ASX Release **30 April 2024**

Quarterly Activities Report and Appendix 4C – March Quarter 2024

Positive cashflow reported in March 2024 quarter; revenue base expansion continues, Dapsone 5%, Gel launched in April

Melbourne, Australia; 30 April 2024: Specialty pharmaceuticals group Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to release its quarterly cashflow for the three months ended 31 March 2024 (Q3 FY24) along with the accompanying business update.

Key Highlights:

- In April Acrux launched its treatment for acne vulgaris, Dapsone Gel, 5%, giving the Company its third revenue-generating product.
- Acrux has made further progress in plans to launch future revenue-generating products, with three currently under FDA review.
- Acrux reports a positive cashflow of $0.763 million in its Q3 FY24, increasing the Company's cash reserves to $5.328 million.
- Positive cashflow has now been reported in four of the past seven quarters.

Acrux's CEO, Michael Kotsanis, said:
"The past three months has seen Acrux continue to deliver on our stated growth strategy, to develop and launch a pipeline of topically applied pharmaceutical products and build a sustainable and growing revenue stream. From a commercial perspective, we were excited to launch our Dapsone 5%, Gel product in April 2024. Looking ahead, our team continues to work with our suppliers, manufacturers, and licensees to support ongoing diversification of our revenue base, including commencement of launch planning for products which are currently under FDA review. We additionally have three new pipeline projects identified and approved to be commenced over the 2024 calendar year."

Acrux launches Dapsone Gel, 5%

The Company's latest new product launch, Dapsone Gel, 5% was announced to the market in April 2024 (see ASX announcement dated 3 April 2024).

Dapsone Gel, 5% is a prescription medicine used on the patient's skin (topical). It has been launched into the US market in partnership with front-end pharma sales and marketing company TruPharma LLC.

Acrux further progresses its stated product expansion strategy

Acrux continues to deliver meaningful progress in its stated growth strategy, which is to develop a pipeline of topically applied pharmaceutical products. These are now being progressively brought to market, which is creating a diversified portfolio of products generating sustainable revenue.

Following the launch of Dapsone 5%, Gel, in early Q4 FY24, Acrux now has four marketed products of which three currently generate revenue for the Group, namely Lidocaine and Prilocaine Cream, USP 2.5%/2.5%. Evamist® and Dapsone Gel, 5% as launched by our licensee in April 2024.

Figure 1: Acrux's revenue generating products

Lidocaine and Prilocaine Cream, 2.5%/2.5%

EVAMIST®

Dapsone Gel, 5%

These revenue generating products continue to penetrate their addressable markets:

- *Lidocaine and Prilocaine Cream, USP 2.5%/2.5%:* The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA, was US$36 million. Acrux has expended significant efforts in conjunction with its commercial licensee, targeting increased robustness of the supply chain to ensure the future availability of product to meet the changing needs of the market.
- *Dapsone Gel, 5% (launched April 2024):* This product's addressable market defined as the 12 months of sales up to end October 2023 and measured by IQVIA, was US$15.5 million.
- *Evamist®* is an established product which continues to deliver a reliable revenue stream.

While building its product portfolio Acrux has also ensured supply chain requirements are in place to effectively grow the business. Consistent manufacturing capacity and capability is prerequisite to exploit market opportunities. These supply chain actions predominantly involve expediting the availability of active pharmaceutical ingredients (APIs), components and excipients to support commercial manufacture. Success here opens the way to deliver consistent manufacturing capacity and capability to exploit addressable markets for current and pending Acrux products.

Product pipeline continues to form

Acrux continues to progress its pipeline of topically applied pharmaceutical products with the goal of bringing to market an expanding number of products.

To this end, late in calendar 2023, the Acrux Board, together with senior management concluded its biannual formal review of Acrux's pipeline and product portfolio. This analysis examines project execution risks, expected remaining development costs, as well as the projected commercial outlook for each product, including anticipated launch dates, future competition and pricing.

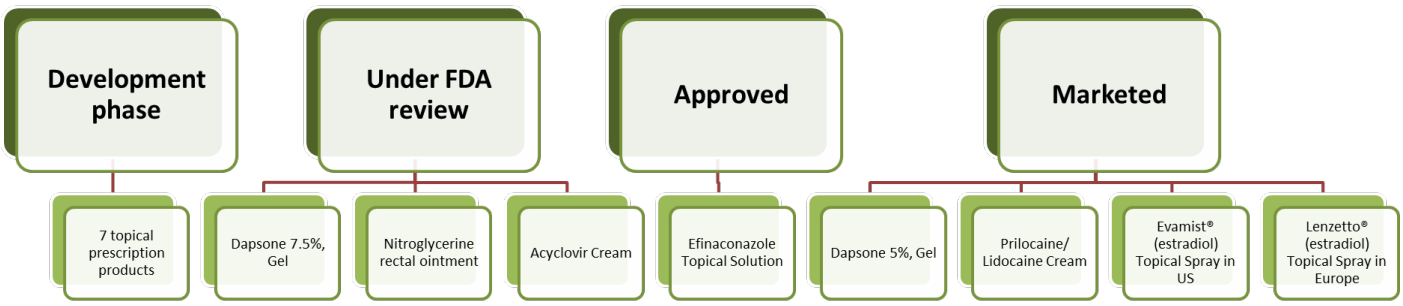
This review also involves a structured assessment of new and emerging opportunities to identify product candidates which could be added to the pipeline to ensure the Company continuously has a basket of commercially attractive product candidates at various stages of development. Following this latest assessment, three new product development opportunities have been identified and approved with one new project initiated in February 2024 and another new project expected to be initiated in coming weeks.

