ASX Release **26 July 2024**

Quarterly Activities Report and Appendix 4C – June Quarter 2024

Highlights: Dapsone 5%, Gel launched in April, secured $1.487million non-dilutive short-term funding facility for R&D Tax Incentive Rebate with Radium Capital

Melbourne, Australia; 26 July 2024: Specialty pharmaceuticals group Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to release its quarterly cashflow for the three months ended 30 June 2024 (Q4 FY24) along with the accompanying business update.

Highlights:

- Acrux's newest revenue-generating product in the United States, Dapsone Gel, 5%, a treatment acne vulgaris, was launched in April by our commercial licensee.
- Progression towards the approval and launch of future revenue-generating products is ongoing, with three ANDA's currently under FDA review.
- Manufacturing activities underway for a further two planned launches during FY25
- In June a funding facility was secured with Radium Capital with $1.487 million received broadly representing 80% of the estimated Research and Development Tax Incentive ('RDTI') for the ten months to 30 April 2024. This facility allows Acrux to more closely match the timing of portfolio development expenditure with the RDTI support and this balance will be repaid later in the 2024 calendar year when the annual FY24 RDTI is received from the Australian Tax Office.
- Positive cashflow has now been reported in four of the past eight quarters.

Acrux's CEO, Michael Kotsanis, said:
"Following from the launch of our Dapsone 5%, Gel product in April 2024 Acrux has continued to progress our strategy of developing a pipeline of topically applied pharmaceutical products which is necessary to build a sustainable and growing future revenue stream. We look forward to receiving approval of further ANDA's later in the 2024 calendar year to support future product launches and drive future revenue growth. We were also pleased to secure the short-term facility with Radium Capital to provide financial resources to support delivery of our product development milestones."

Acrux launched Dapsone Gel, 5%

The Company's latest new product launch, Dapsone Gel, 5% was announced in April 2024[1]. Dapsone Gel, 5% is a prescription medicine used on the patient's skin (topically applied) as a treatment for acne vulgaris. It was launched into the US market in partnership with pharma sales and marketing company TruPharma.

[1] Refer to ASX announcement dated 3 April 2024

Acrux further progresses its stated product expansion strategy

As we progress the development of our pipeline of topically applied pharmaceutical products we will continue to have products approved and launched to support our objective of having a diversified portfolio of products generating sustainable revenue.

Acrux currently has four marketed products, including three which generate revenue in the key United States market, namely Lidocaine and Prilocaine Cream, USP 2.5%/2.5%, launched in December 2022, Dapsone Gel, 5%, launched in April 2024 and Evamist®. Future launches pending FDA approval include Dapsone Gel, 7.5% for acne vulgaris, Nitroglycerine 0.4% Ointment for pain from anal fissure and Acyclovir 5% Cream for cold sores.

Figure 1: Acrux's products sold in the United States

It is important for Acrux to have a reliable and scalable supply chain to support development activities as well as commercial manufacturing capacity to effectively grow the business. Acrux works to expedite the availability of active pharmaceutical ingredients (APIs), components and excipients to support both commercial and development manufacture. Success here provides prerequisite manufacturing capacity and capability to exploit addressable markets for current and future Acrux products.

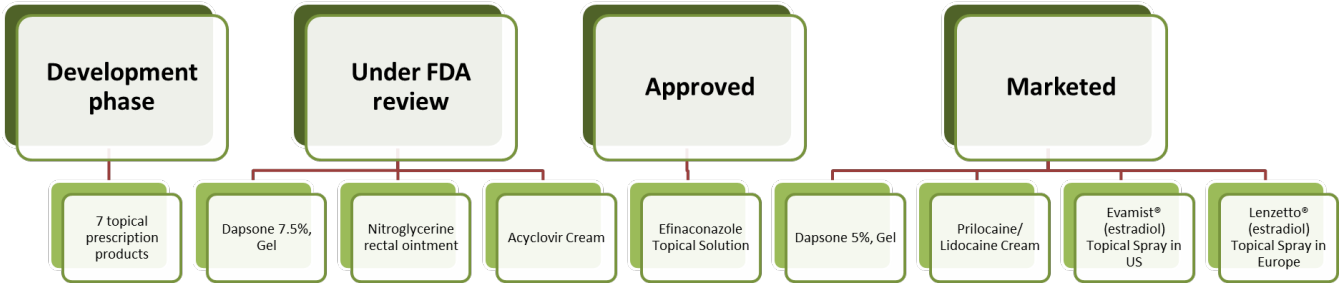
Product pipeline continues to grow

Acrux continues to progress its core objective of having a pipeline of marketed topically applied pharmaceutical products delivering sustainable revenues. To this end the Company continues to progress the development of products within its portfolio adding new products following a structured assessment of new and emerging opportunities.

