

**ASX & Media Release** 

### Commentary on Preliminary Final Report Patrys Advances Pipeline

**Melbourne, Australia; 29 August, 2014:** Patrys Limited **(ASX: PAB),** a clinical stage biotechnology company announces its financial results and provides an overview of operations for the year ended 30 June 2014. Progress subsequent to balance date has been addressed in the Company's ASX announcements of 24 July and 25 August 2014. The period to 30 June 2014 saw a number of positive milestones.

### Operations:

The key focus of the Company was the completion of the Phase I/IIa clinical trial in multiple myeloma (MM) which occurred in December 2013. At all dose levels tested, PAT-SM6 was well tolerated with no serious adverse events (SAEs) or dose limiting toxicities being reported. A maximal tolerated dose (MTD) was not reached. Overall, 4/12 patients (33%) treated with PAT-SM6 showed evidence of stable disease (SD) according to the International Myeloma Working Group (IMWG) criteria. One patient who received 3mg/kg of PAT-SM6 was stable for 138 days before additional therapy was needed whilst another patient, who received 6mg/kg of PAT-SM6, was stable for 157 days before additional therapy was needed. Importantly, patients treated with PAT-SM6 had a mean time to next therapy of 52 days which is considered clinically significant.

Patients who had received prior treatment with proteasome inhibitors responded much better to PAT-SM6 treatment than patients who had been previously treated with immunomodulatory drugs (IMIDs) or other chemotherapeutic agents. This observation is very exciting as it indicates that PAT-SM6 may act synergistically with proteasome inhibitors (such as carfilzomib) to induce better clinical responses. Such a hypothesis will be tested in Patrys' next clinical trial in which PAT-SM6 will be used in combination with Onyx's carfilzomib. Onyx is a fully owned subsidiary of Amgen.

Following completion of the trial a single patient with relapsed MM was treated on an "individual treatment" basis with PAT-SM6 in combination with the marketed drugs, velcade and revlimid. After three doses of this combination therapy, a PET-CT scan revealed significant shrinkage of both the extramedullary and the intramedullary lesions. Of particular note was the disappearance of a large tumour in the testes. The patient has since gone on to receive additional treatment for his remaining disease.

In November 2013, Patrys announced that it is initiating a Phase Ib/IIa clinical trial evaluating the effectiveness of PAT-SM6 in combination with carfilzomib, in patients with relapsed and refractory MM. The trial will be headed by Professor Dr. Hermann Einsele, Director of the Department of Medicine II, University of Würzburg, Germany. Patients will also be recruited into the trial by the Technical University of Dresden, Germany. Since the announcement, Patrys has been manufacturing PAT-SM6 for use in the trial. Subject to approval by the Paul Erhlich Institut (PEI), it is anticipated that the trial will commence by the end of 2014.

During the year the Company was granted orphan drug designation for PAT-SM6 in MM by the USA Food and Drugs Administration (FDA) and the European Medicines Agency (EMA). Orphan drug designation is intended to provide incentives to encourage companies to pursue cures and treatments for rare diseases with high unmet medical needs.



Patrys also continued to expand its PAT-SM6 preclinical data package and was awarded an ARC Linkage Grant to support a partnership with Macquarie University. Under the collaboration PAT-SM6 will be used in the development of novel and sensitive cancer diagnostics.

Patrys presented both preclinical and clinical data at the 55th ASH Annual Meeting and Exposition, run by the American Society of Hematology in New Orleans, held in December 2013. In addition, the MM clinical data was presented at several prestigious European Haematology Meetings held throughout the year.

In addition the Company continued to expand its PAT-LM1 preclinical data package and has continued to evaluate out-licensing opportunities for PAT-SC1.

Patrys has a new collaboration with Monash University, Melbourne, investigating 4 early-stage anticancer IgM antibodies and their cellular targets. It is anticipated that, if successful, this project will enable Patrys to progress these 4 IgMs into formal preclinical development and to file intellectual property around both the antibodies and the novel anti-cancer targets.

