



Appendix 4D -Half year report

Results for announcement to the market

| | |
|--|------------------|
| Name of Entity | Acrux Limited |
| ABN | 72 082 001 152 |
| Half Year Ended | 31 December 2020 |
| Previous Corresponding Reporting Period | 31 December 2019 |

| Results for announcement to the market | \$/A'000 | | | |
|---|-----------------|-----|----|---------|
| Revenues from ordinary activities | Up | 39% | to | 800 |
| (Loss) from ordinary activities after tax attributable to members | Up | 21% | to | (7,786) |
| Net (loss) for the period attributable to members | Up | 21% | to | (7,786) |

No dividends have been declared for the half year ending 31 December 2020 or for the corresponding period.

Please refer to attached accounts for commentary on the results.

| | Current period | Previous corresponding Period |
|--|-----------------------|--------------------------------------|
| NTA Backing | | |
| Net tangible asset backing per ordinary security | \$0.04 | \$0.07 |



ACRUX LIMITED AND CONTROLLED ENTITIES
ABN: 72 082 001 152

FINANCIAL REPORT FOR THE HALF-YEAR ENDED
31 DECEMBER 2020

This half-year financial report is to be read in conjunction
with the financial report for the year ended 30 June 2020

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FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2020

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Company Information
Directors

R Dobinson – Non-executive Chairman
T Oldham – Non-executive Director
G Brooke – Non-executive Director
M Kotsanis – CEO and Managing Director
N Gray – Non-executive Director

Company Secretary

Deborah Ambrosini

Registered Office

103-113 Stanley Street
West Melbourne
Victoria 3003

Principal Business Address

103-113 Stanley Street
West Melbourne
Victoria 3003
Telephone: (03) 8397 0100
Website: www.acrux.com.au

Australian Business Number

72 082 001 152

Auditor

Pitcher Partners
Level 13,
664 Collins Street
DOCKLANDS, VICTORIA 3008

Share Registry

Link Market Services
Level 13, Tower 4
727 Collins Street
Docklands
Victoria 3008

Australia Toll-free: 1300 554 474 (Australia only)
International: +61 1300 554 474

F: (02) 9287 0303
F: (02) 9287 0309 (for proxy voting)

E: registrars@linkmarketservices.com.au
www.linkmarketservices.com.au

Australian Securities Exchange Listing

Australian Securities Exchange Limited
(Home Exchange: Melbourne, Victoria)
ASX Code: ACR

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DIRECTORS' REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2020

The Directors present their report together with the condensed financial report of the consolidated entity consisting of Acrux Limited ('the Company') and its controlled entities ('the Group'), for the half-year ended 31 December 2020 and independent review report thereon.

DIRECTORS' NAMES

The names of the Directors in office at any time during, or since the end of the half-year are:

| Name | | Appointed/resigned |
|------------------|---|----------------------------|
| Ross Dobinson | Non-executive Chairman | Appointed 19 March 1998 |
| Michael Kotsanis | Managing Director & Chief Executive Officer | Appointed 3 November 2014 |
| Timothy Oldham | Non-executive Director | Appointed 1 October 2013 |
| Geoffrey Brooke | Non-executive Director | Appointed 1 June 2016 |
| Norman Gray | Non-executive Director | Appointed 28 November 2019 |

The Directors have been in office since the start of the financial period to the date of this report unless otherwise stated.

REVIEW OF OPERATIONS

A review of the operations of the Group during the half-year and the results of these operations are as follows:

Mission

Acrux is a pharmaceutical company dedicated to developing and commercialising generic topical prescription pharmaceuticals.

Business Strategy

Acrux has 2 commercialised products (2 brands of its Estradiol spray) which are being sold in over 30 countries, including the United States and within the European Union. In addition to its commercialised products, Acrux is expanding its range of topical generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. The Company has entered into a number of manufacturing contracts with US Food and Drug Administration ('FDA') approved contract manufacturers for the supply of its products to the US pharmaceutical market. Acrux has also licensed a number of its products to generic companies in the United States for the commercialisation of its products following FDA approval. The development process required for generic products is substantially shorter and less costly than the equivalent process for new drug development.

Topical Generic Portfolio

At the date of this report, Acrux has 13 generic topical products in various stages of development, including 1 for which approval has been granted by the FDA and 2 for which applications have been submitted for review to the FDA. The addressable market value for this pipeline of 13 products in the United States is approximately US\$1.1 billion, based on IQVIA reported annual sales data at September 2020.

A significant proportion of the 13 products in development currently have no marketed generic alternatives in the United States.

Acrux has engaged with 7 contract manufacturing organisations ('CMOs') to manufacture different products from its portfolio and has licensed 9 products to 4 generic companies to commercialise its products. All commercial licensees have successful track records selling generic products in the US market.

