



ASX Release

Quarterly Activities Report and Appendix 4C – September Quarter 2023

Key Highlights

Acrux has made significant commercial progress with several of our approved products during the September quarter and we have simultaneously progressed several other products in our development pipeline. The following milestones have been achieved:

- Our commercial licensee for Prilocaine 2.5% and Lidocaine 2.5%, Cream has continued to improve the product's market position, with profit share income continuing to grow each quarter.
- Dapsone 5%, Gel (a treatment for acne vulgaris) was approved by the FDA in June 2023. In conjunction with our manufacturing and commercial partners, we are targeting the US product launch in the next calendar quarter.
- The dossier for Nitroglycerin 0.4%, Ointment (a treatment for moderate to severe pain caused by chronic anal fissure) was formally accepted by the FDA for review in July 2023.

Melbourne, Australia; 27 October 2023: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**")

With revenue from commercialised products accelerating we expect positive Net Cashflows for the next quarter.

At 30 September, Acrux had \$4.718 million of receivables, of which \$1.227 million has been received in October. A further \$2.869 million is receivable for the Research and Development Tax Incentive claim for FY23 and (subject to fluctuations in the AUD/USD FX rate) a further \$0.474 million is due for receipt in November in relation to September quarter's profit share income.

We have liaised with our partners to maintain adequate supplies of raw materials and enable scale-up of production to facilitate growth in market share for Prilocaine 2.5% and Lidocaine 2.5%, Cream.

Manufacturing and commercial activities are continuing to support the launch of Dapsone 5%, Gel in the near future.



Payments for operating costs totalled \$3.331 million, which included \$0.921 million costs directly associated with manufacturing and operations support for Prilocaine 2.5% and Lidocaine 2.5%, Cream. As the launch proceeds, there will continue to be temporary differences between the timing of these expenses and the receipt of reimbursement from Padagis. At \$2.410 million, underlying product development and operations costs were comparable with the prior quarter (\$2.343 million).

Staff costs reflect employment related expenses for the Company's employees and Non-executive Directors. Cash payments and superannuation related to the remuneration of Non-executive Directors are additionally disclosed as a Related Party payment at Item 6.

The Acrux product portfolio

The following Acrux pipeline products have been approved by the FDA during the last 12 months:

- Prilocaine 2.5% and Lidocaine 2.5%, Cream, a topical anaesthetic, launched by Padagis in FY22.
- Dapsone 5%, Gel a treatment for acne vulgaris was approved in June 2023, with plans underway to launch in the next calendar quarter.

The FDA has also accepted and is currently reviewing three additional ANDAs that have been submitted by Acrux. Since the FDA administers the ANDA review process, the time to final approval is influenced by the number and nature of questions that may arise as the FDA progresses the review process. The three Acrux products currently under review include:

- Nitroglycerin 0.4%, Ointment, a treatment for moderate to severe pain caused by chronic anal fissure.
- Acyclovir 5%, Cream, a treatment for cold sores.
- Dapsone 7.5%, Gel, a treatment for acne vulgaris.

Acrux has 6 approved products, of which 4 are currently commercialised and one soon to be launched. The Company has a total portfolio of 16 products at various stages of development.

Approved for release by the Acrux Board of Directors.



For more information, please contact:

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About Acruz

Acruz is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acruz has successfully marketed through licensees a number of products worldwide with emphasis on the United States.

Acruz is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acruz encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

For further information on Acruz, visit www.acruz.com.au

Appendix 4C

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

Name of entity: Acrux Ltd

ABN	Quarter ended ("current quarter")
72 082 001 152	September 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	428	428
1.2 Payments for		
(a) research and development	(574)	(921)
(b) product manufacturing and operating costs	(921)	(921)
(c) advertising and marketing	-	-
(d) leased assets	(8)	(8)
(e) staff costs	(1,350)	(1,350)
(f) administration and corporate costs	(478)	(478)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	76	76
1.5 Interest and other costs of finance paid	(47)	(47)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,731
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,872)	(2,872)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(56)	(56)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(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)	-	-
2.6 Net cash from / (used in) investing activities	(56)	(56)
3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	(46)	(46)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	(46)	(46)
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	6,232	6,232
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,872)	(2,872)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(56)	(56)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	(46)	(46)
4.5 Effect of movement in exchange rates on cash held	(2)	(2)
4.6 Cash and cash equivalents at end of period	3,255	3,255

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	3,255	3,255
5.2 Call deposits	-	-
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)	3,255	3,255

6. Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1 Aggregate amount of payments to related parties and their associates included in item 1	48
6.2 Aggregate amount of payments to related parties and their associates included in item 2	-

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.

7. Financing facilities <i>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.</i>	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	120	6
7.4 Total financing facilities	120	6
7.5 Unused financing facilities available at quarter end		114
7.6 <i>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.</i>		
Credit Card facility, ANZ Bank		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,872)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,255
8.3 Unused finance facilities available at quarter end (item 7.5)	114
8.4 Total available funding (item 8.2 + item 8.3)	3,369
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.2

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

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

8.6.1 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: Cash receipts for the December quarter are expected to be materially higher than the September quarter with \$4.739 million receivable as at 30 September, including, 1) FY23 Research and Development Tax Incentive Rebate, \$2.869 million, 2) Revenue from Licensing Agreements of \$1.737 million.

8.6.2 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: No

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

Answer: Yes

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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: 27 October 2023

Authorised by: The Board of Directors, Acrux Ltd

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.