

#### Appendix 4E (Rule 4.3A)

#### Results for announcement to the market

Name of entity: **Suda Limited** ABN 35 909 987 250

The current reporting period is the financial year ended 30 June 2016. The previous corresponding period is the financial year ended 30 June 2015.

	Revenue / Profit	Movement	Change \$'000	Change %	30 June 2016 \$'000	30 June 2015 \$'000
ソマ	Revenues from ordinary activities.	Up	144	2.5	5,872	5,728
))	(Loss) from ordinary activities after tax attributable to members.	Down	1,136	33.7	(2,231)	(3,367)
	Net (loss) for the period attributable to members.	Down	1,136	33.7	(2,231)	(3,367)

NTA Backing	30 June 2016	30 June 2015	
	Cents	Cents	
Net tangible asset per security	0.24	0.55	_

#### Dividends

No interim dividends were paid and no final dividends are proposed.

#### Brief explanation of any of the figures reported above

The revenue is consistent with the prior year and was generated by Suda Ltd's subsidiary company Westcoast Surgical and Medical Supplies Pty Ltd. Whilst maintaining revenue, the Group has reduced operating costs resulting in a decrease in the loss attributable to members from \$3.37m for FY2015 to \$2.23m for FY2016.

#### **Audit Status**

This preliminary report is based on financial statements that are in the process of being audited.



# SUDA LTD AND CONTROLLED ENTITIES

ABN: 35 090 987 250

Preliminary Final Report For The Year Ended
30 June 2016

### SUDA LTD ABN 35 090 987 250 AND CONTROLLED ENTITIES PRELIMINARY FINAL REPORT – APPENDIX 4E

#### **Operating results**

The consolidated loss of the consolidated group after providing for income tax attributable to owners of the parent entity amounted to \$2,230,877 (2015: \$3,367,191). The loss decreased by 34% on the loss reported for the year ended 30 June 2015. Key developments during the year are explained below.

#### Product pipeline and subsidiary activities

#### ZolpiMist™ oral spray for the treatment of insomnia

In December 2015, SUDA amended its cross-licence and collaboration agreement with Amherst Pharmaceuticals (Amherst), a US specialty pharmaceutical company based in New Jersey. As a result, SUDA has expanded its license to ZolpiMist™ to include all countries excluding North America. In the US market, ZolpiMist was successfully relaunched by Magna Pharmaceuticals in March 2016. SUDA is working with a multi-national contract manufacturer regarding the manufacture of ZolpiMist in their facility in Australia. The Company has also embarked on the initial steps towards registration of ZolpiMist by the Australian Therapeutics Good Administration.

#### ArTiMist® oral spray for the treatment of paediatric malaria

SUDA acquired the minority interest in its subsidiary company Malaria Research Company Pty Ltd (MRC) in August 2015 for \$1.2m as full and final settlement of all outstanding liabilities between SUDA and the minority interest shareholder. The Directors believed that this acquisition was an important step towards SUDA's objective to commercialise ArTiMist® through a collaboration or trade sale.

In July 2015, the Company was granted a patent in Africa for its novel ArTiMist anti-malarial spray. The patent was issued by the African Regional Intellectual Property Organization (ARIPO) which is an intergovernmental organisation for cooperation among African states in intellectual property matters. ARIPO comprises 19 member states, including the major countries in malaria-endemic Sub-Saharan Africa.

SUDA and its Clinical Advisory Board finalised the design of the proposed trial of ArTiMist in the pre-referral setting and presented the protocol to the World Health Organisation. SUDA, through its UK-based company, applied for funding through the Horizon 2020 Research and Innovation program (European & Developing Countries Clinical Trials Partnership). Unfortunately, the Company was not successful in its grant application although it had received a very positive response. The Directors of the Company are of the opinion, based on current reports from the UK, that there is a reduction in European grants for UK-based scientists, universities and companies following Brexit and that SUDA Europe Ltd's chance of a successful application were greatly reduced due to the political climate in Europe.

#### SUD-001 sumatriptan oral spray for the treatment of migraine

Early in the financial year, SUDA had a Type C meeting with the US Food and Drug Administration (FDA) whereby the FDA acknowledged SUDA's proposed development strategy and requested only minor justifications to the study design. Furthermore, the agency had no comments regarding SUDA's plans for chemistry, manufacturing, controls and non-clinical studies of SUD-001. The FDA also requested that SUDA submit a paediatric study plan in migraineurs aged 6-17 years who could benefit from SUDA's first-in-class oral-spray migraine therapy.