DIRECTORS' REPORT**REVIEW OF OPERATIONS (Continued)***Licensing and Co-development Agreements***Gedeon Richter**

Acruz has licensed its Estradiol spray to Gedeon Richter for sale of the product in Europe and other markets. Gedeon Richter have branded Acruz's Estradiol spray as Lenzetto® and royalties on sales are received quarterly. The marketing of Estradiol spray in Europe commenced in Q1 2016 and the product has since been launched in over 30 countries across the European Union and other markets. Royalties grew 25.6% year on year and are expected to continue to grow as the product increases market share in existing countries and is progressively launched into new countries.

Perrigo

Acruz has licensed its Estradiol spray to Perrigo for sale of the product in the United States where the product is marketed under the Evamist® brand. Royalties on sales are received quarterly. In the United States Evamist® royalties grew 13.3% compared to the prior year.

TruPharma LLC

In May 2020 Acruz signed an exclusive sales, marketing and distribution agreement with TruPharma, LLC ('TruPharma') in the United States.

Subject to FDA approval, TruPharma will be responsible for the commercialisation of 6 products from the Acruz pipeline, including the sponsorship and management of each FDA application, management of commercial manufacturing, marketing and distribution of each product. The selected products are at various stages of development and have not been submitted to the FDA for review.

Under the terms of the agreement with TruPharma, Acruz will continue to conduct the development, scientific and bioequivalence activities necessary to develop the products and will seek regulatory approval from the FDA. Acruz and TruPharma will share the gross profits generated from the sales of these products and the agreement will have a 10-year term from launch of each product, unless otherwise agreed.

Amring Pharmaceuticals Inc

In June 2020 Acruz entered into an exclusive development and commercialisation agreement with Amring Pharmaceuticals Inc. in the United States.

Under the terms of the agreement with Amring, Acruz will continue to conduct the development, scientific and bioequivalence activities necessary to develop the generic product and Amring will seek regulatory approval for the product from the FDA. Subject to that approval being issued by the FDA, Amring will commercialise the product in the United States. Acruz and Amring will share both the development costs and the profits generated from the sales of the product.

Harris Pharmaceutical

In August 2020 Acruz entered into an exclusive sales, marketing and distribution agreement with Harris Pharmaceutical Inc ('Harris') in the United States for its generic version of EMLA® Cream (Lidocaine 2.5% and Prilocaine 2.5%). On 19 August 2019, Acruz announced that the FDA had accepted Acruz's Abbreviated New Drug Application ('ANDA') for its generic version of EMLA® for review. Sales generated by EMLA® and its generic equivalents (which Acruz's generic version will compete with) exceeded US\$22 million in the 12 months to the end of September 2020, based on IQVIA data. Subject to the product's approval by the FDA, Harris will be responsible for the commercialisation of the product, including the coordination of commercial manufacturing and management of marketing and distribution. Acruz and Harris will share the gross profits generated from the sales of the product and the agreement will have a 5-year term from product launch, unless otherwise agreed.

DIRECTORS' REPORT

REVIEW OF OPERATIONS (Continued)

Dash Pharmaceuticals

In October 2020 Acrux entered into an exclusive sales, marketing and distribution agreement with Dash Pharmaceuticals ('Dash') in the United States for its generic topical Testosterone solution 30mg/1.5mL. On 12 January 2021, Acrux's ANDA for its generic product based on Perrigo's Testosterone Topical Solution, 30mg/1.5mL was approved by the FDA.

Dash will be responsible for the commercialisation of the product, including the coordination of commercial manufacturing and management of sales and distribution. In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$25 million in the 12 months to the end of September 2020, based on IQVIA data. Acrux and Dash will share the profits generated from the sales of the product.

Acrux Regulatory Submissions

Acrux currently has 2 additional products under review by the FDA and is preparing additional regulatory submissions for new products to be submitted prior to the end of the current financial year.

Key Events During Half Year

The following were key events for the Group during the half-year:

- Acrux conducted a successful \$7.8 million two tranche placement to institutional and sophisticated investors.¹
- Acrux signed an exclusive sales, marketing and distribution agreement with Dash Pharmaceuticals.
- Acrux signed an exclusive sales, marketing and distribution agreement with Harris Pharmaceutical Inc for its generic version of EMLA®.
- Acrux continued to make solid progress on its generic portfolio with an additional project added to the pipeline under development.
- Estradiol spray sales and royalties paid to Acrux continue to grow compared to the prior corresponding period.
- Acrux received R&D Tax Incentive Rebates from the Australian Taxation Office of \$2.328 million.
- Milestone revenue from licensees of products in our generic pipeline was received during the half year.

