

# patrys



ANNUAL  
REPORT  
2019 (Extract)



# Contents

Letter from the Chairman	2
Patrys snapshot	4
Target indications and addressable markets	5
Introducing the Deoxymab 3E10 platform	7
Multiple development approaches and pre-clinical data	8
Pipeline and upcoming milestones	11
Corporate directory	13

---

# Letter from the Chairman

Dear Shareholders,

Thank you for your continued support over the past year.

Patrys has made significant progress in the development of the Deoxymab platform during FY19. Deoxymab 3E10 has demonstrated potential to improve therapeutic outcomes across a range of different cancers. The Company has strategically identified metastatic triple negative breast cancer (MTNBC) and glioblastoma multiforme (GBM) as our initial target indications.

Both MTNBC and GBM are challenging cancers to treat, and prognosis for patients remains poor. The targeted indications may be ultimately eligible for FDA fast-track designations, which could accelerate the path to approval and commercialisation. Effective therapies for GBM and MTNBC represent significant market opportunities and the possibility to pair our technology with existing treatments further enhances the attractiveness of our approach to potential partners.

During FY19, the Company continued to produce successful data across a range of pre-clinical studies of PAT-DX1 (Deoxymab 3E10 lead candidate) and its nanoparticle-conjugated form, PAT-DX1-NP. Studies to date have supported the potential to increase tumour suppression and improve therapeutic outcomes, while simultaneously improving the side effect profiles of the current standards of care.

The ability to cross the blood brain barrier creates significant potential to treat a range of brain cancers and drastically improve the prognosis for patients. The pre-clinical data produced by the Company and its partners to date is significant and exciting.

The positive findings from our initial studies have generated interest from both academic and the broader community, providing assurance and validation for the development direction of the Company. Throughout the financial year, the Company has reported several new collaborations and strengthened its financial position through research grants. The Company was also very pleased to finally achieve a \$3 million negotiated settlement with its insurers for prior manufacturing issues.

We look forward to progressing the PAT-DX1 and PAT-DX1-NP development programs with the intention of working towards an IND filing.

Finally, I would like to take this opportunity to thank our shareholders for their continued support of Patrys and I look forward to continuing to share the journey going forward.



John Read

Chairman

“The ability to cross the blood brain barrier creates significant potential to treat a range of brain cancers and drastically improve the prognosis for patients.”



# Patrys snapshot

## Patrys aim and vision

Patrys believes that, despite recent advances, novel therapies are desperately needed to help fight a range of cancers. Patrys is committed to the development and commercialisation of novel antibody technologies and aims to revolutionise patient outcomes across a range of hard-to-treat cancers. The Company is initially focused on targeting underserved oncology indications, such as glioblastoma and metastatic triple-negative breast cancer, with the potential of expanding to other indications.

## Introducing the Deoxymab 3E10 platform

Patrys is a drug development company focused on commercialising antibody therapies for oncology. Patrys has exclusive worldwide rights to develop and commercialise the Deoxymab platform technology developed at Yale University (PAT-DX1, PAT-DX1-NP and 5C6) to form a portfolio of novel anti-cancer and diagnostic agents.

The Company's lead candidate, PAT-DX1 and its nanoparticle conjugated form (PAT-DX1-NP) have demonstrated significant potential as novel cancer therapy that has the capacity to penetrate cancer cell nuclei, inhibit DNA repair and kill DNA repair-deficient cancer cells. These characteristics open up new avenues for researching treatment of BRCA2 and PTEN-related cancers including (but not limited to) breast cancer, brain gliomas, pancreatic cancer, ovarian cancer and prostate cancer.


