Zelda Therapeutics Ltd ACN 103 782 378 www.zeldatherapeutics.com

Level 45 108 St Georges Terrace, Perth Western Australia 6000

### DECEMBER 2016 QUARTERLY REPORT

- Successful \$4 million capital raising to fuel pre-clinical and clinical R&D activities
- Debut on the ASX with strong share price support since listing (up +35% on raising price)
- ) Stellar results from proof of concept study into the anti-cancer effects of its THC-rich medical cannabis formulation
- ) Expansion of pre-clinical research program to include pediatric brain cancers through partnership with prestigious Telethon Kids Institute and pancreatic cancer with Curtin University
- Progression of sleep trials with multiple target locations identified, discussions underway with Clinical Research Organisations (CROs) and submissions for relevant ethics approvals in progress

The Board of Zelda Therapeutics Ltd (ASX: ZLD, Zelda or the Company) is pleased to provide an operational update to accompany its Appendix 4C, released today, for the 3 month period to the 31 December 2016.

#### Corporate

Prior to the quarter, Zelda successfully closed a \$4 million capital raising and on the 22 November 2016 the Company debuted on the ASX.

The capital raising closed oversubscribed and received strong support from domestic and international new investors. The funds raised will be utilised to continue with pre-clinical and clinical trials that leverage its exclusive access to Aunt Zelda's data set. The results of these trials will form readily available data packs that form the basis for licensing deals with large pharmaceutical and biotech companies that can continue trials through to market commercialisation.

The Company has been particularly pleased with the share price support since listing with the share price currently up over 35% on the offer price.

The Company closed the quarter with a cash position of \$3.78m.

**Operational Progress** 

Positive Results from Proof of Concept Study

The Company was pleased to announce positive results of its initial proof of concept study, conducted at Complutense University of Madrid, into the anti-cancer effects of its THC-rich medical cannabis formulation.

Specifically, the study analysed the anti-tumour responses of pure tetrahydrocannabinol (THC) compared to Zelda Therapeutics' formulation of THC-rich oil and at the same time considered the potency against a standard chemotherapy drug, Lapatanib.

The study showed that Zelda Therapeutics' formulation of THC-rich oil was significantly more effective at reducing tumour growth than pure THC and more importantly, was as potent as Lapatanib in reducing tumour growth.

The positive results provide support to continue the study of Zelda's formulations as anti-cancer therapeutics, either as standalone formulations or in combination with current chemotherapy and radiotherapy regimes. A series of follow-on studies are now in progress that includes mechanism of action (MOA) studies, testing of other formulations of Zelda Therapeutics'' cannabinoids and also testing against other cancer cell lines.



#### Expansion of Pre-clinical Research Program

Since listing, the Company has expanded its cancer research into brain cancers (Telethon Kids Institute) and pancreatic cancer (Curtin University).

Through a collaboration agreement with the highly regarded, Perth-based Telethon Kids Institute Zelda will focus on pre-clinical research of its compounds, formulations and protocols in the area of children's brain cancer. Through the research, the Telethon Institute will examine the potential for Zelda's compounds to act as anti-cancer agents. The initial studies are expected to commence in early 2017 with results expected later in the year.

In partnership with Curtin University, a range of Zelda's formulations and protocols will be tested against Curtin's suite of in vitro pancreatic cancer models. The aim of this work is to test the impact of Zelda's cannabinoid formulations as standalone treatments and in combination with existing chemotherapy drugs such as Abraxane that is often used to treat pancreatic cancer.

This program seeks to identify whether Zelda formulations can generate anti-cancer activity and targets one of the most common cancer globally, with over 330,000 diagnoses in 2012<sup>1</sup>.

#### Sleep Trials Progressing

Zelda announced its strategy to target the significant sleep disorder market and has identified trial sites in multiple target locations, including the US and Australia. The Company is also progressing discussions with potential Clinical Research Organisations (CROs) and submissions for the necessary approvals from the relevant ethics committees in each location are now in progress.

The trials will assess the efficacy of Zelda's medical cannabis-based formulation for treating sleep disorders. Zelda will be leveraging the significant amount of anecdotal evidence and data for the compounds' effectiveness in treating sleep disorders available from Aunt Zelda's data set.

The Company anticipates commencing its first trial in the first half of 2017, following the relevant approvals and recruitment of patients with results expected thereafter.

#### Intellectual Property Portfolio Expanded

During the quarter, the Company lodged of a series of provisional patent applications concerning certain aspects of its medical cannabis intellectual property. Its existing data set demonstrates the success of its formulations in a number of medical indications including various cancers, sleep disorders and dermatology indications. There is significant opportunity for Zelda Therapeutics to continue to build a diversified portfolio of intellectual property in these and other indications.

#### Outlook

Zelda Therapeutics has in place the necessary strategy, partners and leadership to rapidly progress along its the path to becoming one of the world's leading medicinal cannabis biotechnology companies.

Since listing on the ASX, the Company has achieved a significant number of milestones towards validating its formulations in a number of medical indications, including breast cancer, brain cancer, pancreatic cancer and sleep disorders.

Harry Karelis, Executive Chairman said "Due to the significant data set and anecdotal evidence of the effectiveness of our medical formulation we're able to fast track our formulations into clinical trials, and in the case of sleep disorders we are able to progress straight to human clinical trials. Whilst we must await the necessary regulatory approvals we're confident of commencing our first human clinical sleep trial in the first half of 2017.