Operating Results

The consolidated loss before tax was \$7.562 million (2019 loss: \$5.892 million) attributable to expenses incurred to progress the Group's generic development pipeline towards commercialisation. The consolidated loss after tax was \$7.786 million (2019 loss: \$6.435 million).

Revenue

Revenue and other income for the half-year increased \$0.588 million or 102% to \$1.164 million (2019: \$0.576 million). This includes \$0.364 million of Australian government support revenue as part of their COVID-19 relief payments. Royalty revenue from existing commercialised products in Europe and in the United States totalled \$0.543 million (2019: \$0.436 million). Royalties from the sale of Acrux's Estradiol spray grew 25.6% while royalties from the sale of Evamist® grew 13.3% compared to the prior half year. Milestone revenue of \$0.245 million (2019: Nil) was received from Acrux distribution partners during the reporting period.

¹ A Share Purchase Plan was offered to shareholders in January at the same price as the Placement and a further \$9.9 million dollars was raised. A total amount of \$17.7 million was raised by the Company.

DIRECTORS' REPORT**REVIEW OF OPERATIONS (Continued)****Operating Results (Continued)**

Interest on cash deposits were \$0.012 million (2019: \$0.140 million).

Expenses

Total operating expenditure for the half-year increased by 34.9% to \$8.726 million (2019: \$6.468 million).

External R&D costs for the half-year increased to \$4.594 million (2019: \$2.440 million) reflecting costs incurred in contract manufacture engagement, API (Active Pharmaceutical Ingredient) procurement for the manufacture of exhibit batches and clinical research organisation engagement.

Employee benefits expense remained flat at \$2.466 million (2019: \$2.506 million).

Income Tax

Income tax expense of \$0.224 million (2019: \$0.543 million) was recorded for the half-year reflecting movements in deductible tax temporary differences and carried forward tax losses. Further details of the income tax expense are provided at Note 4 of the financial report.

Cash flow

Cash received from licensing agreements for the half-year was \$0.700 million (2019: \$0.416 million).

The Group paid \$7.630 million to suppliers and employees (2019: \$6.075 million) as a consequence of continued investment in our R&D pipeline.

Interest received on cash reserves of \$0.027 million (2019: \$0.163 million) decreased in comparison to prior half-year, reflective of reduction in cash reserves and decreasing interest rates on term deposits. The Group also received \$0.364 million (2019: Nil) in COVID relief payments during the half year.

Capital expenditure was \$0.052 million, down 70% on the prior half-year.

The Group received \$6.694 million (2019: Nil) from the issue of shares during the half year.

Cash reserves at the end of the period were \$11.461 million (30 June 2020: \$9.206 million).

Contributed Equity

The number of outstanding share options on issue at the end of the reporting period was nil (30 June 2020: Nil).

The number of outstanding performance rights at the end of the reporting period was 7,364,128 (30 June 2020: 6,943,556), representing 3.49% of the Company's issued share capital. During the half-year 699,999 rights were granted to Mr Norman Gray under the Group's Omnibus Equity Plan. The rights were issued after shareholder approval was received at the Annual General Meeting of the Company held on 12 November 2020. Mr Norman Gray, who was appointed to the Board in November 2019, will receive 50% of his cash remuneration as equity in the form of rights for a period of 3 years from the date of his appointment. The rights will vest on a quarterly basis in arrears.

Significant changes in the state of affairs

On 11th March 2020 the World Health Organisation declared an ongoing global outbreak of a novel coronavirus, known as 'coronavirus disease 2019' ('COVID-19') as a pandemic. Acrux has largely maintained its operational activity during 2020 and has implemented a series of precautionary measures in line with the Victorian Government recommendations including enhanced daily

DIRECTORS' REPORT**REVIEW OF OPERATIONS (Continued)****Significant changes in the state of affairs (Continued)**

cleaning services, administration staff working from home, educating all staff on appropriate hygiene and social distancing requirements and activating business continuity plans internally and with business partners. Acrux has also prepared and implemented a COVID Safe Plan which all employees and visitors must follow.

While the broader economy has been impacted significantly, the Group has experienced a limited impact from the COVID-19 operating environment. The COVID-19 operating environment has in some cases affected operations at contract research organisations (CROs) and CMOs that has caused delays to some projects to date. There have been no significant implications to either revenue or operational expenditure in the current period. There may however be longer term implications beyond the balance date, the extent of which the Company cannot estimate.