## Key investment highlights

 <p><b>Patrys is operating in a favourable space</b></p>	<ul style="list-style-type: none"><li>✓ Target indications addressable market worth ~US\$1bn p.a.</li><li>✓ Active pre-clinical biological deals environment with large transactions at the pre-clinical stage</li><li>✓ Target indications are traditionally hard-to-treat, streamlining development timelines and potential expansion to other indications</li></ul>
 <p><b>Potential game changer for cancer treatment</b></p>	<ul style="list-style-type: none"><li>✓ PAT-DX1 inhibits key mechanisms of DNA repair in tumour cells</li><li>✓ Crosses the blood brain barrier</li><li>✓ Safe and potentially low-toxicity treatment option</li></ul>
 <p><b>Promising pre-clinical study results</b></p>	<ul style="list-style-type: none"><li>✓ Suppresses tumour growth and increases survival rates in animal studies</li><li>✓ Significantly reduces presence of brain metastases in animal studies</li><li>✓ Shows efficacy as a single agent and in combination with radiotherapy</li></ul>
 <p><b>Multiple options for development</b></p>	<ul style="list-style-type: none"><li>✓ Significant pre-clinical development pipeline for CY19/CY20</li><li>✓ PAT-DX1 cell line development due to be completed in CY20</li><li>✓ IND filing scheduled for the end of CY20 paving the path towards the clinic</li><li>✓ Growing interest from industry players</li><li>✓ Potential business development opportunities</li></ul>

# Target indications and addressable markets

The Deoxymab 3E10 (PAT-DX1 platform) has broad applicability across multiple indications. Informed by disease mechanism and market attractiveness, Patrys is currently prioritising glioblastoma (GBM) and metastatic triple-negative breast cancer (MTNBC) as target indications to progress towards the clinic.

As a single agent, PAT-DX1 is selectively toxic to cancer cells that have deficiencies in DNA repair, indicating there is a wide range of malignancies that Patrys could potentially target in the future including endometrial, pancreatic, colon, prostate, breast and ovarian cancers.



“GBMs constitute approximately 17% of all primary brain cancers, with ~12,000 new cases diagnosed in the U.S. annually”

---

## Glioblastoma

GBM is a particularly aggressive, highly malignant form of brain cancer characterised by rapid cellular reproduction, nourished by ample and abnormal tumour vessel blood supply. GBM are generally found in the cerebral hemispheres of the brain but can develop anywhere in the brain. Common symptoms include seizures, headaches, nausea and vomiting, memory loss, changes in personality, mood or concentration and localised neurological problems.

GBMs constitute approximately 17% of all primary brain cancers, with ~12,000 new cases diagnosed in the U.S. annually. GBM can be difficult to treat as some cells may respond to certain therapies, while others may not be affected. As a result, treatment plans for GBM often combine several approaches. The current standard of care for GBM is surgical resection followed by radiation and chemotherapy (temozolomide, trade name TEMODAR®), with a median survival period of 15 months, depending on disease severity.

## Metastatic triple-negative breast cancer

Breast cancer is a leading cause of cancer death in women, with ~1.67 million new cases diagnosed each year globally. Subtypes of breast cancer are stratified in accordance with their expression of estrogen, progesterone, and HER2 receptors. TNBC tumours lack all three receptors. This subtype makes up 15-20% of breast cancer cases globally and is the most aggressive and difficult to treat. The global market for TNBC was US\$296m in 2015 and is expected to increase to US\$1.59bn by 2025.

TNBC sufferers are also more likely to develop metastasis, a secondary cancer forming in other areas of the body. Metastatic TNBC (MTNBC) is a challenging disease, with up to 50% of patients developing brain metastases that have devastating effects on overall quality of life and survival. There remains a large unmet medical need for new therapeutic approaches to target and treat TNBC brain metastases. An inability to cross the blood brain barrier has created an obstacle for many potential therapeutics, creating a significant barrier to the development of more effective treatments.

- 
- 1 Alifieris, C; Trafalis, DT (August 2015). "Glioblastoma multiforme: Pathogenesis and treatment". *Pharmacology & Therapeutics*. 152: 63–82.
  - 2 American Association of Neurological Surgeons (AANS), Glioblastoma Multiforme
  - 3 Davis ME. Glioblastoma: Overview of Disease and Treatment. *Clin J Oncol Nurs*. 2016;20(5 Suppl):S2–S8. doi:10.1188/16.CJON.S1.2-8
  - 4 American Cancer Association. Global Cancer Facts and Figures. 3rd Edition
  - 5 GlobalData Her2-/Her2+ and Triple Negative Breast Cancer- GlobalDrug Forecast and Market Analysis to 2025



# Introducing the Deoxymab 3E10 platform

Deoxymab 3E10 is one of the world’s first cell-penetrating anti-DNA antibodies for the treatment of cancer.

Deoxymab 3E10 is a lupus anti-DNA autoantibody which has been re-engineered as a humanised di-single chain fragment, called PAT-DX1, for use in our pre-clinical development program.

