAZIA THERAPEUTICS	GLOBAL COALITION FOR ADAPTIVE RESEARCH	St. Jude Children's Research Hospital	DANA-FARBER	NIH NATIONAL CANCER INSTITUTE	DANA-FARBER	Memorial Sloan Kettering Cancer Center
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Funded by Kazia

Funded Primarily Through Partnerships and External Funding



Data read-outs this year have been highly encouraging



Note: figures for existing therapy are for temozolomide, per Hegi et al. (2005); comparison between different studies is never perfectly like-for-like



GBM AGILE is the planned pivotal study for paxalisib in glioblastoma

What is GBM AGILE?

- A 'platform study', designed by the leading experts in brain cancer to expedite the approval of new drugs for glioblastoma
- Multiple drugs can be evaluated in parallel, saving time and money; Bayer's Stivarga (regorafenib) is the first drug to participate, and Kazia's paxalisib will be the second
- FDA has provided strong endorsement, saying that positive data from GBM AGILE will be suitable for product registration
- The study is currently active at approximately 31 hospitals in the United States and Canada and recruiting very well; expansion to Europe and China is expected in 1H CY2021
- Cutting-edge 'adaptive design' ensures that the study will only recruit the number of patients needed to reach an answer (up to 200 on paxalisib), avoiding redundancy and ensuring the fastest possible path to market

Who is Behind It?

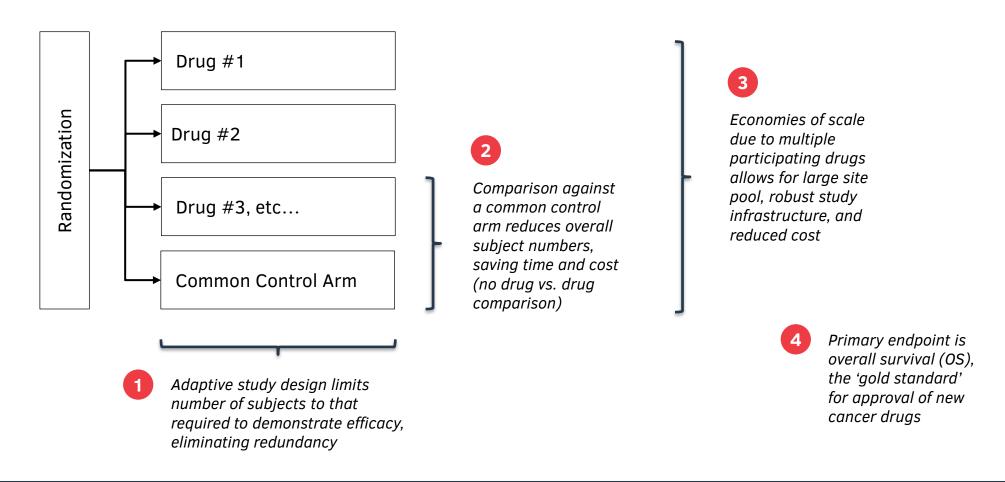
GBM AGILE is sponsored by the Global Coalition for Adaptive Research (GCAR), a not-for-profit entity based in the United States

The study's scientific leadership includes world-leading experts in glioblastoma, among them several clinicians who have participated in clinical trials of paxalisib

GBM AGILE has received substantial grant funding, substantially reducing the cost of participation for companies such as Kazia



GBM AGILE is an adaptive multi-drug registrational study, with strong FDA support





GBM AGILE directly addresses the key challenges faced by small biotechs and their investors