After balance date events

On 12 January 2021 the FDA approved Acrux's generic product based on Perrigo's Testosterone Topical Solution, 30mg/1.5mL. As announced on 12 October 2020, Acrux has entered into an exclusive sales, marketing and distribution agreement with Dash Pharmaceuticals ("Dash") for this product. Dash will be responsible for the commercialisation of the product in the United States, including the coordination of commercial manufacturing and management of marketing and distribution. In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$25 million in the 12 months to the end of September 2020, based on IQVIA data. Acrux and Dash will share the profits generated from the sales of the product.

On 28 January 2021 shareholders approved the issue of 7,613,658 shares to raise an additional amount of \$1.2 million under the two tranche placement announced on 21 December 2020. A total of \$7.8 million was raised under the placement to institutional and sophisticated investors.

A further \$9.9 million was raised after Acrux Limited conducted a Share Purchase Plan ('the SPP'). The SPP opened on 8 January 2021 and closed 7.5 times oversubscribed on 29 January 2021 with \$15.1 million being raised. Given the strong support shown by eligible shareholders for the SPP, the Directors determined to increase the size of the SPP to \$9.9 million. The Proceeds from the Offer will be used for the further development and commercialisation of its current and future product pipeline in topical generics. The Company raised a total of \$17.7 million from the two tranche placement and the SPP.

The Group operates an Omnibus Equity Plan which was approved by members on 12 November 2020. On 4 February 2021, employees accepted 751,419 performance rights and 147,364 Exempt Shares offered by the Board under this Plan. The performance rights and shares were issued at nil cost and hold no participation rights. Shares issued on exercise of rights rank equally with existing shares. Performance rights will vest annually, subject to performance hurdles being achieved. The Exempt shares will be escrowed for a period of 3 years from the date of issue.

On 8 January 2021 Acrux Pharma Pty Ltd received approval from AusIndustry for an Advance and Overseas Finding application. The finding covers financial years 2018/19, 2019/20 and 2020/21 and means that eligible overseas research and development expenditure, in addition to Australian expenditure, will be subject to a 43.5% cash rebate under the Australian Federal Government's R&D Tax Incentive Program.

There have been no other matters or circumstances which have arisen since 31 December 2020 that have significantly affected or may significantly affect:

- a) the operations, in financial periods subsequent to 31 December 2020, of the Group, or
- b) the results of those operations, or
- c) the state of affairs, in financial periods subsequent to 31 December 2020, of the Group.

Auditor's independence declaration

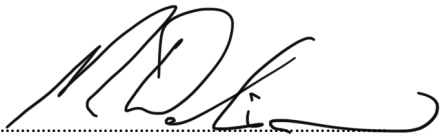
A copy of the Auditor's Independence Declaration as required under section 307C of the Corporation Act 2001 in relation to the review for the half-year is provided with this report.

DIRECTORS' REPORT

Rounding of amounts

In accordance with ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191, the amounts in the Directors' Report have been rounded to the nearest one million dollars and in the Financial Report have been rounded to the nearest one thousand dollars, or in certain cases, to the nearest dollar (where indicated).

Signed in accordance with a resolution of the Directors:

A handwritten signature in black ink, appearing to read 'R. Dobinson', written over a dotted line.

Ross Dobinson

Non-executive Chairman

Melbourne

Dated this day 24 February 2021

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ACRUX LIMITED AND CONTROLLED ENTITIES
ABN 72 082 001 152



**AUDITOR'S INDEPENDENCE DECLARATION
TO THE DIRECTORS OF ACRUX LIMITED AND CONTROLLED ENTITIES**

In relation to the independent auditor's review for the half-year ended 31 December 2020, to the best of my knowledge and belief there have been:

- (i) no contraventions of the auditor independence requirements of the *Corporations Act 2001*; and
- (ii) no contraventions of APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)*.

This declaration is in respect of Acrux Limited and the entities it controlled during the period.

A handwritten signature in black ink, appearing to be 'N R Bull'.

N R BULL
Partner

24 February 2021

A handwritten signature in black ink, appearing to be 'Pitcher Partners'.

PITCHER PARTNERS
Melbourne

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**CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND
OTHER COMPREHENSIVE INCOME**

