

### **Cynata Therapeutics Limited**

ABN 98 104 037 372

and its controlled entities

Half year report for the half-year ended 31 December 2015

### **Corporate directory**

### **Board of Directors**

Dr Stewart Washer Executive Chairman

Dr Ross Macdonald Managing Director/Chief Executive Officer

Dr John Chiplin Non-Executive Director
Mr Peter Webse Non-Executive Director

### **Company Secretary**

Mr Peter Webse

### **Registered and Principal Office**

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Fax: +61 3 9822 7735
Email: admin@cynata.com

### **Postal Address**

PO Box 7165 Hawthorn North, Victoria 3122

### Website

www.cynata.com

### **Auditors**

Stantons International Level 2, 1 Walker Avenue West Perth, Western Australia 6005

### **Share Registry**

Automic Registry Services Level 1, 7 Ventnor Avenue WEST PERTH, Western Australia 6005

Tel: +61 8 9324 2099 Fax: +61 8 9321 2337

### **Stock Exchange**

Australian Securities Exchange Level 40, Central Park 152-158 St Georges Terrace Perth, Western Australia 6000

#### **ASX Code**

CYP

# Half year report for the half-year ended 31 December 2015

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### **Directors' report**

The directors of Cynata Therapeutics Limited ("Cynata" or "the Company") submit herewith the financial report of Cynata Therapeutics Limited and its subsidiaries ("the Group") for the half-year ended 31 December 2015. In order to comply with the provisions of the *Corporations Act 2001*, the directors report as follows:

### **Names of Directors**

The names of the directors of the Company during or since the end of the half-year are:

Dr Stewart Washer Dr Ross Macdonald Dr John Chiplin Mr Peter Webse

### **Review of operations**

The loss of the Group for the half-year ended 31 December 2015, after providing for income tax, amounted to \$2,468,220 compared to a loss of \$1,418,725 for the half-year ended 31 December 2014. The higher comparative loss for the half-year was due to a substantial increase in product development activities being undertaken by the Company in the course of moving the lead product CYP-001 toward a clinical trial, offset by an R&D rebate receivable of \$932,581.

During the half-year ended 31 December 2015, the Company undertook a successful share placement to US institutional investors yielding gross proceeds of \$5,000,004. Investor interest in Cynata was aided by favourable research analyses published by SeeThruEquity, a leading US-based independent equity research and corporate access firm, with a price target of \$1.55 per share and by a US investment bank (Rodman & Renshaw, a unit of H.C. Wainwright & Co.) with a near term price target of \$1. The Company will continue to build on this solid base through its investor relations activities, including building a strong profile on social media platforms.

Cynata continued to execute on its business strategy with the signing of Letters of Intent (LOI) with two potential commercial partners: Regience K.K., a Japanese regenerative medicine company and apceth GmBH & Co. KG, a German company developing a range of modified stem cell therapeutic products. The Company has active dialogue proceeding with both parties to complete the transactions contemplated in the LOI's. Discussions with other potential partners are ongoing as the Company seeks to derive maximal value from the proprietary Cymerus™ mesenchymal stem cell (MSC) technology.

Besides the commercial collaborations that are in the pipeline, the Company continues to leverage interest in potential clinical applications of its unique technologies through select collaborations with leading international clinical research centres of excellence. Thus, new collaborations have been established with world leading researchers at Massachusetts General Hospital (MGH), part of Harvard Medical School, and with the University of Sydney, to investigate the potential use of Cymerus™ MSCs in the treatment of cancer and heart disorders, respectively. The scientists leading these studies, Dr Khalid Shah at Harvard and Dr James Chong at Westmead Hospital/University of Sydney are among the leaders in their respective fields and have enviable records of accomplishment in clinical and translational research. These high profile research collaborations validate the value of the Cymerus™ technology in the international stem cell community. They are further recognition that Cynata's Cymerus™ technology provides a next generation solution to the production scale-up challenges faced by current processes that rely on multiple donors for manufacturing therapeutic MSCs. The collaborations also broaden the potential commercial opportunities for the Company's intellectual property.

