

## ASX Release

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# Appendix 4C: First Quarter FY 2021 Activities Report

**PERTH, AUSTRALIA – 26 October 2020:** SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, today released its Appendix 4C for the consolidated group for the first quarter of FY 2021.

### Highlights

- TGA approved registration of ZolpiMist®
- Australian patent granted for anagrelide
- Hypothesis for oral spray of anagrelide confirmed
- Successful capital raise of \$4.1m
- End of period cash balance of \$1.5m plus \$2m held in term deposit

During the quarter ended 30 September 2020, the Company was pleased with the following developments:

- The Therapeutics Goods Administration (TGA) approved the registration of the Company's lead product ZolpiMist (zolpidem tartrate) for the treatment of short-term insomnia in adults. Completion of the TGA review was expected Q4 2020 and the Company is currently in discussions to secure its Australian commercialisation partner. The TGA approval with the amended API supplier and manufacturer will assist SUDA's current partners, TEVA, Mitsubishi Tanabe Pharma Singapore and MTP Korea, for their submissions in their respective territories.
- There were two positive developments for the anagrelide project:
  - the Australian Patent Office will grant SUDA's Application No. 2015370666 titled "Prevention and Treatment of Metastatic Disease in Thrombocytotic Cancer Patients". The patent has an expiry date of December 2035. This adds to the granted patents that the Company has in Europe and Japan.
  - the Company received the final report for the pharmacokinetic study that was completed at Covance Inc., in the UK. The data revealed that one of the carefully selected oral spray formulations resulted in a statistically significant increase in bioavailability of anagrelide with a lesser increase in the levels of the unwanted cardiostimulatory intermediate. This means that

patients may be able to take less of the drug and reduce their exposure to the cardiostimulatory intermediate. This supports SUDA's hypothesis that an oral spray version of anagrelide may provide a safer route of administration of the drug for the treatment of metastatic disease.

Dr Baker commented "This has been a busy quarter and we are proud that SUDA has received its first TGA approval for ZolpiMist. The next step is to secure our Australian partner for commercialization of the product and to continue to work with our existing partners for their regulatory submissions and commercialisation efforts.

It is also pleasing to have ticked off two important milestones for the anagrelide program, receiving notification that the Australian patent will proceed to grant and confirming the hypothesis that an oral spray version of anagrelide may provide a safer route of administration to treat patients with metastatic disease and elevated platelet levels."

### **Corporate Update**

The net outflow from operating activities for the quarter was \$1.148m with a bank balance of \$1.527m and an additional \$2.000m held in term deposits (which is greater than 90 days) as at 30 September 2020.

Higher costs were incurred as SUDA had intended to complete a material in-licensing transaction in the previous quarter, to secure a new technology from a leading U.S. cancer research institute. Unfortunately, the transaction did not proceed and some of the payments incurred in relation to this transaction are included in item 1.8 of the Appendix 4C. The Company is continuing to assess the landscape for additional technologies to acquire and it has identified a number of assets that it believes could enhance the current product portfolio.

The non-renounceable pro rata entitlement offer announced on 3 July 2020 closed on 29 July 2020 and was strongly supported by the Company's shareholders, including institutional shareholders, and closed heavily oversubscribed. Applications for entitlements and additional top-up shares received from shareholders totalled \$5.2m. Accordingly, the company had to scale back top-up applications in relation to the entitlement offer. In total, the Company raised \$3.56m (before costs) via the entitlement offer and issued 142,254,397 shares and 47,418,132 listed options.

In preparation for any shortfall that may have arisen for the entitlement offer, the lead manager Baker Young, received bids in excess of \$3.4m. Due to the overwhelming demand, the Company placed a further 21,338,159 fully paid ordinary shares at \$0.025, raising an additional \$533,453 ("Placement") to sophisticated investors to strengthen the Company's financial position. There were no attaching options issued as part of the Placement.

We thank our shareholders for their support in the recent entitlement offer and we welcome those that joined the register in the placement.

During the quarter, Mr Phillip Hains took over as Company Secretary after becoming Joint Company Secretary on 1 July 2020. He replaces Mr Joseph Ohayon, who held the role as Company Secretary from March 2011 and had been a director of the company from December 2012 until May 2019.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates all directors' fees, remuneration, superannuation and consulting fees at commercial rates. In addition, an exclusivity fee was

paid to a related party in relation to the in-licensing transaction that the company pursued earlier in the year.

*Dr Michael Baker, CEO and Managing Director of Suda Pharmaceuticals Ltd has authorised the release of this announcement to the market.*

For and on behalf of the Board and for further information please contact:

**Dr Michael Baker**

**Chief Executive Officer & Managing Director**

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#### **NOTES TO EDITORS:**

##### **About SUDA Pharmaceuticals Ltd**

SUDA Pharmaceuticals Ltd (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (i.e. cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist®, a first-in-class oral spray of zolpidem tartrate for the treatment of short-term insomnia. ZolpiMist is approved by the TGA and is marketed in the USA. SUDA has rights to the product outside of the US and Canada. Other products in development include oral sprays for the treatment of migraine headache, motion sickness, drug resistant epilepsy and certain cancers.

For more information, visit [www.sudapharma.com](http://www.sudapharma.com)

## Appendix 4C

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

**Name of entity**

Suda Pharmaceuticals Ltd

**ABN**

35 090 987 250

**Quarter ended ("current quarter")**

30 September 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	20	20
1.2 Payments for		
(a) research and development	(142)	(142)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(23)	(23)
(e) staff costs	(519)	(519)
(f) administration and corporate costs	(501)	(501)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	180	180
1.8 Other	(163)	(163)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,148)</b>	<b>(1,148)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(12)	(12)
(d) investments	(2,000)	(2,000)
(e) intellectual property	(112)	(112)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(2,124)</b>	<b>(2,124)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	4,090	4,090
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(262)	(262)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>3,828</b>	<b>3,828</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	977	977
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,148)	(1,148)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(2,124)	(2,124)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,828	3,828
4.5	Effect of movement in exchange rates on cash held	(6)	(6)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>1,527</b>	<b>1,527</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	477	977
5.2	Call deposits	1,050	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,527</b>	<b>977</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

<b>Current quarter \$A'000</b>
251
-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

Item 6.1 Reflects amounts paid to all directors including director's fees, salaries, superannuation and consulting fees. In addition, an exclusivity fee was paid to a related party.

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

**7. Financing facilities**

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-

7.5 **Unused financing facilities available at quarter end** -

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,148)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	1,527
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	1,527
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	1.3

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: SUDA has \$2,000,000 in term deposit (which is greater than 90 days) in addition to the \$1,527,364 cash on hand. As such, the Company has and expects that it will continue to have the current level of net operating cash flows for the time being.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The Company has and expects to continue to have the current level of net operating cash flows for the time being. As such, it is not proposing steps to raise further cash to fund its operations at this time. The board will continue to monitor the cash position closely.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: The Company does expect to be able to continue its operations and to meet its business objectives as it has \$2,000,000 in term deposit (which is greater than 90 days) in addition to the \$1,527,364 it has in cash as of 30 September 2020.

## 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.

Date: 26 October 2020

Authorised by: By the Board  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.