PAT-DX1 was selected from several variants due to its superior physiochemical attributes and ability to penetrate cell nucleus, selectively causing DNA damage and death in cells with DNA repair defects.

The platform technology’s unique mechanism of action opens new therapeutic windows for a range of underserved oncology and diagnostic applications.

## The advantages of PAT-DX1

### 1. PAT-DX1 preferentially localises to tumours

Specifically attracted to extracellular DNA from dying cancer cells

### 2. Penetrates the cell membrane and nucleus

Intracellular delivery means PAT-DX1 is able to penetrate the cell membrane, then enter the nucleus

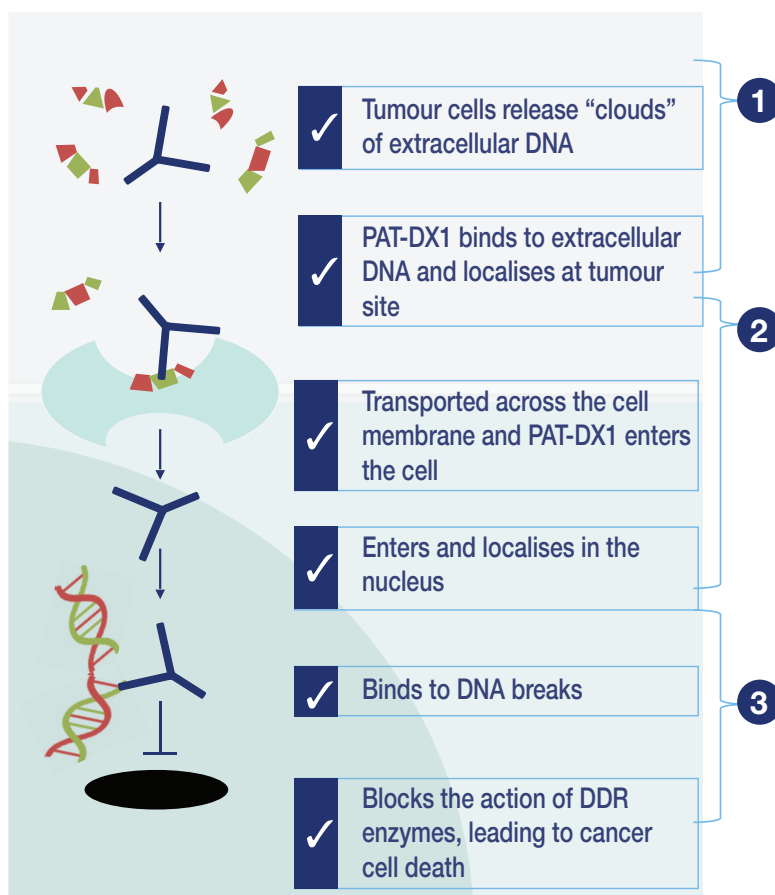
### 3. Kills cancer cells deficient in DNA repair

Diminishes cancer cells’ ability to repair themselves  
Has high therapeutic value against a wide range of cancer repair pathways such as those with mutations in the BRCA1/2 and PTEN genes

Targets primary and secondary tumours

### 4. Crosses the blood brain barrier

Resolving one the greatest challenges in the development of therapeutics for brain diseases.