Development of Cynata's lead therapeutic MSC product, CYP-001 continues on schedule and budget and the engagement of a CRO for the upcoming Phase 1 clinical study in steroid-refractory graft versus host disease (GvHD) was an important milestone. More particularly the favourable outcome from the meeting with the regulatory authority in the United Kingdom, announced subsequent to the end of calendar year, provided the key to scheduling the commencement of the Phase 1 clinical study in that country. Further jurisdictions will be considered following upcoming formal meetings with national regulatory bodies. This was a major achievement for the Company and its shareholders, positioning Cynata to be the first company in the world to conduct a clinical trial with an allogenic iPSC-derived MSC product.

### Auditor's independence declaration

The auditor's independence declaration is included on page 3 of the half-year report.

Signed in accordance with a resolution of directors made pursuant to s.306(3) of the *Corporations Act* 2001.

On behalf of the directors

Dr Ross Macdonald Managing Director

Melbourne, 26 February 2016



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26 February 2016

Board of Directors Cynata Therapeutics Limited Suite 1, 1233 High Street ARMADALE, VICTORIA, 3143

**Dear Directors** 

### RE: CYNATA THERAPEUTICS LIMITED

In accordance with section 307C of the *Corporations Act 2001*, I am pleased to provide the following declaration of independence to the directors of Cynata Therapeutics Limited.

As the Audit Director for the review of the financial statements of Cynata Therapeutics Limited for the half-year ended 31 December 2015, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- (ii) any applicable code of professional conduct in relation to the review.

Yours sincerely

STANTONS INTERNATIONAL AUDIT AND CONSULTING PTY LTD (Trading as Stantons International) (Authorised Audit Company)

Samir Tirodkar

force

Director





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## INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF CYNATA THERAPEUTICS LIMITED

#### Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Cynata Therapeutics Limited, which comprises the consolidated statement of financial position as at 31 December 2015, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity, and consolidated statement of cash flows for the half-year ended on that date, condensed notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration for Cynata Therapeutics Limited ("the consolidated entity"). The consolidated entity comprises both Cynata Therapeutics Limited ("the Company") and the entities it controlled during the half year.

#### Directors' Responsibility for the Half-Year Financial Report

The directors of Cynata Therapeutics Limited are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Cynata Therapeutics Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Whilst we considered the effectiveness of management's internal controls over financial reporting when determining the nature and extent of our procedures, our review was not designed to provide assurance on internal controls.

Our review did not involve an analysis of the prudence of business decisions made by the directors or management.



### Stantons International

### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act* 2001. We confirm that the independence declaration required by the *Corporations Act* 2001, has been provided to the directors of Cynata Therapeutics Limited on 26 February 2016.

### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Cynata Therapeutics Limited is not in accordance with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.

STANTONS INTERNATIONAL AUDIT AND CONSULTING PTY LTD

(Trading as Stantons International)
(An Authorised Audit Company)

Stanton International

Samir Tirodhan

Samir Tirodkar Director

West Perth, Western Australia 26 February 2016

### **Directors' declaration**

The directors declare that:

- (a) in the directors' opinion, there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable; and
- (b) in the directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standard AASB 134 'Interim Financial Reporting' and giving a true and fair view of the financial position and performance of the Group.

Signed in accordance with a resolution of the directors made pursuant to s.303(5) of the *Corporations Act 2001*.

On behalf of the directors

Dr Ross Macdonald

**Managing Director** 

Melbourne, 26 February 2016

# Condensed consolidated statement of profit or loss and other comprehensive income for the half-year ended 31 December 2015

		Consolidated		
		Half-yea	r ended	
		31 Dec 2015	31 Dec 2014	
	Note	\$	\$	
Revenue from continuing operations	4	77,592	43,354	
Other income	4	934,781	-	
Total revenue and other income		1,012,373	43,354	
Product development and marketing costs		(2,441,528)	(539,068)	
Employee benefits expenses		(392,773)	(376,241)	
Share based payments expenses		(63,081)	(365,670)	
Depreciation and amortisation expenses	6	(140,366)	-	
Other operational expenses		(442,845)	(181,100)	
Loss before income tax		(2,468,220)	(1,418,725)	
Income tax expense		-	-	
Loss for the period		(2,468,220)	(1,418,725)	
Other comprehensive income, net of income tax				
Items that will not be reclassified subsequently to profit or loss		-	-	
Items that may be reclassified subsequently to profit or loss		-	(815)	
Other comprehensive (loss)/income for the period, net of			· · · · · · · · · · · · · · · · · · ·	
income tax		-	(815)	
Total comprehensive loss for the period		(2,468,220)	(1,419,540)	
Loss attributable to:				
Owners of Cynata Therapeutics Limited		(2,468,220)	(1,418,725)	
·				
Total comprehensive loss attributable to:				
Owners of Cynata Therapeutics Limited		(2,468,220)	(1,419,540)	
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Loss per share:				
Basic and diluted (cents per share)		(3.42)	(2.56)	
Table and a located per original		(3.12)	(2.50)	