Challenge

Limited Funding

Many biotech companies cannot afford world-class phase III studies

Long Study Timelines

Phase III studies can sometimes take many years to deliver a result

Regulatory Uncertainty

Small biotechs can struggle to get regulatory support for study design

Clinician Engagement

Competition for top hospitals and clinicians can be intense

Execution Risk

Small companies can struggle to operationalise a complex trial











Many of the world-leading experts in this disease are part of GBM AGILE

Live Study

GBM AGILE is already underway, recruiting well, and run by IQVIA

Approach

More Cost-Effective Approach

AGILE achieves huge efficiencies, and is partly grant-funded

Adaptive Study Design

AGILE is an 'adaptive' study, only recruiting the patients needed

Strong FDA Endorsement

FDA has provided written backing to the GBM AGILE study design

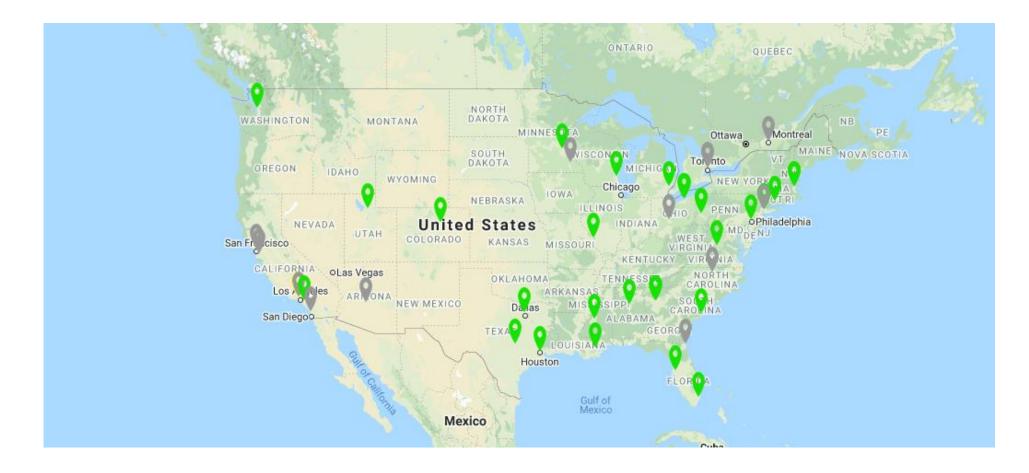
Top-Tier Clinical Leadership

Indicative Parameters

- Primary patient population essentially identical to Kazia's successful phase II study
- Recruitment of up to 200 patients on paxalisib (but likely fewer due to adaptive design)
- Approximately equivalent number of patients in control group, making for a ~400 patient dataset
- Approximately 2-3 years to completion
- Approximately one-third cost of a comparable company-sponsored study



GBM AGILE is currently operational at 31 sites in US and Canada, and will open EU and China in CY2021





Source: www.gcaresearch.org

Recent regulatory achievements position paxalisib well as it moves towards commercialisation

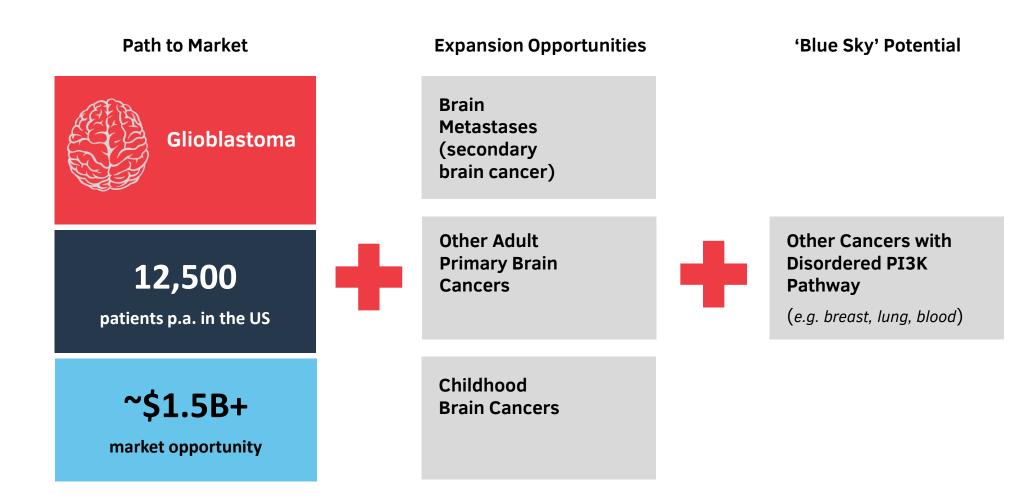
	Glioblastoma Most common and most aggressive form of brain cancer	DIPG Highly aggressive childhood brain cancer
Orphan Designation	February 2018	August 2020
Rare Pediatric Disease Designation	(not applicable)	August 2020
Fast Track Designation	August 2020	for future consideration
Breakthrough Designation	for future consideration	for future consideration