As planned Acrux added one further project into its portfolio this quarter bringing the total number of products in the portfolio to 15. Three products under evaluation by the US Food and Drug Administration (FDA) are complimented by seven which are at various stages of pre-submission development (see Figure 2 below).

This pipeline places Acrux well to deliver a steady stream of FDA product approvals, launches and growing profit share income through the remainder of calendar 2024 and beyond.

Figure 2: Acrux's current product pipeline



The 3 Acrux ANDAs currently under FDA review are:

- *Nitroglycerin 0.4%, Ointment*, treats moderate to severe pain caused by chronic anal fissure. The addressable market for this product for the 12 months to end October 2023 and measured by IQVIA was US$22 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.
- *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.

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 which have been submitted to the FDA for review. This engagement may take place through Controlled Correspondence[2], 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 94 Controlled Correspondences, including 40 addressing potential new product candidates. In that period, the Company has also had 40 other interactions with the FDA via video, teleconference, or written correspondence.

[2] A Controlled Correspondence is a communication submitted to FDA by or on behalf of a generic drug manufacturer 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

As foreshadowed in our March Quarterly update, for Q4 we report a reduction in total Cash Reserves of $2.383 million principally due to payment of $2.436 million for Active Pharmaceutical Ingredients ('API') used for the manufacture of Lidocaine and Prilocaine Cream, USP 2.5%/2.5% for which the corresponding receivable balance was settled in the March quarter. These API Purchases support the commercial manufacture of Lidocaine and Prilocaine Cream, USP 2.5%/2.5%.

We were pleased to announce that we secured short-term non-dilutive funding from Radium Capital in June. To date we have received $1.487 million and will continue to utilise the facility to more closely match the timing of our portfolio expenditure with the receipt of RDTI support from the Australian Federal Government.

In addition to outgoings for API purchases, cash outflows for other operating expenses totaled $2.052 million for the June Quarter and $9.119 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.

For more information, please contact:

Michael Kotsanis
Acrux Limited
CEO & Managing Director
P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

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	June 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	659	5,604
1.2	Payments for		
	(a) research and development	(688)	(2,941)
	(b) product manufacturing and operating costs	(2,436)	(3,839)
	(c) advertising and marketing	-	-
	(d) leased assets	(7)	(30)
	(e) staff costs	(1,132)	(4,740)
	(f) administration and corporate costs	(186)	(1,232)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	18	174
1.5	Interest and other costs of finance paid	(39)	(176)
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**	**(3,811)**	**(4,311)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(289)
	(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**	**(2)**	**(289)**

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	1,487	1,487
3.6	Repayment of borrowings	(52)	(195)
3.7	Transaction costs related to loans and borrowings	(2)	(2)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**1,433**	**1,290**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,328	6,232
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,811)	(4,311)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(289)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,433	1,290
4.5	Effect of movement in exchange rates on cash held	(3)	23
4.6	**Cash and cash equivalents at end of period**	**2,945**	**2,945**

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	2,945	5,328
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)**	**2,945**	**5,328**

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	1,487	1,487
7.2	Credit standby arrangements	-	-
7.3	Other	120	3
7.4	**Total financing facilities**	1,607	1,490
7.5	**Unused financing facilities available at quarter end**		117
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.*		

Acrux maintains a $120k Credit Card facility with the ANZ Bank

During the June Quarter, Acrux established a short term funding facility with Radium Capital whereby Acrux received $1.487million, broadly representing 80% of the estimated Research and Development Tax Incentive ('RDTI') for eligible R&D expenditure incurred over the ten months to 30 April 2024. This balance will be repaid later in the 2024 calendar year when the FY24 annual RDTI balance is received from the Australian Federal Government. This facility is secured against this RDTI receivable balance and attracts an interest charge of 1.33% per month. Acrux may receive further funds under this short term facility based on ongoing eligible R&D expenditure.

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,811)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,945
8.3	Unused finance facilities available at quarter end (item 7.5)	117
8.4	Total available funding (item 8.2 + item 8.3)	3,062
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.8

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: June's quarterly operating cash outflows were unusually high due to payment of $2.437 million for raw materials in the form of Active Pharmaceutical Ingredients for which the corresponding balance was received in the prior quarter.

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: Yes. Acrux has established a short term funding facility with Radium Capital which enables the Group to more closely match the timing of cash outflows associated with progressing its pipeline of development products with cash inflows associated with the Research and Development Tax Incentive.

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. Acrux is determined to execute its strategy of developing a portfolio of topically applied pharmaceutical products predominantly for commercialisation in US markets. To this end we have established a short term funding facility with Radium Capital which allows the Group to more closely match the timing of portfolio development expenditure with funding associated with the RDTI. Furthermore, Acrux expects the approval and launch of new products in FY25 will support future growth in Receipts from Customers.

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: 26 July 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.