# Condensed consolidated statement of financial position as at 31 December 2015

		Consolidated		
		31 Dec 2015	30 Jun 2015	
	Note	\$	\$	
Current assets				
Cash and cash equivalents		6,366,984	4,703,689	
Trade and other receivables	5	989,451	47,809	
Total current assets		7,356,435	4,751,498	
Non-current assets				
Intangibles	6	4,233,488	4,373,854	
Total non-current assets		4,233,488	4,373,854	
Total assets		11,589,923	9,125,352	
Current liabilities				
Trade and other payables		669,121	313,691	
Borrowings		-	32,691	
Provisions		41,454	29,011	
Total current liabilities		710,575	375,393	
Total liabilities		710,575	375,393	
Net assets		10,879,348	8,749,959	
Equity				
Issued capital	7	28,791,762	24,460,404	
Option reserves	8	3,542,399	3,276,148	
Foreign currency translation reserves		4,476	4,476	
Accumulated losses		(21,459,289)	(18,991,069)	
Total equity		10,879,348	8,749,959	

# Condensed consolidated statement of changes in equity for the half-year ended 31 December 2015

	Issued	Shares yet to be	Option	Foreign currency translation	Accumulated	
<u>Consolidated</u>	Capital	issued	Reserve	reserve	losses	Total
	\$	\$	\$	\$	\$	\$
Balance at 1 July 2014	22,281,642	-	2,846,691	5,291	(15,278,992)	9,854,632
Loss for the period	-	-	-	-	(1,418,725)	(1,418,725)
Other comprehensive income/(loss), net of tax		-	-	(815)	-	(815)
Total comprehensive income/(loss) for the period	-	-	-	(815)	(1,418,725)	(1,419,540)
Issue of ordinary shares	1,332,829	-	-	-	-	1,332,829
Ordinary shares yet to be issued	-	680,816	-	-	-	680,816
Share issue costs	-	-	-	-	-	-
Share based payments	-	-	365,670	-	-	365,670
Balance at 31 December 2014	23,614,471	680,816	3,212,361	4,476	(16,697,717)	10,814,407
Balance at 1 July 2015	24,460,404	_	3,276,148	4,476	(18,991,069)	8,749,959
Loss for the period	-	_	-	-,470	(2,468,220)	(2,468,220)
Other comprehensive income, net of tax	-	-		-	-	-
Total comprehensive income/(loss) for the period	-	-	-	-	(2,468,220)	(2,468,220)
Issue of ordinary shares	5,000,004	-	-	-	-	5,000,004
Share issue costs	(668,646)	-	203,170	-	-	(465,476)
Share based payments	-	-	63,081	-	-	63,081
Balance at 31 December 2015	28,791,762	-	3,542,399	4,476	(21,459,289)	10,879,348

# Condensed consolidated statement of cash flows for the half-year ended 31 December 2015

		Consolidated		
		Half-year ended		
		31 Dec 2015	31 Dec 2014	
Not	te	\$	\$	
Cash flows from operating activities				
Grants received		2,200	-	
Payments to suppliers and employees		(705,891)	(531,769)	
Interest received		60,628	43,354	
Product development costs paid		(2,228,170)	(507,015)	
Net cash (used) in operating activities		(2,871,233)	(995,430)	
			_	
Cash flows from financing activities				
Proceeds from equity instruments of the Company	7	5,000,004	1,332,829	
Proceeds from equity instruments not yet issued		-	724,505	
Payment for share issue costs		(465,476)	-	
Net cash provided by financing activities		4,534,528	2,057,334	
Net increase in cash and cash equivalents		1,663,295	1,061,904	
Cash and cash equivalents at the beginning of the period		4,703,689	5,094,582	
Cash and cash equivalents at the end of the period		6,366,984	6,156,486	