A novel mechanism of action

# Multiple development approaches and pre-clinical data

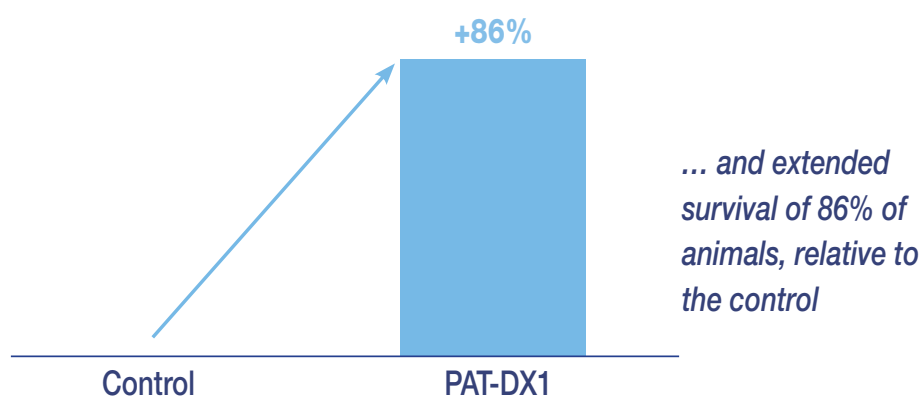
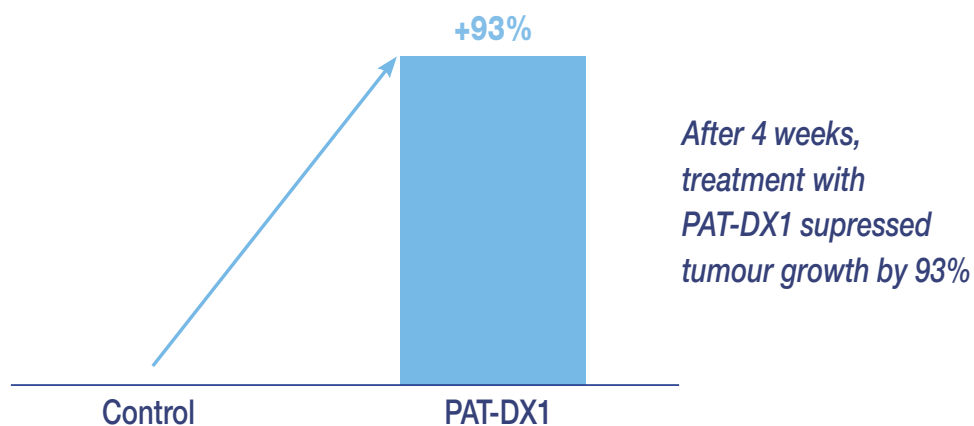
During the financial year, Patrys further explored the unique properties of PAT-DX1 and made significant discoveries in the treatment of GBM and MTNBC. Patrys continued to make good development progress, and the Company has released positive data from multiple pre-clinical studies throughout FY19.

Overall, animal models of TNBC brain metastasis and GBM brain tumours showed that PAT-DX1 crosses the blood brain barrier, suppresses tumour growth, increases survival and enhances radiation treatment. PAT-DX1 also has the potential to target not only primary tumours, but also secondary tumours, indicating that an eventual therapeutic could have broad utility. The fact that PAT-DX1 enhances the efficacy of low dose radiation is particularly exciting, as it could significantly improve treatment outcomes whilst reducing side effects.

**As a single agent:** PAT-DX1, suppresses TNBC brain metastases and increases survival in an orthotopic TNBC metastatic animal model

- After 4 weeks PAT-DX1 suppressed tumour growth by 93%
- 86% of mice treated with PAT-DX1 were alive after all mice in the control group had died

Refer to ASX announcement released on 20 December 2018



**Combination approach:** PAT-DX1 enhanced low dose radiation in an animal study of TNBC brain

- PAT-DX1 was able to cross the blood brain barrier and no toxicity was observed
- PAT-DX1 as a single agent caused similar tumour growth suppression to that of low dose radiation treatment
- Combination of PAT-DX1 and radiation treatment resulted in significantly greater tumour suppression than either treatment alone