Patrys has recently commenced a collaboration programme with a global biotechnology company to genetically engineer T cells through the introduction of a chimeric antigen receptor (CAR). These engineered T cells have the ability to produce a more targeted and potent attack against cancer cells. Many major pharmaceutical and biotechnology companies are engaged in CAR research and many clinical trials using these modified T cells are now underway. Although early data from these trials look promising, it is acknowledged by experts in the field that engineered T cells directed against *novel* anticancer targets are required.

All of Patrys' IgM antibodies in both clinical and preclinical development are directed against novel anti-cancer targets. Therefore, in this CAR project, parts of these IgM antibodies will be utilised to generate the genetically engineered T cells which, in turn, will attack and kill cancer cells expressing the novel target.

### Financials:

In November 2013, Patrys announced a 1 for 2 rights issue. The primary aim of the rights issue was to raise funds for the manufacturing of PAT-SM6 for the planned PAT-SM6 / carfilzomib combination clinical trial as well as the ongoing advancement of the pipeline. The Company raised \$5.5 million from existing shareholders from the rights issue in December 2013 and placed \$2.2 million of the shortfall in January 2014.

In addition to this rights issue, Patrys raised a further \$1,580,000 from the exercise of options.

### -Ends-

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### **PATRYS LIMITED**

(ABN 97 123 055 363)

**APPENDIX 4E** 

PRELIMINARY FINAL REPORT

**YEAR ENDED 30 JUNE 2014** 

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### **APPENDIX 4E**

### **PATRYS LIMITED ABN 97 123 055 363**

### PRELIMINARY FINAL REPORT

### Current reporting period

Previous corresponding period

Year ended 30 June 2014 Year ended 30 June 2013

### Results for announcement to the market

				% increase /(decrease) over previous	
		\$		corresponding period	
Revenue from continuing activ	/ities	759,6	683	(22.5%)	
(Loss) from continuing activities after tax attributable to members		(7,289,0	90)	106.5%	
Net (loss) for the period attributable to members		(7,289,0	90)	106.5%	
Dividends (distributions)	Amount per security F		Fra	ranked amount per security	
Final Dividend	N/A	N/A			
Interim Dividend	N/A	N/A			
Record date for determining entitlements to the dividends (if any)			N/A		
Brief explanation of any of the figures reported above necessary to enable the figures to be understood: N/A					

### **Dividends**

Date the dividend is payable	N/A
Record date to determine entitlement to the dividend	N/A
Amount per security	N/A
Total dividend	N/A
Amount per security of foreign sourced dividend or distribution	N/A
Details of any dividend reinvestment plans in operation	N/A
The last date for receipt of an election notice for participation in any dividend	N/A
reinvestment plans	

### **NTA Backing**

	Current Period	Previous corresponding period
Net tangible asset backing per ordinary security (cents per share)	1.0 cents	0.9 cents

### **Control Gained Over Entities Having Material Effect**

Name of entity (or group of entities)	N/A
Date control gained	N/A
Profit / (loss) from ordinary activities after tax of the controlled entity since the	N/A
date in the current period on which control was acquired.	
Profit / (loss) from ordinary activities after tax of the controlled entity (or group	N/A
of entities) for the whole of the previous corresponding period.	IN/A

### **Loss of Control Gained Over Entities Having Material Effect**

### **Details of Associates and Joint Venture Entities**

Name of Entity (or group of entities)		N/A
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Foreign Entities Accounting Framework

For foreign entities provide details of which accounting standards have been adopted (e.g. International Accounting Standards) N/A

### **Audit/Review Status**

This report is based on accounts to which one of the following applies:  (Tick one)				
The accounts have been audited	The accounts are in the process of being audited	✓		
If the accounts are subject to audit dispute or qualification, a description of the dispute or qualification: N/A				

### **Attachments Forming Part of Appendix 4E**

Attachment #	Details
1	Statement of Profit or Loss and Other Comprehensive Income
2	Statement of Changes in Equity
3	Statement of Financial Position
4	Statement of Cash Flows
5	Notes to the Preliminary Final Report

Roger McPherson Company Secretary 29 August 2014

### PATRYS LIMITED ABN 97 123 055 363 STATEMENT OF PROFIT OR LOSS AND COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2014