FOR THE HALF-YEAR ENDED 31 DECEMBER 2020

Half Year

| | Note | 31 December 2020 \$'000 | 31 December 2019 \$'000 |
|--|------|-------------------------------|-------------------------------|
| Revenue and Other Income | | | |
| Revenue from licensing agreements | 2 | 788 | 436 |
| COVID-19 relief payments | 2 | 364 | - |
| Other revenue | 2 | 12 | 140 |
| Total | | 1,164 | 576 |
| Less: Expenses | | | |
| Employee benefits expense | | (2,466) | (2,506) |
| Directors' fees | | (92) | (159) |
| Share options expense | | (303) | (134) |
| Depreciation and amortisation expense | | (331) | (346) |
| Occupancy expense | | (132) | (76) |
| External research and development expense | | (4,594) | (2,440) |
| Professional fees | | (264) | (175) |
| Other expense | | (544) | (632) |
| Loss Before Income Tax | | (7,562) | (5,892) |
| Income tax expense | 4 | (224) | (543) |
| Net loss for the half year | | (7,786) | (6,435) |
| Other comprehensive income | | - | - |
| Total comprehensive loss for the half year | | (7,786) | (6,435) |
| Total Comprehensive Loss attributable to members of the parent entity arises from: | | | |
| Continuing operations | | (7,786) | (6,435) |
| Total Comprehensive Loss attributable to parent | | (7,786) | (6,435) |
| Loss Per Share - | | | |
| Basic loss per share | | (4.46) cents | (3.86) cents |
| Diluted loss per share | | (4.46) cents | (3.86) cents |

The accompanying notes form part of these financial statements.

**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2020**

| | | Consolidated | |
|---|------|-------------------------------|---------------------------|
| | | 31 December 2020 \$'000 | 30 June 2020 \$'000 |
| | Note | | |
| Current Assets | | | |
| Cash and cash equivalents | | 11,461 | 9,206 |
| Receivables | | 304 | 2,559 |
| Other current assets | | 864 | 577 |
| Total Current Assets | | 12,629 | 12,342 |
| Non-Current Assets | | | |
| Plant and equipment | | 651 | 761 |
| Intangible assets | 6 | 536 | 589 |
| Deferred tax asset | | 1,581 | 1,805 |
| Lease assets | 7 | 2,223 | 2,339 |
| Total Non-Current Assets | | 4,991 | 5,494 |
| Total Assets | | 17,620 | 17,836 |
| Current Liabilities | | | |
| Payables | | 2,550 | 1,878 |
| Provisions | | 660 | 620 |
| Lease liabilities | 7 | 174 | 167 |
| Total Current Liabilities | | 3,384 | 2,665 |
| Non-Current Liabilities | | | |
| Provisions | | 107 | 88 |
| Lease liabilities | 7 | 2,145 | 2,234 |
| Total Non-Current Liabilities | | 2,252 | 2,322 |
| Total Liabilities | | 5,636 | 4,987 |
| Net Assets | | 11,984 | 12,849 |
| Equity | | | |
| Contributed equity | | 102,852 | 96,137 |
| Reserves | | 788 | 582 |
| Retained earnings | | (91,656) | (83,870) |
| Equity attributable to equity holders of the Parent | | 11,984 | 12,849 |
| Non-controlling interests | | - | - |
| Total Equity | | 11,984 | 12,849 |

The accompanying notes form part of these financial statements.

**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
 FOR THE HALF-YEAR ENDED 31 DECEMBER 2020**

| Consolidated | Contributed equity \$'000 | Reserves \$'000 | Retained earnings \$'000 | Total Equity \$ |
|--|---------------------------------|--------------------|--------------------------------|-----------------------|
| Balance at 1 July 2019 | 95,879 | 639 | (74,582) | 21,936 |
| Loss attributable to members of the consolidated entity | - | - | (6,435) | (6,435) |
| Other comprehensive income | - | - | - | - |
| Total comprehensive loss for the half year | - | - | (6,435) | (6,435) |
| Transactions with owners in their capacity as owners: | | | | |
| Employee share scheme | 16 | 118 | - | 134 |
| Vested employee share options that lapsed during the half year | - | (182) | 182 | - |
| Balance at the half year ended 31 December 2019 | 95,895 | 575 | (80,835) | 15,635 |
| Balance at 1 July 2020 | 96,137 | 582 | (83,870) | 12,849 |
| Loss attributable to members of the consolidated entity | - | - | (7,786) | (7,786) |
| Other comprehensive income | - | - | - | - |
| Total comprehensive loss for the half year | - | - | (7,786) | (7,786) |
| Transactions with owners in their capacity as owners: | | | | |
| Employee share scheme | 96 | 206 | - | 302 |
| Issue of shares – December 2020 placement | 6,694 | - | - | 6,694 |
| Capital raising expenses | (75) | - | - | (75) |
| Balance at the half year ended 31 December 2020 | 102,852 | 788 | (91,656) | 11,984 |

The accompanying notes form part of these financial statements.

