ASX Release

Quarterly Activities Report and Appendix 4C – December Quarter 2023

Melbourne, Australia; 31 January 2024: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**")

For the December Quarter Acrux is pleased to report a positive cashflow of $1.309 million resulting in an increase of Cash Reserves to $4.565 million.

The cash surplus for the December Quarter is predominantly driven by the receipt of $2.869 million from the Research and Development Tax Incentive for the year ended 30 June 2023 as well as $1.762 million received in relation to client contracts.

Income from client contracts includes:

- Profit share and royalties paid to Acrux by our commercial partners ($0.449 million received in the December Quarter, $0.817 million YTD); and
- Supply of Prilocaine and Lidocaine Active Pharmaceutical Ingredients ('API') which has increased following the scale up of commercial manufacture of Prilocaine 2.5% and Lidocaine 2.5%, Cream ($1.313 million received for the December Quarter, $1.373 million YTD).

In addition to outgoings for API purchases, cash outflows for operating expenses totaled $2.747 million for the December Quarter and $5.157 million for the year to date with the major drivers being external Research and Development expenditure and staff costs.

Staff costs reflect employment related expenses for the Company's employees as well as the 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.

Quarterly Activities Report

For the December Quarter our supply chain has been a key operational focus, firstly to support the manufacture of the first commercial volumes of Dapsone 5%, Gel which is planned to be launched early in 2024 and secondly to support the supply for the Prilocaine 2.5% and Lidocaine 2.5%, Cream market opportunity. This supply chain activity has mainly involved expediting the availability of components, excipients and both expediting and expanding the availability of active pharmaceutical ingredients.

In November the Board, together with senior management, conducted a formal analysis of its pipeline and portfolio of products. On a twice yearly basis, our pipeline of products is analysed in detail where execution risks and projected development costs associated with completion of each project are balanced against the commercial outlook for each product. This review also involves a structured assessment of new and emerging opportunities to identify product development candidates which could be added to the pipeline. The Company reviews the market to identify new product development candidates and continuously has a basket of products that it reviews in detail to determine the attractiveness of adding a new product into the Company's development portfolio. Following this assessment, it was determined that work on two early stage projects will be ceased and three new product development opportunities have been identified and approved to be added to the development portfolio. Furthermore, the options for Testosterone Topical Solution have been evaluated and it has been concluded that as this is no longer a commercially viable product for Acrux.

Acrux continues to focus on its strategy to develop a pipeline of topically applied pharmaceutical products with the goal of bringing to market an expanding number of products. Our overriding corporate objective is to generate sustainable and diversified revenue growth.

The Acrux product portfolio

Acrux currently has 6 products which have achieved regulatory approval, including 2 which are currently generating revenue, namely Prilocaine 2.5% and Lidocaine 2.5%, Cream and Evamist®. Additionally, Dapsone 5%, Gel is planned for launch shortly.

Furthermore, 3 Acrux ANDAs are currently under FDA review:

- 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.

The FDA administers the ANDA review process and accordingly the time to final approval is influenced by the nature of questions that may arise as the review progresses.

There are additional products at stages of development ranging from early stage formulation development through to process development and demonstration of bioequivalence and finally to regulatory dossier preparation.

Acrux presently has 14 topical generic products in our portfolio (including Testosterone Topical Solution) and a further 3 products have been identified and approved for commencement over CY24. It is our expectation that the portfolio will continue to be expanded through the addition of 2 new projects each year.

Half year summary

Since June 2023 Acrux has made the following material announcements to the ASX:

- FDA approval of Dapsone 5%, Gel;
- acceptance for review by the FDA of Nitroglycerine 0.4%, Ointment;
- termination of the distribution agreement for Testosterone Topical Solution; and
- the receipt of the annual R&D Tax Incentive for FY23 totalling $2.88 million.

Further to those announcements the Company was engaged in continuing efforts in a number of focussed areas.

Prilocaine 2.5% and Lidocaine 2.5%, Cream.

The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA was US$37.9 million. The Company has expended significant efforts in coordination with our commercial licensee to increase the robustness of the supply chain to ensure the ongoing future availability of product to meet the changing needs of the market for this product.

Dapsone 5%, Gel.

The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA was US$15.5 million. Launch plans are well underway for this product with the rate limiting step for the commercial launch being the availability of certain components, which has been resolved. This is not an exclusive issue for Acrux or any specific supplier, but a common issue faced by companies in our sector.

Testosterone Topical Solution.

The addressable market for this product, defined as the 12 months of sales up to end October 2024 and measured by IQVIA was US$9.9 million. The Company has a long history of generating value from this market segment, having initiated development of the product around two decades ago. Nonetheless, annual market volumes have declined by over 50% since 2018 and pricing has also substantially declined and we no longer believe the market is longer attractive to further pursue this product. We will now be taking steps to divest or discontinue this product.

FDA engagement

We frequently engage with the FDA on future product candidates through either Controlled Correspondence[1], or other meetings that we schedule with the FDA. This is in addition to active engagement through the review process of the 3 products we currently have under FDA assessment. Since the start of July 2023, the Company has submitted 36 Controlled Correspondences, including 17 for new product candidates. In that period, the Company has also had 14 other interactions with the FDA via video or teleconference, or as written correspondence to the FDA.

[1] A Controlled Correspondence is a communication submitted to FDA by or on behalf of a generic drug manufacturer or related industry requesting information on a specific element of generic drug product development or certain post approval submission requirements. Further information on Controlled Correspondence can be found here: https://www.fda.gov/industry/generic-drug-user-fee-amendments/controlled-correspondence-related-generic-drug-development

Pipeline progression

In December 2023, Acrux also entered into an additional manufacturing contract for one of its pipeline products with a new contract manufacturer and the technical transfer process for this product has begun ahead of the planned manufacturing of exhibit batches required for a regulatory submission for FDA review.

> Acrux's CEO, Michael Kotsanis said, "*We are encouraged by the progress Acrux has made in the December quarter, as reflected in this Activities Statement and half year summary. We thank shareholders for their ongoing support and look forward to making further constructive announcements in coming months*."

Approved for release by the Acrux Board of Directors.

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About Acrux

Acrux 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, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States.

Acrux 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. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

For further information on Acrux, visit www.acrux.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	December 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,762	2,190
1.2	Payments for		
	(a) research and development	(1,260)	(1,834)
	(b) product manufacturing and operating costs	(421)	(1,342)
	(c) advertising and marketing	-	-
	(d) leased assets	(7)	(15)
	(e) staff costs	(1,137)	(2,487)
	(f) administration and corporate costs	(343)	(821)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	46	122
1.5	Interest and other costs of finance paid	(45)	(92)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,869	2,869
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**1,464**	**(1,410)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(100)	(156)
	(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 (12 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**	**(100)**	**(156)**

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	(38)	(94)
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**	**(38)**	**(94)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,255	6,232
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,464	(1,410)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(100)	(156)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(38)	(94)
4.5	Effect of movement in exchange rates on cash held	16	(7)
4.6	**Cash and cash equivalents at end of period**	**4,565**	**4,565**

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	4,565	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)**	**4,565**	**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	44
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 *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	120	6
7.4	**Total financing facilities**	120	6
7.5	**Unused financing facilities available at quarter end**		114
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.*		
	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)	1,464
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,565
8.3	Unused finance facilities available at quarter end (item 7.5)	114
8.4	Total available funding (item 8.2 + item 8.3)	4,678
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A
	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: N/A

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: N/A

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: N/A

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: 31 January 2024

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.