Advantages to Kazia

- 'Data exclusivity' provides additional protection against competition beyond granted patents
- Waiver of up to US\$ 6 million in FDA fees at time of filing for marketing authorisations
- Eligibility for orphan grants
- Eligibility for priority review voucher at time of filing for marketing authorisation in DIPG (up to US\$ 350 million in value)
- Enhanced access to FDA, with scope for more frequent and informal meetings
- Ability to submit a 'rolling NDA' in which sections are given to FDA as they are generated, instead of waiting until the end of development



Brain cancer represents a significant commercial opportunity for paxalisib, with limited competition





Agenda

- Operational Report
- Financial Report
- Looking Ahead



Kazia has raised a total of ~AU\$ 42 million to drive forward the paxalisib program

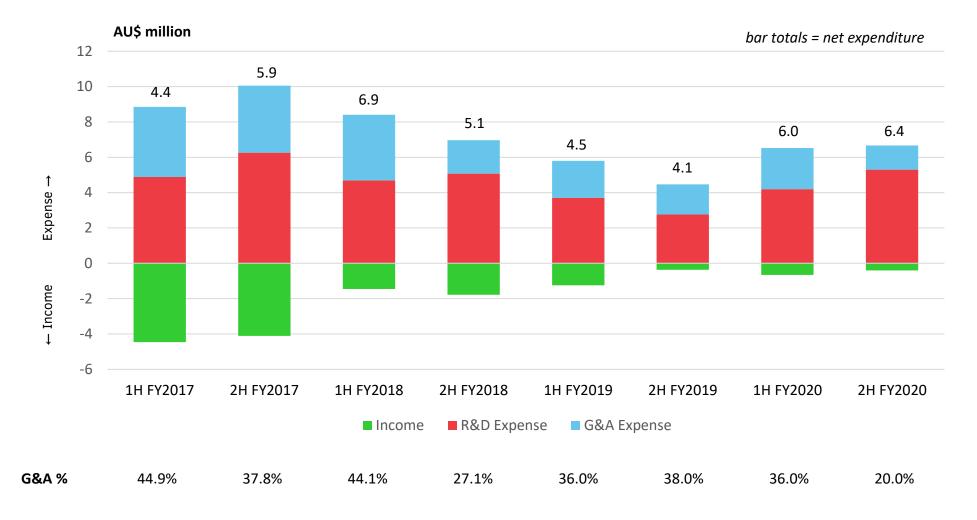


 Collaboration with DFCI in PCNSL (Sept 2020

(Dec 2019)