		Consolidated		
		2014	2013	
	Note	\$	\$	
Revenues from continuing operations	2(a)	759,683	980,389	
Other income	2(b)	-	195,235	
Expenses from continuing operations				
Research & development	2(c)	(6,298,246)	(3,301,725)	
Management & administration		(1,742,366)	(1,396,533)	
Loss from continuing operations before tax	_	(7,280,929)	(3,522,634)	
Income tax (expense)		(8,161)	(6,461)	
Loss for the year from continuing operations after income tax	-	(7,289,090)	(3,529,095)	
Other comprehensive income				
Items that may be reclassified subsequently to profit or loss				
Exchange differences on translating foreign operations		9,860	44,991	
Derecognition of foreign currency reserve		-	6,068	
	5(a) _	9,860	51,059	
Total comprehensive income/(loss) for the year attributable to members of the Company		(7,279,230)	(3,478,036)	
. ,	=			
Earnings per share:				
Earnings per sitate.				
Basic loss per share - from continuing operations		(1.21¢)	(0.72¢)	
Diluted loss per share - from continuing operations		(1.21¢)	(0.72¢)	

The above consolidated Statement of Profit or Loss and Other Comprehensive Income should be read in conjunction with the accompanying notes.

## PATRYS LIMITED ABN 97 123 055 363 STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2014

Consolidated	Fully paid ordinary shares	Foreign currency translation reserve	Share option reserve	Share loan plan reserve	Accumulated losses	Total
2014	\$	\$	\$	\$	\$	\$
At 1 July 2013	50,712,575	(56,323)	1,048,958	297,228	(41,229,836)	10,772,602
Loss for the period Other comprehensive income	<u>-</u>	9,860	- -	-	(7,289,090)	(7,289,090) 9,860
Total comprehensive income/(loss) for the year	-	9,860	-	-	(7,289,090)	(7,279,230)
Transactions with owners in their capacity as owners: Issued capital	9,240,136	-	-	-	-	9,240,136
Re-allocation of value of options exercised during the period	118,058	-	(118,058)	-	-	-
Re-allocation of value of expired and cancelled equity Transaction costs related to	-	-	(787,917)	(20,444)	808,361	-
shares issued Cost of share based payment	(624,602) 229,804	- -	75,440 9,829	- 10,290	- -	(549,162) 249,923
At 30 June 2014	59,675,971	(46,463)	228,252	287,074	(47,710,565)	12,434,269
2013	\$	\$	\$	\$	\$	\$
At 1 July 2012	49,136,175	(107,382)	848,122	269,644	(37,700,741)	12,445,818
Loss for the period Other comprehensive income	<u>-</u>	- 51,059	- -	- -	(3,529,095)	(3,529,095) 51,059
Total comprehensive income/(loss) for the year	-	51,059	-	-	(3,529,095)	(3,478,036)
Transactions with owners in their capacity as owners:						
Issued capital Transaction costs related to	1,858,200	-	5,000	-	-	1,863,200
shares issued Cost of share based payment	(281,800)	-	181,800 14,036	- 27,584	-	(100,000) 41,620
At 30 June 2013	50,712,575	(56,323)	1,048,958	297,228	(41,229,836)	10,772,602

The above consolidated Statement of Changes in Equity should be read in conjunction with the accompanying notes.

## PATRYS LIMITED ABN 97 123 055 363 STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2014

		Consolidated	
		2014	2013
No	ote	\$	\$
Current assets			
Cash and cash equivalents 6a	a	8,643,507	5,232,298
Trade and other receivables		74,187	52,346
Other current assets	_	109,267	153,288
Total current assets	_	8,826,961	5,437,932
Non-current assets			
Property, plant and equipment		251,115	287,281
Intangible assets	_	5,735,622	6,128,632
Total non-current assets		5,986,737	6,415,913
Total assets	_	14,813,698	11,853,845
Current liabilities	_		
Trade and other payables		2,143,821	925,427
Current tax liabilities		-	-
Derivative financial instruments		40,607	-
Provisions		151,705	119,054
Total current liabilities	_	2,336,133	1,044,481
Non-current liabilities	_		
Provisions		43,296	36,762
Total non-current liabilities	_	43,296	36,762
Total liabilities	_	2,379,429	1,081,243
Net assets	_	12,434,269	10,772,602
	=		
Equity			
Issued capital 4		59,675,971	50,712,575
Reserves 5		468,863	1,289,863
Accumulated losses 5		(47,710,565)	(41,229,836)
Total equity	_	12,434,269	10,772,602

The above consolidated Statement of Financial Position should be read in conjunction with the accompanying notes.