Acrux currently has three products under evaluation by the US Food and Drug Administration (FDA) and another seven products at various stages of pre-submission development (see Figure 2 below). This has Acrux well-placed to deliver a steady stream of FDA product approvals, launches and growing profit share income through the remainder of calendar 2024 and beyond.

Over the course of Q3 FY24, the Acrux team was actively engaged in development activities for several products that are progressing through the development stages prior to regulatory submission. Partnering with contracted manufacturers has been a key activity at this stage to ensure our products achieve the necessary development and progression goals and timelines.

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 build a diversified portfolio of products generating sustainable revenue.

Figure 2: Acrux's current product pipeline



FDA engagement

The 3 Acrux ANDAs currently under FDA review are:

- *Nitroglycerin 0.4%, Ointment*, a treatment for moderate to severe pain caused by chronic anal fissure. The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA was US$22 million.
- *Acyclovir 5%, Cream*, a treatment for cold sores. The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA was US$14 million.
- *Dapsone 7.5%, Gel*, a treatment for acne vulgaris. The addressable market for this product, defined as the 12 months of sales up to end October 2023 and measured by IQVIA was US$38 million.

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.

Acrux frequently engages with the FDA on future product candidates or products that have been submitted to the FDA for review. The engagement may take place through Controlled Correspondence[1], questions from the FDA related to products under review or other meetings that we schedule with the FDA. Since the start of July 2023, the Company has submitted 62 Controlled Correspondences, including 35 addressing potential new product candidates. In that period, the Company has also had 27 other interactions with the FDA via video or teleconference, or as written correspondence with the FDA.

Pipeline progression

In December 2023, Acrux 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 commenced ahead of the planned manufacturing of exhibit batches required for a regulatory submission for FDA review.

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 15 topical generic products in our portfolio with 3 products 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.

[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

Financial and corporate

The cash surplus reported by Acrux for Q3 FY24 includes $2.752 million received from Padagis as payment for raw materials in the form of Active Pharmaceutical Ingredients ('API') used for the manufacture of Lidocaine and Prilocaine Cream, USP 2.5%/2.5%. The corresponding balance due in relation to the purchase of this API was paid to our supplier in April. Purchases of Lidocaine and Prilocaine API have been ramped up to support the scale up of commercial manufacture of Lidocaine and Prilocaine Cream, USP 2.5%/2.5% with $4.125 million received for the year to date. Other than the timing difference for the latest supply these receipts are matched with equivalent offsetting payments for API purchases.

In addition to outgoings for API purchases, cash outflows for other operating expenses totaled $1.771 million for the March Quarter and $6.929 million for the year to date with the major cost components continuing to be external Research and Development expenditure and staff costs.

Staff costs reflect all 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.

ENDS

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	March 2024

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	2,755	4,945
1.2	Payments for		
	(a) research and development	(417)	(2,251)
	(b) product manufacturing and operating costs	(61)	(1,403)
	(c) advertising and marketing	-	-
	(d) leased assets	(8)	(23)
	(e) staff costs	(1,122)	(3,609)
	(f) administration and corporate costs	(224)	(1,046)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	34	156
1.5	Interest and other costs of finance paid	(45)	(137)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	2,869
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**912**	**(499)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(131)	(287)
	(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**	**(131)**	**(287)**

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	(48)	(142)
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**	**(48)**	**(142)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,565	6,232
4.2	Net cash from / (used in) operating activities (item 1.9 above)	912	(499)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(131)	(287)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(48)	(142)
4.5	Effect of movement in exchange rates on cash held	30	24
4.6	**Cash and cash equivalents at end of period**	**5,328**	**5,328**

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	5,328	4,565
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)**	**5,328**	**4,565**

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	14
7.4	**Total financing facilities**	120	14

7.5	**Unused financing facilities available at quarter end**	106
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)	912
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,328
8.3	Unused finance facilities available at quarter end (item 7.5)	106
8.4	Total available funding (item 8.2 + item 8.3)	5,434
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: 30 April 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.