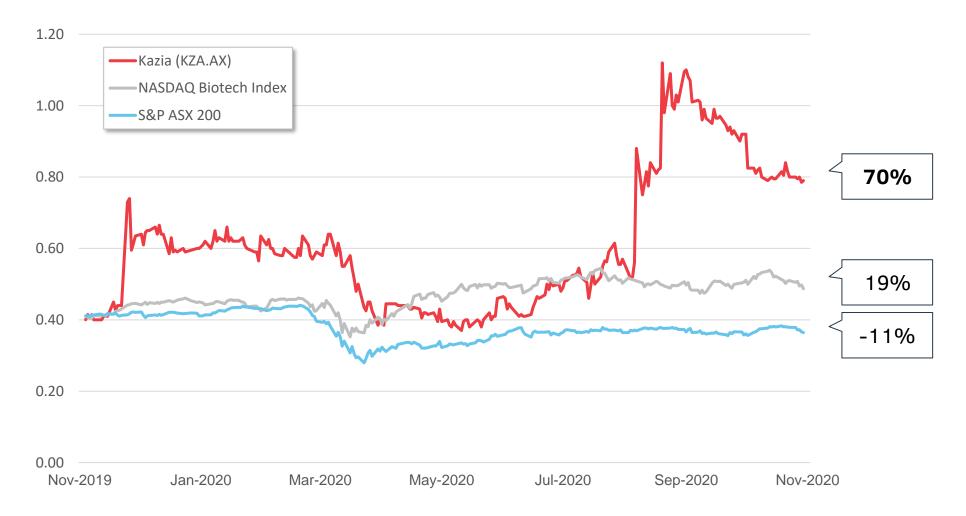
KAZIA THERAPEUTICS

Almost \$0.75 in every dollar the company spends is invested directly into R&D activity





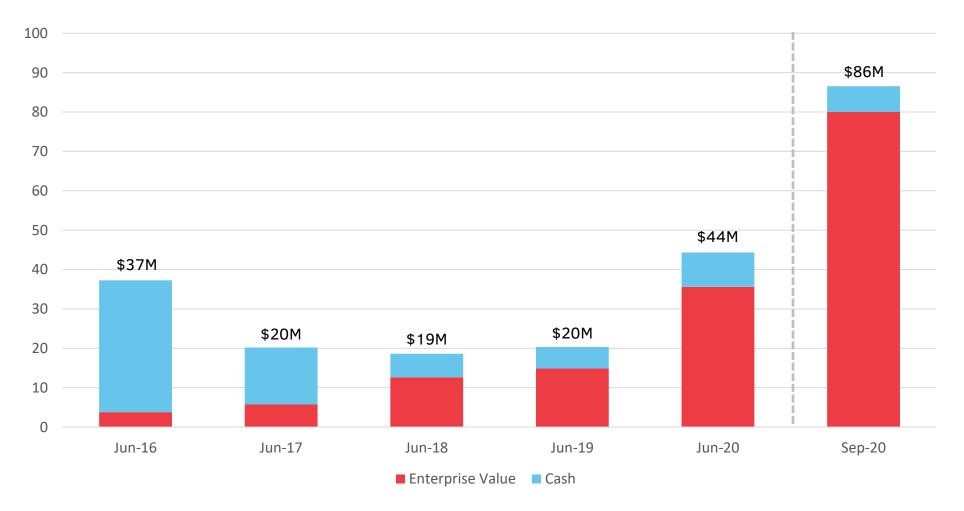
In the last 12 months, Kazia has achieved a 70% total shareholder return



Source: Bloomberg; period is 1 Nov 2019 to 30 Oct 2020



Kazia's enterprise value has grown from \$4M to \$36M in four years, and is now ~\$80M



The company is well covered by sector-leading analysts

Tuesday, 13 October 2020

RESEARCH REPORT

Kazia Therapeutics



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	EDIT Sm	-12.7	-18.7	-10.5	27.3
	NPAT (underlying) \$m	-12.4	-19.5	-10.6	27.2
s	NPAT (reported) \$m	-12.4	-19.5	-10.6	27.2
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and the second	EPS growth %	nm	-	nm.	3.8
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CORPORATE

-CONNECT

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Valuation Methodology: I have used a	and all the second	and all a second second	and from	Mr. Bryce Ca	mine	NED		
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discount rate is also a big decision beca				Chart				
Most large pharmaceutical companies u								
to keep my valuation on the conservativ	e side. The third	key assumpti	on was that					
the US accounted for 55% of the world's					N.	1 (31		
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that the target price target can be reach	ed, if not exceed	led.						
Recommendation: Kazia's fate is in nat	alisib's hands :	and that is how	r it should		Tenner Tab	-		

snare Price

Recomment be. We initiate coverage with a 12-month price target of \$2.05.