**CONDENSED CONSOLIDATED STATEMENT OF CASHFLOWS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020**

HALF YEAR

| Note | 31 December 2020 \$'000 | 31 December 2019 \$'000 |
|---|-------------------------------|-------------------------------|
| Cash flows from operating activities | | |
| Receipts from product agreements | 700 | 416 |
| Payments to suppliers and employees | (7,630) | (6,075) |
| Interest received | 27 | 163 |
| Finance costs | (94) | (97) |
| Research and development tax incentive | 2,328 | 2,015 |
| COVID relief payments | 364 | - |
| Income tax refunded/(paid) | - | - |
| Net cash used in operating activities | (4,305) | (3,578) |
| Cash flows from investing activities | | |
| Payment for property, plant and equipment | (52) | (177) |
| Net cash used in investing activities | (52) | (177) |
| Cash flows from financing activities | | |
| Lease liability principal repayments | (82) | (61) |
| Proceeds from share issue | 6,694 | - |
| Net cash used in investing activities | 6,612 | (61) |
| Net decrease in cash and cash equivalents | 2,255 | (3,816) |
| Cash and cash equivalents at beginning of half year | 9,206 | 18,152 |
| Cash at the end of the period | 11,461 | 14,336 |

The accompanying notes form part of these financial statements

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020****1 BASIS OF PREPARATION OF THE HALF-YEAR FINANCIAL REPORT**

This condensed consolidated half-year financial report does not include all the notes of the type usually included in an annual financial report.

It is recommended that this half-year financial report be read in conjunction with the annual financial report for the year ended 30 June 2020 and any public announcements made by Acrux Limited during the half-year in accordance with any continuous disclosure obligations arising under the *Corporations Act 2001*.

This condensed half-year financial report covers Acrux Limited and controlled entities as a consolidated entity. Acrux Limited is a company limited by shares, incorporated and domiciled in Australia. The address of Acrux Limited registered office and principal place of business is 103-113 Stanley Street, West Melbourne, Vic, 3003. Acrux Limited is a for-profit entity for the purpose of preparing the financial statements.

The half-year financial report was authorised for issue by the directors on 24 February 2021.

(a) Basis of preparation

This condensed consolidated half-year financial report has been prepared in accordance with Australian Accounting Standard AASB 134 Interim Financial Reporting, as appropriate for for-profit entities, and the *Corporations Act 2001*. Compliance with AASB 134, as appropriate for for-profit entities, ensures compliance with International Financial Reporting Standard IAS 34 *Interim Financial Reporting*.

The half-year financial report has been prepared under the historical cost convention, as modified by revaluations to fair value for certain classes of assets as described in the accounting policies.

The accounting policies applied in this half-year financial report are consistent with those of the annual financial report for the year ended 30 June 2020 and the corresponding half-year except as described below in Note 1(b).

(b) Summary of the significant accounting policies

The consolidated entity has adopted new and revised Standards and Interpretations issued by the Australian Accounting Standards Board (the AASB) that are relevant to their operations and effective for the current half year.

(c) Rounding amounts

In accordance with *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, the amounts in the financial report have been rounded to the nearest one thousand dollars, or in certain cases, to the nearest dollar (where indicated).

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020 (continued)
2 SEGMENT REPORTING

The Group operates as a single operating segment. Internal management reporting systems present financial information as a single segment. The segment derives its revenue from developing and commercialising products using unique technology.

The following table includes the disaggregation of revenue disclosures in line with AASB 15 Revenue from Contract with Customers.

Geographical segment information

| | 31 December 2020 | 31 December 2019 |
|--------------------------|-----------------------------|-----------------------------|
| | \$'000 | \$'000 |
| <i>Revenue</i> | | |
| Australia ⁽¹⁾ | 376 | 140 |
| Germany | 213 | 182 |
| United States of America | 40 | 36 |
| Other ⁽²⁾ | 535 | 218 |
| | 1,164 | 576 |

Product information

| | 31 December 2020 | 31 December 2019 |
|---|-----------------------------|-----------------------------|
| | \$'000 | \$'000 |
| <i>Revenue by product group / service</i> | | |
| Lenzetto | 503 | 400 |
| Evamist | 40 | 36 |
| Other ⁽³⁾ | 621 | 140 |
| | 1,164 | 576 |

All assets are located in Australia.

⁽¹⁾ Australian revenue consists of interest revenue and government support payment as part of Covid-19 relief scheme.

⁽²⁾ Other revenue consists of milestone income and sales to other geographical locations.

⁽³⁾ Other income consists of milestone income, interest revenue and government support payment as part of Covid-19 relief scheme.