## PATRYS LIMITED ABN 97 123 055 363 STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2014

		Consol	idated
		2014	2013
	Note	\$	\$
Cash flows from operating activities			
Payments to suppliers and employees		(5,831,869)	(3,588,550)
Income tax paid		(3,321)	(10,073)
Interest received		163,362	213,152
R&D tax incentive		582,595	754,908
Other income			2,643
Net cash used in operating activities	6 (b)	(5,089,233)	(2,627,920)
Cash flows from investing activities			
Proceeds from disposal of property, plant and equipment		-	22,957
Payments for property, plant and equipment		-	(8,502)
Payments for intangible assets		(74,595)	(223,058)
Net cash used in investing activities		(74,595)	(208,603)
Cash flows from financing activities			
Net proceeds from issue of shares		9,240,136	1,863,200
Payment for share issue expenses		(319,358)	(175,333)
Net cash provided by financing activities		8,920,778	1,687,867
Net increase/(decrease) in cash and cash equivalents		3,756,950	(1,148,656)
Effects of exchange rate changes on the balance of assets held in foreign currencies		(345,741)	191,844
Cash and cash equivalent at beginning of year		5,232,298	6,189,110
Cash and cash equivalents at end of year	6 (a)	8,643,507	5,232,298

The above consolidated Statement of Cash Flows should be read in conjunction with the accompanying notes.

# PATRYS LIMITED ABN 97 123 055 363 NOTES TO THE PRELIMINARY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2014

#### **INTRODUCTION**

The preliminary final report covers Patrys Limited and its controlled entities. This report is based on financial statements that are in the process of being audited.

#### NOTE 1: BASIS OF PREPARATION OF PRELIMINARY FINANCIAL REPORT

This preliminary financial report does not include all of the notes of the type normally included in an annual financial report. Accordingly, it should be read in conjunction with the Annual Report for the year ended 30 June 2013 and the financial report for the six months ended 31 December 2013 and any public announcements made by Patrys Limited during the year in accordance with continual disclosure requirements of the Corporations Act 2001. This preliminary final report has been prepared in accordance with the measurement and recognition requirements of Australian Accounting Standards, Accounting Interpretations and the Corporations Act 2001.

This preliminary financial report has been prepared on the basis of historical cost, except for the revaluation of certain noncurrent assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for the assets. All amounts are presented in Australian dollars, unless otherwise noted. All values are rounded to the nearest dollar.

The accounting policies and methods of computation adopted in the preparation of the preliminary financial report are consistent with those adopted and disclosed in the company's annual financial report for the year ended 30 June 2013 and the half year ended 31 December 2013.

### NOTE 2: REVENUE AND EXPENSES FROM CONTINUING OPERATIONS

	Consolidated		
	2014	2013	
	\$	\$	
(a) Revenue			
Interest received – bank deposits	177,088	222,838	
R&D tax incentive	582,595	754,908	
Other	0	2,643	
Total revenue from continuing operations	759,683	980,389	
(b) Other income			
Foreign currency exchange gain		195,235	
Foreign currency exchange gain	-	195,255	
(c) Expenses			
Employee salary and benefit expenses:			
Salary and employee benefit expenses	1,587,078	1,298,946	
Defined contribution superannuation expenses	79,876	49,068	
Share based payments	20,119	41,620	
Total employee salary and benefit expenses	1,687,073	1,389,634	
Depreciation, amortisation and impairment of non-current assets:			
Plant and equipment	44,442	46,762	
License and registered patents	500,358	600,363	
Total depreciation, amortisation and impairment expenses	544,800	647,125	
Foreign currency exchange differences:			
Foreign currency exchange losses	155,537		
Total foreign currency exchange differences	155,537	-	
Operating expenses:			
Research and development expenses	6,298,246	3,301,725	
Operating lease expenses	87,405	81,261	
Loss on disposal of non-current assets	-	61,817	