Refer to ASX announcement released on 30 May 2019

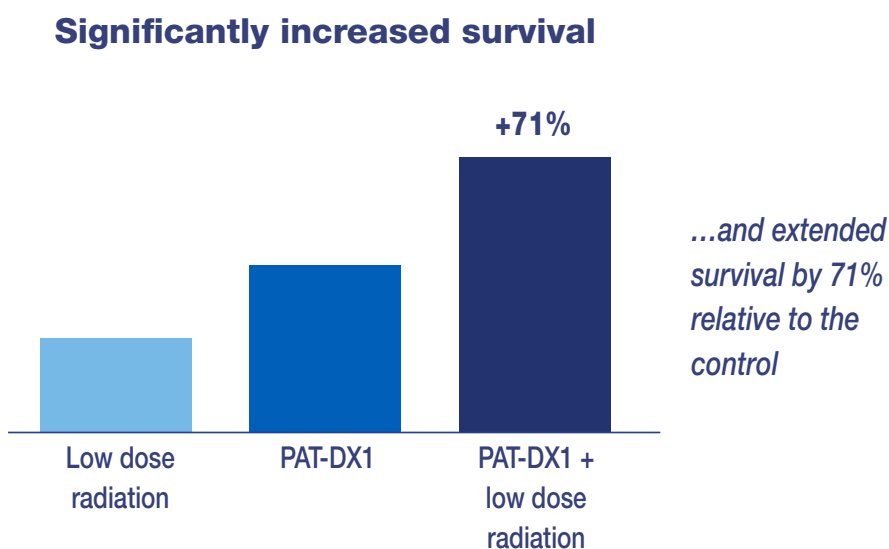
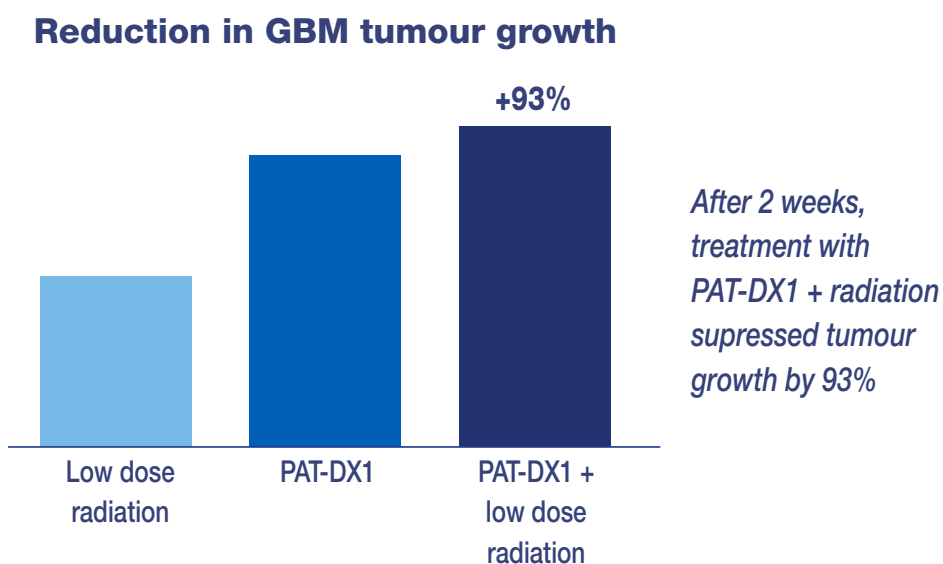


## PAT-DX1 in GBM orthotopic animal model

Subsequent to the year end, Patrys released data from an orthotopic animal model of highly aggressive GBM brain tumours. PAT-DX1 in combination with low dose radiation treatment resulted in significantly more tumour suppression and prolonged survival compared to low dose radiation alone

- PAT-DX1 reduced tumour size by 87% as a single agent and 93% in combination with radiation
- PAT-DX1 extended survival by 41% as a single agent and 71% in combination with radiation