3 RESEARCH AND DEVELOPMENT RELATED COSTS

The expenses incurred by the Group are categorised and presented in the statement of profit or loss and other comprehensive income according to their nature. A significant portion of these expenses relate to product research and development including direct cost and indirect management and overhead costs. ⁽¹⁾

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020 (continued)**

3 RESEARCH AND DEVELOPMENT RELATED COSTS (continued)

| | HALF YEAR | |
|----------------------------------|-------------------------------|-------------------------------|
| | 31 December 2020 \$'000 | 31 December 2019 \$'000 |
| Employee costs | 2,274 | 2,241 |
| Laboratory and development costs | 4,588 | 2,400 |
| Facility costs | 543 | 458 |
| Other costs | 13 | 45 |
| | 7,418 | 5,144 |

⁽¹⁾ This differs from the classification of research and development costs pursuant to AASB138 which only comprises direct costs.

4 INCOME TAX

The parent entity, Acrux Limited is a Pooled Development Fund (PDF):

- PDFs are taxed at 15% on income and gains from investments in small to medium enterprises;
- PDFs are taxed at 25% on other income;
- Groups containing a PDF are not permitted to consolidate for tax purposes.

Income tax expense of \$0.224 million (2019: \$0.543 million) was recorded for the half-year reflecting movements in deductible tax temporary differences and carried forward tax losses.

5 FAIR VALUE MEASUREMENTS

The carrying amount of financial assets and financial liabilities approximate their fair values.

6 INTANGIBLE ASSETS

| | 31 December 2020 \$'000 | 30 June 2020 \$'000 |
|----------------------------------|-------------------------------|---------------------------|
| Capitalised development | | |
| <i>Estradiol</i> | | |
| External development expenditure | 1,071 | 1,071 |
| Accumulated amortisation | (535) | (482) |
| | 536 | 589 |
| Total intangible assets | 536 | 589 |

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020 (continued)**

6 INTANGIBLE ASSETS (continued)

(a) Reconciliations

Reconciliations of the carrying amounts of capitalised development at the beginning and end of the current financial year:

| | 31 December 2020 \$'000 | 30 June 2020 \$'000 |
|------------------------------|--|------------------------------------|
| Capitalised development | | |
| <i>Estradiol</i> | | |
| Carrying amount at beginning | 589 | 696 |
| Additions | - | - |
| Amortisation | (53) | (107) |
| | <u>536</u> | <u>589</u> |
| Total intangible assets | <u>536</u> | <u>589</u> |

The remaining useful life of Estradiol Capitalised Development is approximately 5.0 years.

7 LEASING

The Group has an operating lease for its office, laboratory and warehouse facilities for which the lease was renewed by Acrux DDS Pty Ltd for a period of 4 years from 1 June 2018, with a further three options to extend for three (3) years each. Acrux DDS Pty Ltd does not have an option to purchase the leased asset at the expiry of the lease period.

Lease liabilities are presented in the statement of financial position as follows:

| Lease Liabilities | 31 December 2020 000's | 30 June 2020 000's |
|---|-----------------------------------|-------------------------------|
| Lease liabilities (current) | 174 | 167 |
| Lease liabilities (non-current) | 2,145 | 2,234 |
| Total carrying amount of lease liabilities | <u>2,319</u> | <u>2,401</u> |

| Leased Assets | 31 December 2020 000's | 30 June 2020 000's |
|--|-----------------------------------|-------------------------------|
| Carrying amount of lease assets, by class of underlying asset: | | |
| Buildings under lease arrangements | | |
| At cost | 2,409 | 2,409 |
| Accumulated depreciation | (301) | (201) |
| | <u>2,108</u> | <u>2,208</u> |
| Plant and Equipment | | |
| At cost | 142 | 142 |
| Accumulated depreciation | (27) | (11) |
| | <u>115</u> | <u>131</u> |
| Total carrying amount of leased assets | <u>2,223</u> | <u>2,339</u> |

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020 (continued)**

7 LEASING (continued)

Reconciliation of carrying amount of leased assets at the half year:

Buildings under lease arrangements

| | | |
|-------------------------------------|-------|-------|
| Carrying amount at 1 July 2020 | 2,208 | 2,409 |
| Additions | - | - |
| Depreciation | (100) | (201) |
| Carrying amount at 31 December 2020 | 2,108 | 2,208 |

Plant and equipment under lease arrangements

| | | |
|-------------------------------------|------|------|
| Carrying amount at 1 July 2020 | 131 | - |
| Additions | - | 142 |
| Depreciation | (16) | (11) |
| Carrying amount at 31 December 2020 | 115 | 131 |

| Leased expenses and cashflows | 31 December 2020 | 30 June 2020 |
|--|------------------|--------------|
| | 000's | 000's |
| Interest expense on lease liabilities | 94 | 191 |
| Depreciation expense on lease assets | 116 | 212 |
| Total cash outflow in relation to leases | 176 | 351 |

8 CONTINGENT LIABILITIES

There were no contingent liabilities as at 31 December 2020.