## PATRYS LIMITED ABN 97 123 055 363 NOTES TO THE PRELIMINARY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2014

#### **NOTE 3: SEGMENT INFORMATION**

A segment is a component of the consolidated entity that engages in business activities to provide products or services within a particular economic environment. The consolidated entity operates in one business segment, being the conduct of research and development activities in the biopharmaceutical sector. The Board of Directors assess the operating performance of the group based on management reports that are prepared on this basis. The group has established activities in more than one geographical area, however these activities support the research and development conducted by the consolidated entity and are considered immaterial for the purposes of segment reporting. The group invests excess funds in short term deposits but this are not regarded as being a separate segment.

#### **NOTE 4: CONTRIBUTED EQUITY**

The Company does not have authorised capital nor par value in respect of its issued shares.

Ordinary shares participate in dividends and the proceeds on winding up of the Company in equal proportion to the number of shares held. At shareholder meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands.

(a) Movements in issued capital during the year were as follows:

	2014 No.	2013 No.	2014 \$	2013 \$
Issued shares:			•	•
At the beginning of the reporting period	507,362,177	413,612,177	50,712,575	49,136,175
Share Placement shares issued at 2 cents per share Share Purchase Plan shares issued at 2 cents per share	-	55,000,000 37,910,000	-	1,100,000 758,200
Rights Issue shares issued at 5 cents per share Shares issued on exercise of options	153,202,727	-	7,660,136	-
Re-allocation of value of options exercised during the period	31,600,000	-	1,580,000 118,058	- -
Value of shares issued to Financial Advisors <sup>1</sup> Transaction costs arising on issue of shares	4,596,082	- -	229,804 (624,602)	- (281,800)
Shares issued pursuant to the Loan Share Plan (LSP)	300,000	840,000	-	-
At end of the reporting period	697,060,986	507,362,177	59,675,971	50,712,575
Issued shares are comprised as follows:				
Ordinary shares	692,058,901	502,660,092		
Restricted shares issued under the LSP  Balance at end of the year	5,002,085 <b>697,060,986</b>	4,702,085 <b>507,362,177</b>		
Dalatice at effu of the year	091,000,900	301,302,111		

On 18 March 2014 the Company issued 4,596,082 fully paid ordinary shares to Azure Capital Ltd (at 5 cents per share) in part consideration for fundraising and advisory services provided in connection with the Rights Issue announced on 13 November 2013.

### NOTE 5: RESERVES AND ACCUMULATED LOSSES

	Note	Note Consolidated	
		2014	2013
		\$	\$
Foreign currency translation reserve	(a)	(46,463)	(56,323)
Share options reserve	(b)	228,252	1,048,958
Share loan plan reserve	(c)	287,074	297,228
Total reserves		468,863	1,289,863

### **PATRYS LIMITED ABN 97 123 055 363**

### NOTES TO THE PRELIMINARY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2014

	Consolidated		
	2014	2013	
	\$	\$	
Opening balance 1 July Net adjustment arising from the translation of foreign controlled	(56,323)	(107,382)	
entities' financial statements	9,860	44,991	
De-recognition of foreign currency reserve	-	6,068	
Closing balance	(46,463)	(56,323)	

Exchange differences relating to translation from functional currencies of the Group's foreign controlled entities into Australian Dollars are bought to account by entries made directly to the foreign currency translation reserve. The foreign currency translation reserve in relation to Patrys Inc. was derecognised during the prior reporting period.