# Condensed notes to the consolidated financial statements for the half-year ended 31 December 2015

### 1. Significant accounting policies

### Statement of compliance

The half-year financial report is a general purpose financial report prepared in accordance with the *Corporations Act 2001* and AASB 134 '*Interim Financial Reporting*'. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 '*Interim Financial Reporting*'. The half-year report does not include notes of the type normally included in an annual financial report and should be read in conjunction with annual financial statements of the Company for the year ended 30 June 2015 together with any public announcements made during the following half-year.

The half-year financial report was authorised for issue by the directors on 26 February 2016.

### **Basis of preparation**

The condensed consolidated financial statements have been prepared on the basis of historical cost. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars, unless otherwise noted.

The accounting policies and methods of computation adopted in the preparation of the half-year financial report are consistent with those adopted and disclosed in the Company's 2015 annual financial report for the financial year ended 30 June 2015, except for the impact of the Standards and Interpretations described below. These accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards.

#### **Principles of consolidation**

The consolidated financial statements incorporate all assets, liabilities and results of the parent and all of its subsidiaries. Subsidiaries are entities the parent controls. The parent controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity.

The assets, liabilities and results of all subsidiaries are fully consolidated into the financial statements of the consolidated entity from the date on which control is obtained by the Company. The consolidation of a subsidiary is discontinued from the date that control ceases. Intercompany transactions, balances and unrealised gains or losses on transactions between entities are fully eliminated on consolidation. Accounting policies of subsidiaries have been changed and adjustments made where necessary to ensure uniformity of the accounting policies adopted by the Group.

### Significant accounting judgements and key estimates

The preparation of interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expense. Actual results may differ from these estimates.

In preparing these half-yearly statements, the significant judgements made by management in applying the Company's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the annual financial report for the year ended 30 June 2015.

### Amendments to AASBs and new Interpretations that are mandatorily effective for the current reporting period

The Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board (the AASB) that are relevant to their operations and effective for the current half-year.

New and revised Standards and amendments thereof and Interpretations effective for the current half-year that are relevant to the Group include:

 AASB 2015-3 'Amendments to Australian Accounting Standards arising from the Withdrawal of AASB 1031 Materiality'

Impact of the application of AASB 2015-3 'Amendments to Australian Accounting Standards arising from Withdrawal of AASB 1031 Materiality'

Completes the withdrawal of references to AASB 1031 in all Australian Accounting Standards and Interpretations.

The adoption of the amending Standard does not have any impact on the disclosures or the amounts recognised in the Group's condensed consolidated financial statements.

### 2. Segment information

The Group operates in one business segment and one geographical segment, namely the development and commercialisation of therapeutic products in Australia only. AASB 8 'Operating Segments' states that similar operating segments can be aggregated to form one reportable segment. However, none of the operating segments currently meet any of the prescribed quantitative thresholds, and as such do not have to be reported separately. The Company has therefore decided to aggregate all its reporting segments into one reportable operating segment.

The revenue and results of this segment are those of the Group as a whole and are set out in the condensed consolidated statement of profit or loss and other comprehensive income. The segment assets and liabilities are those of the Group and set out in the condensed consolidated statement of financial position.

### 3. Dividends

No dividends were paid or declared for the half-year ended 31 December 2015 and the directors have not recommended the payment of a dividend.

### 4. Revenue and other income

**Revenue from continuing operations** 

Interest income

Other income

Grants received

R&D rebate receivable (refer to note 5(i))

<b>31 Dec 2014</b> \$
43,354
-
-
-

### 5. Trade and other receivables

Deposits made Other receivables R&D rebate receivable (i)

<b>31 Dec 2015</b>	<b>30 Jun 2015</b> \$
3,568	3,568
53,302	44,241
932,581	-
989,451	47,809

- (i) This amount represents an R&D Tax Incentive refund for the 2014/2015 financial year which was received subsequent to 31 December 2015.
- (ii) None of the trade and other receivables are past due at the reporting date.