9 AFTER BALANCE DATE EVENTS

On 12 January 2021 the FDA approved Acrux's generic product based on Perrigo's Testosterone Topical Solution, 30mg/1.5mL. As announced on 12 October 2020, Acrux has entered into an exclusive sales, marketing and distribution agreement with Dash Pharmaceuticals ("Dash") for this product. Dash will be responsible for the commercialisation of the product in the United States, including the coordination of commercial manufacturing and management of marketing and distribution. In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$25 million in the 12 months to the end of September 2020, based on IQVIA data. Acrux and Dash will share the profits generated from the sales of the product.

On 28 January 2021 shareholders approved the issue of 7,613,658 shares to raise an additional amount of \$1.2 million under the two tranche placement announced on 21 December 2020. A total of \$7.8 million was raised under the placement to institutional and sophisticated investors.

A further \$9.9 million was raised after Acrux Limited conducted a Share Purchase Plan ("the SPP"). The SPP opened on 8 January 2021 and closed 7.5 times oversubscribed on 29 January 2021 with \$15.1 million being raised. Given the strong support shown by eligible shareholders for the SPP, the Directors determined to increase the size of the SPP to \$9.9 million. The Proceeds from the Offer will be used for the further development and commercialisation of its current and future product pipeline in topical generics. The Company raised a total of \$17.7 million from the two tranche placement and the SPP.

The Group operates an Omnibus Equity Plan which was approved by members on 12 November 2020. On 4 February 2021, employees accepted 751,419 performance rights and 147,364 Exempt Shares offered by the Board under this Plan. The performance rights and shares were issued at nil cost and hold no participation rights. Shares issued on exercise of rights rank equally with existing shares. Performance rights will vest annually, subject to performance hurdles being achieved. The Exempt shares will be escrowed for a period of 3 years from the date of issue.

On 8 January 2021 Acrux Pharma Pty Ltd received approval from AusIndustry for an Advance and Overseas Finding application. The finding covers financial years 2018/19, 2019/20 and 2020/21 and means that eligible overseas research and development expenditure,

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2020 (continued)**

9 AFTER BALANCE DATE EVENTS (Continued)

in addition to Australian expenditure, will be subject to a 43.5% cash rebate under the Australian Federal Government's R&D Tax Incentive Program.

There have been no other matters or circumstances which have arisen since 31 December 2020 that have significantly affected or may significantly affect:

- a) the operations, in financial periods subsequent to 31 December 2020, of the Group, or
- b) the results of those operations, or
- c) the state of affairs, in financial periods subsequent to 31 December 2020, of the Group.

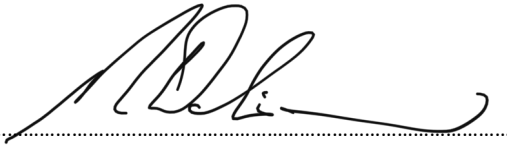
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DIRECTORS' DECLARATION

In accordance with a resolution of the directors of Acrux Limited, I state that: In the opinion of the directors:

- (a) the financial statements and notes of the Group are in accordance with the *Corporations Act 2001*, including:
- (i) giving a true and fair view of the financial position of the Group as at 31 December 2020 and of its performance for the half-year ended on that date; and
 - (ii) complying with Australian Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001;
- (b) there are reasonable grounds, at the date of this declaration, to believe that Acrux Limited will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

A handwritten signature in black ink, appearing to read "R. Dobinson", written over a horizontal dotted line.

Ross Dobinson
Non-executive Chairman
Melbourne
Dated this day 24 February 2021

INDEPENDENT AUDITOR'S REVIEW REPORT
TO THE MEMBERS OF ACRUX LIMITED AND CONTROLLED ENTITIES

Report on the Half-Year Financial Report

Conclusion

We have reviewed the half-year financial report of Acrux Limited, "the Company" and its controlled entities "the Group", which comprises the condensed consolidated statement of financial position as at 31 December 2020, the condensed consolidated statement of comprehensive income, condensed consolidated statement of changes in equity and condensed consolidated statement of cash flows for the half-year ended on that date, a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Acrux Limited does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of Acrux Limited's financial position as at 31 December 2020 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's review report.

Responsibility of the Directors for the Financial Report

The directors of Acrux Limited are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility for the Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2020 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

ACRUX LIMITED AND CONTROLLED ENTITIES
ABN 72 082 001 152



**INDEPENDENT AUDITOR'S REVIEW REPORT
TO THE MEMBERS OF ACRUX LIMITED AND CONTROLLED ENTITIES**

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

A handwritten signature in black ink, appearing to be "N R Bull".

N R BULL
Partner

A handwritten signature in black ink, appearing to be "Pitcher Partners".

PITCHER PARTNERS
Melbourne

24 February 2021

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