"I have been delighted with the progress made during the December 2016 quarter. We have a strong news flow pipeline as we enter 2017 and I look forward to sharing further exciting updates with our shareholders in due course."

#### CONTACTS

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About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics ("Zelda") is an Australian-based bio-pharmaceutical company that has secured exclusive, global access to an extensive set of human data related to medicinal cannabis based formulations and treatment protocols. This human data has been generated over several years by a California-based group (Aunt Zelda's) that has a very high profile within the USA and a growing international profile based upon its deep knowledge of the scientific rationale for certain cannabis-based formulations and protocols to treat a variety of medical conditions.

Zelda has been granted a worldwide, exclusive and perpetual licence to this data, related systems, formulations and treatment protocols. Zelda will use this information to design a series of human clinical trials that have a high probability of success given the existing patient data and experiences it has access to.

In addition, Zelda is building a pre-clinical research portfolio targeting cancer. It has partnered with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry. A similar programme is in place with the Australian Telethon Kids Institute targeting paediatric brain cancer and Curtin University targeting pancreatic cancer.

+Rule 4.7B

# **Appendix 4C**

## Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Quarter ended ("current quarter	r")
31 December 2016	· 1 ! !

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		     
1.1	Receipts from customers		-
1.2	Payments for		
	(a) research and development	(64)	(91)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	   -       	-
   	(c) advertising and marketing	(23)	(23)
	(d) leased assets	-	-
	(e) staff and board remuneration	(115)	(170)
i 1	(f) administration and corporate costs	(115)	(208)
1.3	Dividends received (see note 3)	 	 -   
1.4	Interest received	2	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	i - i	-
1.7	Government grants and tax incentives	i i I – I I – I	i -   
1.8	Other (provide details if material)		-
1.9	Net cash from / (used in) operating activities	(315)	(489)

On 18 November 2016, ZLD completed the acquisition of Zelda Therapeutics Pty Ltd (Zelda), an Australian based biotechnology company conducting research with medicinal cannabis, by issuing 320,000,000 consideration shares and 52,500,000 conversion shares in ZLD. In accordance with the Accounting Standards the acquisition of Zelda has been accounted for as a reverse acquisition transaction under the guidelines and principles of AASB 2 Share Based Payments. As a result, the statement of cash flows for the current quarter comprises the cash transactions for Zelda for the full quarter and the cash transactions of ZLD from the date of acquisition being 18 November 2016 to the period ended 31 December 2016.

+ See chapter 19 for defined terms

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
2.	Cash flows from investing activities	<u>-</u>	
2.1	Payments to acquire:		
	(a) property, plant and equipment		-
	(b) businesses (see item 10)		-
	(c) investments	-	-
	(d) intellectual property	i - i	-
	(e) other non-current assets		-
2.2	Proceeds from disposal of:	· · · · · · · · · · · · · · · · · · ·	
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments		-
	(d) intellectual property		-
	(e) other non-current assets		-
2.3	Cash flows from loans to other entities	-	31
2.4	Dividends received (see note 3)		-
2.5	Other (provide details if material)		-
	Proceeds from acquisition of Zelda Therapeutics Ltd (the deemed acquire for accounting purposes)	9	9
2.6	Net cash from / (used in) investing activities	9	40
3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	4,006	4,006
3.2	Proceeds from issue of convertible notes		-
3.3	Proceeds from exercise of share options		-
3.4	Transaction costs related to issues of shares, convertible notes or options	(336)	(336)
3.5	Proceeds from borrowings	i     	-
3.6	Repayment of borrowings	(165)	(165)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid		-
3.9	Other (provide details if material)	i i i - i	-
3.10	Net cash from / (used in) financing activities	3,505	3,505

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	579	722
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(315)	(489)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	9	40
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,505	3,505
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	3,778	3,778

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	270	579
5.2	Call deposits	3,500	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	3,778	579

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	168
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transaction items 6.1 and 6.2	ons included in
Board	Remuneration – 115,000	
Non-D	irector Services – 30,000	1
Expens	se Reimbursements – 23,000	
1		

7.	Payments to related entities of the entity and their associates		Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2		
7.2	Aggregate amount of cash flow from loans t in item 2.3	Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3	Include below any explanation necessary to items 7.1 and 7.2	understand the transac	tions included in
8.	<b>Financing facilities available</b> Add notes as necessary for an understanding of the position	Total facility amour at quarter end \$A'000	t Amount drawn at quarter end \$A'000
8.1	Loan facilities		- 1 - 1
8.2	Credit standby arrangements		
8.3	Other (please specify)		
8.4	Include below a description of each facility a whether it is secured or unsecured. If any a proposed to be entered into after quarter en	dditional facilities have b	een entered into or are
9.	Estimated cash outflows for next qua	irter	\$A'000
9.1	Research and development		<b>ЪА 000</b>
	Research and development		365
9.2	Product manufacturing and operating costs		
9.2 9.3	·		
	Product manufacturing and operating costs		365
9.3	Product manufacturing and operating costs Advertising and marketing		365
9.3 9.4	Product manufacturing and operating costs Advertising and marketing Leased assets		365 - 15 -
9.3 9.4 9.5	Product manufacturing and operating costs Advertising and marketing Leased assets Staff costs and board remuneration		365 - 15 - 168

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	   	
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

#### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: (Director/Company secretary)

Date: ......31 January 2017.....

#### Notes

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.