### 6. Intangibles

Balance at the beginning of the period (i) Amortisation (ii) Balance at the end of the period

31 Dec 2015	30 Jun 2015
\$	\$
4,373,854	4,821,799
(140,366)	(447,945)
4.233.488	4.373.854

- (i) The fair value attributable to interests in research and development of stem cells is due to, and in recognition of, the successful development of activities and data generated by Cynata Incorporated as at the acquisition date (1 December 2013) representing progress toward the eventual commercialisation of the relevant technology.
- (ii) An amortisation expense of \$140,366 has been recognised in profit or loss for the half-year ended 31 December 2015 (30 June 2015: \$447,945). For more information on the Group's accounting policy on intangibles and amortisation, refer to the 2015 annual financial report.

### 7. Issued capital

72,738,075 fully paid ordinary shares (30 June 2015: 66,071,403)

31 Dec 2015	30 Jun 2015
\$	\$
28,791,762	24,460,404

### **Fully paid ordinary shares**

Balance at beginning of period Share Placement (i) Exercise of share options (ii) Exercise of share options (iii) Exercise of share options (iv) Exercise of share options (v) Exercise of share options (vi) Share issue costs

31 De	c 2015	30 Jun 2015		
No.	\$	No.	\$	
66,071,403	24,460,404	54,959,153	22,281,642	
6,666,672	5,000,004	-	-	
-	-	13,750	2,750	
-	-	456,250	91,250	
-	-	20,157	4,032	
-	-	6,173,987	1,234,797	
-	-	4,448,106	889,621	
-	(668,646)	-	(43,688)	
72,738,075	28,791,762	66,071,403	24,460,404	

- (i) Issue of fully paid ordinary shares at \$0.75 each on 17 July 2015 to institutional investors in USA via a private placement.
- (ii) Exercise of listed options at \$0.20 each during the month of September 2014.
- (iii) Exercise of listed options at \$0.20 each during the month of October 2014.
- (iv) Exercise of listed options at \$0.20 each during the month of November 2014.
- (v) Exercise of listed options at \$0.20 each during the month of December 2014.
- (vi) Exercise of listed options at \$0.20 each during the month of January 2015.

### 8. Option reserves

### **Share-based payments**

Balance at beginning of period

Recognition of share-based payments (i)

Balance at end of period

<b>31 Dec 2015</b> \$	<b>30 Jun 2015</b> \$
3,276,148	2,846,691
266,251	429,457
3,542,399	3,276,148

The equity-settled employee benefits reserve arises on the grant of share options to executives, employees, consultants and advisors.

(i) Total amount arising from share-based payment transactions recognised during the half-year ended 31 December 2015 was \$266,251 (30 June 2015: \$429,457). The amount of \$266,251 includes \$63,081 which represents the expenses related to the participation of key management personnel in equity-settled benefit schemes as measured by the fair value of the options granted on grant date. The remaining amount of \$203,170 represents the fair value of options granted to the placement agent in USA pursuant to the capital raising mandate.

### 9. Contingent liabilities and contingent assets

There has been no significant change in contingent liabilities and/or contingent assets since the last annual report. Please refer to the 30 June 2015 annual financial report.

### 10. Commitments

#### **Research commitments**

During the half-year ended 31 December 2015, the Company entered into a number of agreements related to research and development activities. Under these agreements, the Company is committed to making payments over future periods, as follows:

- During the period 1 Jan 2016 30 June 2016
- During the period 1 July 2016 30 June 2017
- During the period 1 July 2017 30 June 2020

Α\$			
1,678,626			
899,994			
821,828			

Where commitments are denominated in foreign currencies, the amounts have been converted to Australian dollars based on exchange rates prevailing as at 31 December 2015.

### 11. Key management personnel

Remuneration arrangements of key management personnel are disclosed in the annual financial report. Arrangements with related parties continue to be in place. For details of these arrangements, please refer to the 30 June 2015 annual financial report.

Key management personnel continue to receive compensation in the form of short-term employee benefits, post-employment benefits and share-based payments.

### 12. Subsequent events

There has not been any matter or circumstance, other than that referred to below, that has arisen since the end of the half-year that has significantly affected, or may significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

(i) On 22 February 2016, the Company issued 600,000 unlisted options to a third party pursuant to the terms of an advisory services agreement. The options have an exercise price of \$0.53 and expire on or before 22 February 2019.