Under the acknowledged development plan, SUDA expects to save significant time and capital by avoiding the need to conduct costly efficacy studies in adults prior to registration of SUD-001 in the US.

#### SUD-002 ondansetron for the treatment of chemotherapy-induced nausea and vomiting

SUDA received the North American rights back to SUD-002 from Amherst under the amended agreement in December 2015. SUDA is completing stability and compatibility studies with the SUD-002 formulation before requesting a meeting with the FDA to discuss the submission of a New Drug Application. In July 2015, SUDA received a Notice of Grant from the US Patent Office for a new patent covering SUD-002, entitled "Buccal, Polar and Non-Polar Spray Containing Ondansetron".

#### SUD-003 sildenafil oral spray for the treatment of erectile dysfunction

SUDA is continuing the development of a new-generation formulation of SUD-003, which includes flavouring, taste masking and a new and novel process that is designed to enhance and further improve the permeation characteristics and bioavailability. The Company has completed *in vitro* and *ex vivo* studies and is conducting an *in vivo* study before presenting a clinical development plan to the FDA. SUDA also plans to lodge a new patent application for the novel permeation-enhancing technology that has been developed with new-generation SUD-003 sildenafil formulation. This platform technology has broad application for optimising mucosal permeation of many types of molecules.

### SUDA LTD ABN 35 090 987 250 AND CONTROLLED ENTITIES PRELIMINARY FINAL REPORT – APPENDIX 4E

#### **Westcoast Surgical & Medical Supplies (Westcoast)**

Westcoast continues to be a strong player in the supply of medical consumables within the Aged Care, Allied Health, Mining and Hospital sectors in Western Australia. During the year, Westcoast reduced operating costs whilst maintaining revenue in a difficult economic environment.

#### Significant events

The significant events during the 2015-16 financial year were:

i. Acquired minority shareholding in MRC

The minority shareholder sold its 20% shareholding in MRC to SUDA for \$1.2 million. This payment was in full and final settlement of all outstanding liabilities between the two companies.

ii. FDA response to SUD-001

SUDA submitted a Type C meeting briefing package to the FDA in June 2015 containing details of the proposed pivotal study of SUD-001 and other activities intended to support a New Drug Application in the USA. The Company received a written response from the US FDA regarding the development plan for the Company's SUD-001 sumatriptan oral spray for the treatment of migraine.

iii. Patent application for SUD-003 in the USA

The US Patent and Trademark Office has allowed SUDA's first patent application for its sildenafil based products, SUD-003 and SUD-004, in the USA. The patent application (US 14/363,245) is titled: "Oral Spray Formulations and Methods for Administration of Sildenafil". A patent directed to similar subject matter has already been granted in New Zealand and patent applications are pending in other jurisdictions

iv. Rolled over 2013 convertible notes

The Company's 2013 convertible note matured on 30 September 2015. At that date, the number of convertible notes on issue were 1,625,000. A total of 920,000 convertible notes were redeemed on 30 September, 705,000 rolled over under amended terms and new subscribers to the 2015 convertible note totalled 1,025,000.

v. Statement of claim received from HC Berlin Pharma AG

The Company received a Statement of Claim in relation to a lawsuit between the Company and HC Berlin Pharma AG (in liquidation). The Administrator is seeking a payment of EURO 4.0 million with interest of 5% from 25 August 2008.

Based on legal advice, the Directors of SUDA are confident that the Administrator's Statement of Claim is deficient and factually incorrect and, as such, has little chance of success.

#### Dividends Paid or Recommended

The Directors have recommended that no dividend be paid by the company in respect of the financial year ended 30 June 2016.

#### After Balance Date Events

There have been no after balance date events.

The Board thanks our shareholders for their ongoing support and looks forward to an exciting 2016/17 year.

# SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2016

	Note	Group	
		2016	2015
		\$	\$
Revenues	2	5,871,615	5,727,589
Other income		96,402	136,417
Raw materials and consumables used	3	(5,044,696)	(5,022,888)
Employee benefits expense		(2,301,495)	(2,469,576)
Depreciation and amortisation expense		(122,363)	(181,244)
Finance costs	3	(209,556)	(156,200)
Other expenses		(1,320,784)	(2,070,346)
Loss before income tax		(3,030,877)	(4,036,248)
Income tax benefit		800,000	657,917
Net loss for the period		(2,230,877)	(3,378,331)
Total comprehensive loss for the period		(2,230,877)	(3,378,331)
7		(=)===;===	(0,010,000)
Loss and total comprehensive loss attributable to:			
Owners of the parent		(2,230,877)	(3,367,191)
Non-controlling interests		-	(11,140)
		(2,230,877)	(3,378,331)
Earnings per share			
Basic loss per share (cents)	4	(0.20)	(0.33)
Diluted loss per share (cents)	4	(0.20)	(0.33)
<u>(15)</u>			

The accompanying notes form part of these financial statements.

# SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2016

Gro	oup
2016	2015
\$	\$
2,448,771	6,251,947
1,573,056	1,318,621
1,132,176	1,540,555
194,930	233,257
5,348,934	9,344,380
271 763	388,617
•	•
	•
19,571,420	22,820,743
1,179,271	1,795,156
1,730,000	1,725,000
2,909,271	3,520,156
2,909,271	3,520,156
16,662,149	19,300,587
55,716,942	55,573,622
2,108,522	628,255
(41,163,315)	(38,932,438)
16,662,149	17,269,439
-	2,031,148
16,662,149	19,300,587
	<del></del>
	2016 \$ 2,448,771 1,573,056 1,132,176 194,930 5,348,934  271,763 13,950,723 14,222,486  19,571,420  1,179,271 1,730,000 2,909,271  2,909,271  16,662,149  55,716,942 2,108,522 (41,163,315) 16,662,149  -

The accompanying notes form part of these financial statements.

#### **SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES CONSOLIDATED STATEMENT OF CHANGES IN EQUITY** FOR THE YEAR ENDED 30 JUNE 2016

1	ssued Capital	Accumulated Losses	Share-based Payments Reserve	Minority Interest Acquisition Reserve	Non- controlling interests	Total
_	\$	\$	\$	\$	\$	\$
Balance as at 1 July 2014	48,944,557	(35,565,247)	569,958	-	2,042,288	15,991,556
Shares issued during the year	6,925,386	-	-	-	-	6,925,386
Share-based payments	-	-	58,297	-	-	58,297
Transaction costs	(296,321)	-	-	-	-	(296,321)
Loss for the year attributable to members of the pa	-	(3,367,191)	-	-	- (44.440)	(3,367,191)
interest	-	-	-	-	(11,140)	(11,140)
balance as at 30 June 2013	55,573,622	(38,932,438)	628,255	-	2,031,148	19,300,587
Balance as at 1 July 2015	55,573,622	(38,932,438)	628,255	_	2,031,148	19,300,587
Shares issued during the year	143,320	(50,552,450)	-	_	2,031,140	143,320
Acquisition of minority shareholding	143,320				(2,031,148)	(2,031,148)
Recognition of share-based payments expense	_	_	76,000	_	(2,031,110)	76,000
Project development reserve on acquisition of			70,000			70,000
minority shareholding Loss for the year attributable to members of the	-	-	-	1,404,267	-	1,404,267
parent entity	-	(2,230,877)	-	-	-	(2,230,877)
Balance as at 30 June 2016	55,716,942	(41,163,315)	704,255	1,404,267	-	16,662,149
The accompanying notes form part of these financia	l statements.					



# SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2016

	Group	
	2016	2015
	\$	\$
CASH FLOWS FROM OPERATIONS		
Receipts from customers	5,889,989	6,298,415
Payments to suppliers	(8,338,004)	(9,630,256)
Receipts for R&D tax concession	687,626	188,290
Interest received	109,651	102,774
Interest paid	(151,365)	(113,630)
Net cash used in operations	(1,802,103)	(3,154,407)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(40 420)	(202 200)
Purchase of other non-current assets	(48,428)	(282,390)
Payments for equity investments	(1,396,273)	(995,823)
	(647,077)	
Proceeds from sale of property, plant and equipment	21,705	5,455
Net cash used in investing activities	(2,070,073)	(1,272,759)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from share issues	-	6,986,164
Proceeds from borrowings	1,025,000	-
Repayment of borrowings	(920,000)	_
Payments for capital raising costs	(36,000)	(296,321)
Net cash provided by financing activities	69,000	6,689,843
Net increase / (decrease) in cash held	(3,803,176)	2,262,677
Cash at the begining of period	6,251,947	3,990,397
Effect of exchange rates on cash holdings in foreign currencies	-	(1,127)
Cash at the end of period	2,448,771	6,251,947
Reconciliation of Cash and Cash Equivalents		
	2016 \$	2015 \$
Cash at bank and in hand	2,448,771	6,251,947
Cash at the end of the period as shown in the cash flow statement is reconciled to items in the balance sheet as follows:		
Cash and cash equivalents	2,448,771	6,251,947
	2,448,771	6,251,947

The accompanying notes form part of these financial statements.

## SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2016

The preliminary final report of the Company for the year ended 30 June 2016 comprises the Company and its controlled entities (the "Consolidated Entity" or "Group").

#### Note 1 Statement of Significant Accounting Policies

#### **Basis of Preparation**

The preliminary final report is presented in Australian dollars and has been prepared on an accrual basis and is based on historical cost basis except for selected current and non-current assets which are measured at fair value at reporting date.

The preliminary final report has been prepared in accordance with Australian Securities Exchange Listing Rules as they relate to Appendix 4E and in accordance with the recognition and measurement requirements of the Australian Accounting Standards (including Australian Accounting Interpretations) adopted by the AASB and the Corporations Act 2001.

As such, the preliminary final report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide a full understanding of the financial performance and financial position as the full financial report. It is recommended that the preliminary final report be considered together with any public announcements made by the Company in accordance with the continuous disclosure obligations of the Australian Securities Exchange Listing Rules.

#### Note 2 Revenue and Other Income

		Consolidate	d Group
		2016	2015
((((((((((((((((((((((((((((((((((((		\$	\$
Sales Re	venue		
_	sale of goods	5,785,802	5,624,815
Other Re	evenue		
_	interest received from other persons	85,813	102,774
Jotal Sa	les Revenue and Other Revenue	5,871,615	5,727,589
Other In	come		
	gain on disposal of property, plant and equipment	78	5,455
2	other income	96,324	130,962
Total Ot	her Income	96,402	136,417
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Note 3	Loss for the Year		
		Consolidate	d Group
		2016	2015
(a)	Expenses	\$	\$
	Cost of sales	4,619,427	4,709,576
	Write-down inventories to net realisable value	27,794	182,615
	Write-off of obsolete stock	397,475	130,697
		5,044,696	5,022,888
(b)	Finance costs		
()	Interest expense on financial liabilities through profit or loss:		
	<ul> <li>Other persons</li> </ul>	209,556	156,200

#### **SUDA LTD ABN: 35 090 987 250 AND CONTROLLED ENTITIES** NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2016

#### Note

Shares issued during year:

- Employee Share Scheme

At reporting date

- conversion of convertible notes

- settlement of interest on convertible notes

- settlement of premium on redemption of convertible notes

Note 4	Earnings per Share			
	0.7.		Consolidated	d Group
			2016	2015
			\$	\$
(a)	Reconciliation of earnings to profit or loss			
	Loss		(2,230,877)	(3,378,331)
	Earnings used to calculate basic EPS	_	(2,230,877)	(3,378,331)
	Earnings used in the calculation of dilutive EPS	_	(2,230,877)	(3,378,331)
		_	No.	No.
(b)	Weighted average number of ordinary shares outs	standing during the year		
	used in calculating basic EPS	=	1,139,508,407	1,015,727,042
5	Options convertible to ordinary shares are not co	nsidered to be dilutive as		
	their exercise will not result in diluted earnings p			
Note 5	Controlled Entities			
<u>ال</u>				
	Controlled Entities Consolidated	Country of	Percentage Ov	
		Incorporation	2016	2015
	Subsidiaries of Suda Ltd:			
	Westcoast Surgical and Medical Supplies Pty Ltd	Australia	100	100
	Malaria Research Company Pty Ltd	Australia	100	80
	Eastland CN Nominees Pty Ltd	Australia	100	100
	Suda Europe Ltd	United Kingdom	100	-
	Suda Limited acquired the minority interest in Ma	laria Research Company Pty	Ltd on 26 August 20	)15.
	Suda Europe Ltd was established on 24 August 201	.5.		
Note 6	Issued Capital			
			Consolidated	d Group
			2016	2015
5			\$	\$
Gross ca	apital proceeds		58,014,172	57,870,852
Capital	raising costs	_	(2,297,230)	(2,297,230)
1,141,27	72,286 (2015: 1,136,010,587) fully paid ordinary shar	res =	55,716,942	55,573,622
	Oudinamy Chausa			
	Ordinary Shares		No	No
	At the heginning of reporting period		No.	No.
<i>)</i> )	At the beginning of reporting period		1,136,010,587	950,262,913
	Shares issued 1 July 2014 to 30 June 2015		-	185,747,674

1,049,500

3,339,880

752,319

120,000

1,141,272,286 1,136,010,587