### (b) Share option reserve

	Consolidated	
	2014	2013
	\$	\$
Opening balance 1 July	1,048,958	848,122
Value of options issued under the Employee Share Option Plan		
(recognised over vesting period) <sup>1, 3</sup>	9,829	14,036
Consideration received for options granted to financial advisors	<del>-</del>	5,000
Net value of options granted to financial advisors <sup>2,3</sup>	75,440	181,800
Re-allocation of value of options exercised during the period	(118,058)	-
Re-allocation of value of expired options	(787,917)	-
Closing balance	228,252	1,048,958

### (c) Share loan plan reserve

(6)	Consolidated	
	2014	2013
	\$	\$
Opening balance 1 July	297,228	269,644
Net value of shares recognised over vesting period	10,290	27,584
Re-allocation of value of cancelled shares	(20,444)	-
Closing balance	287,074	297,228

- The equity settled employee benefits reserves arise on issue of equity under the Loan Share Plan or the Executive Share
  Option Plan to executives and senior employees. Amounts are transferred out of the reserves and into issued capital
  when the loans are repaid or the options are exercised. Amounts are transferred to accumulated losses when the shares
  or options are cancelled.
- 2. On 21 August 2012 the Company granted 50,000,000 options to Forrest Capital Pty Ltd (Financial Advisor options) in part consideration for fundraising and advisory services. These options vested on grant, expire on 30 June 2014 and had an exercise price of 5 cents each. The fair value of the options at the grant date, which approximates the fair value of the services rendered, has been determined using standard industry pricing models, as \$181,800. The Company received consideration of 0.01 cents per option (\$5,000). Following the announcement of the Rights Issue on 13 November 2013, 31,600,000 of these options were exercised, the balance were cancelled on 30 June 2014 when they expired.
- 3. Following the Rights Issue announced on 13 November 2013, in accordance with ASX Listing Rule 6.22 all options were repriced. The adjustment to the value of the vested options (including the Financial Advisor options) has been recognised in the current year. The adjustment to the value of the unvested options is being recognised over the vesting period.

### PATRYS LIMITED ABN 97 123 055 363

### NOTES TO THE PRELIMINARY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2014

### (d) Movement in accumulated losses

(a) movement in adduntation to see	Consolidated		
	2014	2013	
	\$	\$	
Opening balance 1 July	(41,229,836)	(37,700,741)	
Re-allocation of value of expired equity	808,361	-	
Net loss attributable to the members of the parent entity for the			
period	(7,289,090)	(3,529,095)	
Closing balance	(47,710,565)	(41,229,836)	

### **NOTE 6: CASH FLOW INFORMATION**

#### (a) Reconciliation of cash

	Consolidated		
	2014	2013	
	\$	\$	
Cash at bank	26,143	21,659	
Deposit at call	2,988,848	2,247,701	
Term deposits	5,628,516	2,962,938	
Total cash and cash equivalents	8,643,507	5,232,298	

### (b) Reconciliation of cash used in operating activities with loss after income tax

	Consolidated		
	2014	2013	
	\$	\$	
Loss from continuing operations after income tax	(7,289,090)	(3,529,095)	
Non cash movements:			
Depreciation, amortisation and impairment expense	544,800	647,125	
Equity settled share based payment	20,119	41,620	
Unrealised foreign exchange losses/(gains)	387,931	(175,495)	
Loss on disposal of non-current assets	-	61,817	
Changes in assets and liabilities:			
(Increase)/decrease in trade and other receivables	(21,841)	(16,249)	
(Increase)/decrease in prepaid expenses	44,021	(29)	
Increase/(decrease) in trade creditors and accruals	1,185,642	279,121	
Increase/(decrease) in provisions	39,185	63,265	
Cash used in operating activities	(5,089,233)	(2,627,920)	

### (c) Non cash financing and investing activities

There were no non cash financing activities during the year.

### NOTE 7 EVENTS AFTER BALANCE SHEET DATE

On 24 July 2014 the Company provided an update on its preclinical programmes.

On 18 August 2014 the Company announced that results related to its novel anti-cancer PAT-SM6 multiple myeloma trial in relapsed and refractory patients has been accepted for presentation as a lecture at the Annual Meeting of the German, Austrian and Swiss Associations for Hematology and Medical Oncology in Hamburg, to be held on 11 October 2014.

On 25 August 2014 the Company released details on its planned PAT-SM6, carfilzomib and dexamethasone Phase Ib/IIa clinical trial.

No other matter or circumstance has arisen since 30 June 2014 that has significantly affected or may significantly affect: -

- Patrys Limited's operations in future financial years, or
- the results of those operations in future financial years, or
- Patrys Limited's state of affairs in future years.