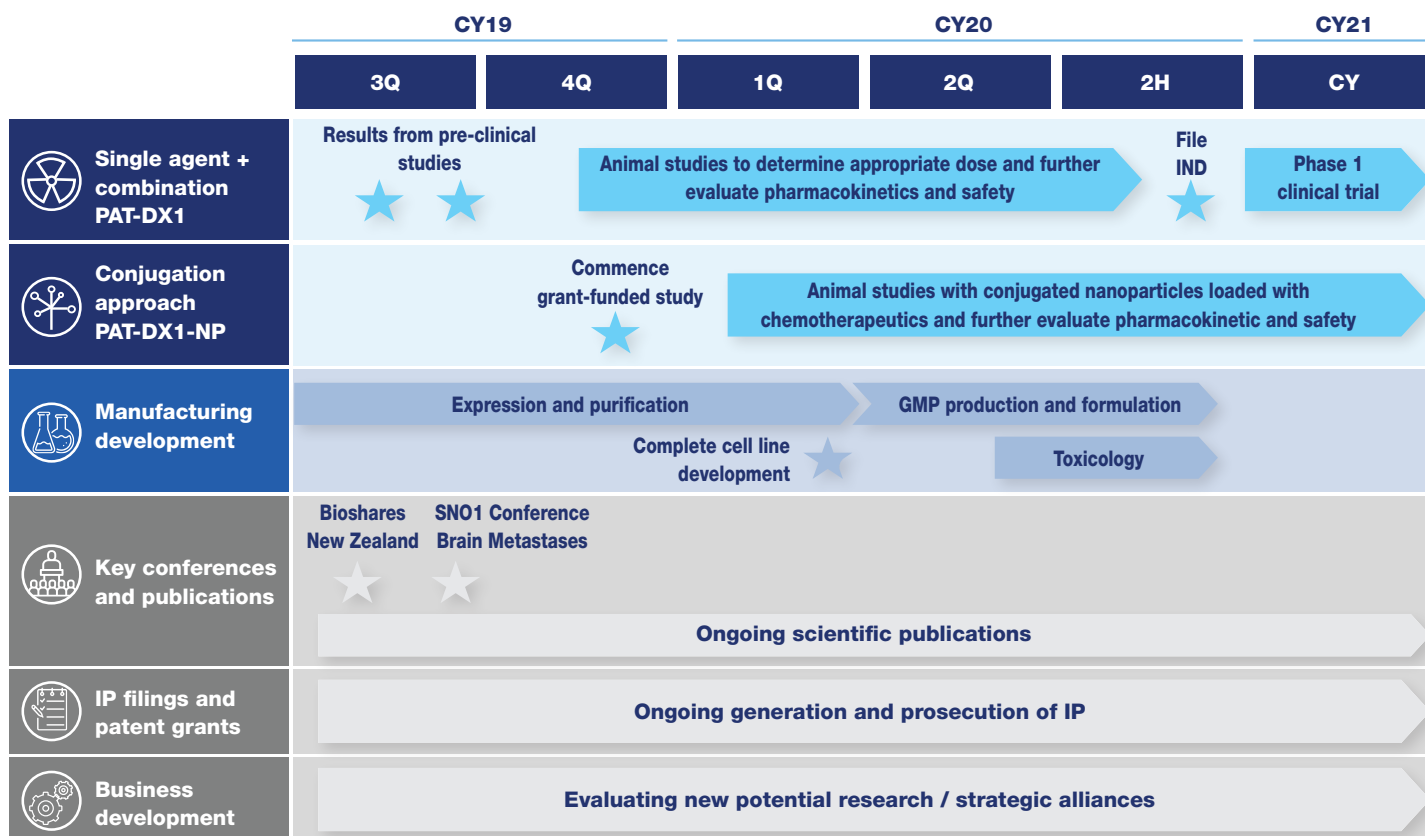
Refer to ASX announcement released on 22 July 2019



# Pipeline and upcoming milestones

Patrys is focused on developing its Deoxymab platform and progressing lead candidates PAT-DX1 and PAT-DX1-NP in a consolidated pre-clinical program. In the coming financial year, Patrys will continue to strengthen and extend its compelling pre-clinical data package with planning currently underway for further pharmacokinetics, safety and toxicology studies.

During the financial year, Patrys' well-respected international service provider continued to progress the cell line development of PAT-DX1. The development of a stable cell line is an important milestone for the Company and development is anticipated to be complete in 1H CY20.





# Corporate Directory

## DIRECTORS

Mr. John Read (Non-Executive Chairman)  
 Dr. James Campbell (Managing Director & CEO)  
 Mr. Michael Stork (Non-Executive Director and Deputy Chairman)  
 Ms. Suzy Jones (Non-Executive Director)

## COMPANY SECRETARY

Ms. Melanie Leydin

## REGISTERED OFFICE

Level 4, 100 Albert Road  
 South Melbourne VIC 3205  
 Phone: 03 9692 7222

## PRINCIPAL PLACE OF BUSINESS

Level 4, 100 Albert Road  
 South Melbourne VIC 3205  
 Phone: 03 9692 7222

## SHARE REGISTER

Computershare Investor Services Pty Limited  
 452 Johnston Street  
 Abbotsford VIC 3067  
 Phone: 1300 850 505 (within Australia)  
 Phone: +61 3 9415 5000

## AUDITOR

BDO East Coast Partnership  
 Tower 4, Level 18, 727 Collins Street  
 Melbourne VIC 3008  
 Australia

## STOCK EXCHANGE LISTING

Patrys Limited shares are listed on the Australian Securities Exchange (ASX code: PAB)

## WEBSITE

[www.patrys.com](http://www.patrys.com)

## ANNUAL GENERAL MEETING

Patrys Limited advises that its Annual General Meeting will be held on Thursday, 21 November 2019. The time and other details relating to the meeting will be advised in the Notice of Meeting to be sent to all Shareholders and released to the ASX in due course.



patrys

[www.patrys.com](http://www.patrys.com)