The recommendations and opinions expressed in this research report accurately reflect the research analysts personal, independent, and objective views about any and all the companies and securities that are the subject of this report discussed herein. For important information, please see the important biolocurums on apare 24 of this document.



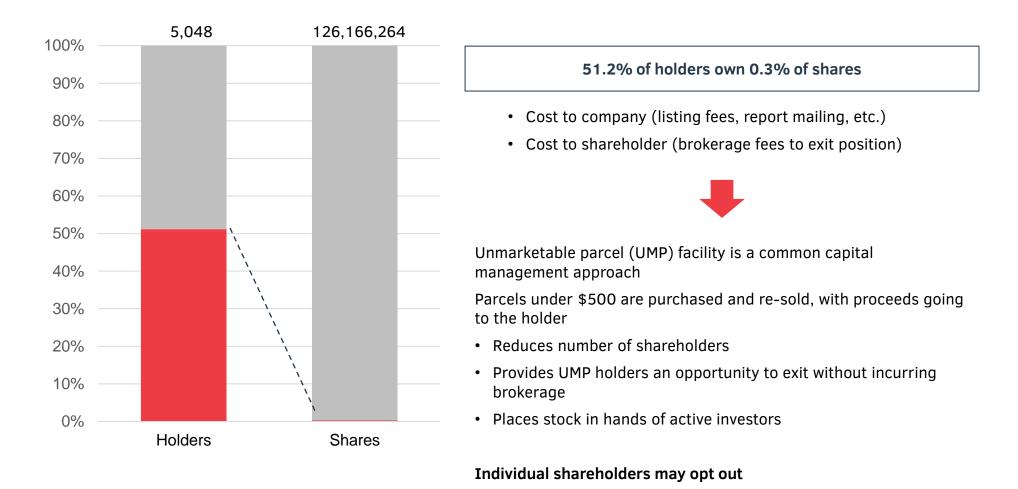
EDISON Kazia Therapeutics Re-initiation of coverage Bringing a vetted drug class to the brain Pharma & biotech 1 September 2020 We are reinitiating on Kazia Therapeutics, which is entering late-stage trials for its lead product, paxalisib, for glioblastoma multiforme (GBM). The product is a PI3K inhibitor originally developed by Genentech to cro Price A\$1.03 tech to cross Market cap A\$97m the blood-brain barrier. The drug is scheduled to be included in the ongoing GBM AGILE study, an innovative investigator-sponsored study A\$1.40/US\$ Net cash (A\$m) at 30 June 2020 8,76 testing multiple candidates against the disease, with the first paxalisib patients being enrolled by the end of 2020. We are reinitiating with a valuation of A\$145m or A\$1.54. 94.6m Shares in issue Free float 52.5% Code KZA Primary eachang ASX (0.13) (0.15) (0.12) (0.11) (A\$m) (7.4) (10.8) (11.4) (12.0) (%) NA Secondary each NASDAO 0.00 Share price perfe Note: "PBT and EPS are non exceptional items and shareized en A new type of PI3K inhibitor 85 05-Paxalisib belongs to the PI3K inhibitor class of drugs, which has had a varied history in drug development, with four approved drugs and many (50 or more) ************ abandoned programs. The class has the promise of providing broad spectrum anti-1m 3m 12n cancer activity, but many drugs of this class have limiting safety and tolerability 67.5 151.2 171.1 issues. While not being, pavalisib has not showed any of these major safety issues, and interim data from the ongoing open label Phase II GBM study appear to 63.7 134.3 182.0 Rel (local) show improvement in survival (median 17.7 months) compared to historical controls A\$1 12 A\$0 35 \$2-mark high-fee (13-15 months). Given the severe lack of options for patients with GBM (only two Business description edications with only modest efficacy), any benefit from paxalisib would be significant for this disease. Kazia is a pharmaceutical company with lead asset paxalisib, a PI3K inhibitor licensed from Generalech pasalisb, a PI3K inhibitor licensed from Generale that can cross the blood-brain barrier, which is entering a pixotal study for GBM. It is also being investigated for other brain cancers (DIPG and brain metastasce), and the company has the beancy avect Cantrial in Phase 1 for oursian cance A different type of pivotal study Paxalisib has a unique clinical development pathway, because instead of the drug being examined in a pivotal study sponsored by the company, it will be included in the investigator-sponsored GBM AGILE study, which is investigating multiple drug candidates against a common GBM control. Typically, investigator-sponsored trials Next events are insufficient to serve as pivotal studies, but the FDA has provided assurances DIPG Phase I result H220 that GBM AGILE can support approval in the event it shows positive results. This BCBM Phase II results H220 will allow Kazia to have a pivotal study that is beyond the scope of what it could Inclusion in GBM AGILE signal study Before YE20 afford to run independently. The company plans to include 200 patients on paxalisib, and enrolment is slated to begin before the end of 2020. GRM Phone II results End 2020 or endy 2021 Analysts Valuation: Reinitiating at A\$145m or A\$1.54 We are reinitiating on Kazia, with new models and assumptions, at A\$145m or National Collowry +1 646 653 7036 A\$1.54 per share. Paxalisib for GBM is our highest value program (A\$115m) and Wildonia O'Hare +1 645 653 7028 we forecast US\$450m peak sales. We expect the company to need A\$45m in ealthcare@edi additional capital to reach approval of paxalisib in 2025. Edison profile page Kazia Therapeutics is a



esearch client of Edisor

Investment Research Limited

Ongoing UMP facility is part of a long-term program of optimal capital management



KAZIA THERAPEUTICS

Agenda

- Operational Report
- Financial Report
- Looking Ahead



Key Objectives for CY2021





Drive data from broader paxalisib program



Intensify partnering activity



Commence 'rolling NDA' filing activities



The partnering market for new oncology drugs remains active, with a premium for late-stage assets

Select CY2020 Licensing Transactions

Licensee	Licensor	Stage	Asset(s)	Deal Value (US\$)
astellas	Adaptimmune	Discovery	CAR-T platform	\$900M
astellas	СутомХ	Discovery	T-cell engagers	\$1,680M
Johnson 4Johnson	Fete THERAPEUTICS	Discovery	CAR-NK & CAR-T platform	\$3.1B
abbvie		Phase I	CD47 antibody	\$2,940M
Genentech		Phase I	Pralsetinib (RET inhibitor)	\$1,702M
abbvie	Genmab	Phase I	CD37 & CD3x5T4 antibodies	\$3.9B
Gyowa kirin	pharma	Phase II	PI3K delta inhibitor	\$683M
MERCK	SeattleGenetics	Phase II	Ladiratuzumab vedotin	\$4.2B
Incyte	illorphosys	Phase III	CD19 antibody	\$2.0B



Key Milestones and Anticipated Newsflow

Execution of definitive agreement with GCAR for GBM AGILE pivotal study	October 2020 🗸
Further interim data from Kazia phase II glioblastoma trial	November 2020
Initial interim data from phase I DIPG trial at St Jude	November 2020
Initial interim data from phase II BCBM trial at Dana-Farber	Q4 CY2020
Commencement of recruitment to GBM AGILE pivotal study in glioblastoma	Q4 CY2020
Commencement of recruitment to phase II PCNSL study at Dana-Farber	Q1 CY2021
Half-Year Report	Q1 CY2021
Initial interim data from phase II brain mets study by Alliance Group	H1 CY2021
Initial interim data from phase I brain mets study at Sloan-Kettering	H1 CY2021
Final data from Kazia phase II glioblastoma trial	H1 CY2021

Note: all guidance is indicative, and subject to amendment in light of changing conference schedules, operational considerations, etc.



