



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 2021
Previous Corresponding Reporting Period	31 December 2020

Results for announcement to the market	\$A'000			
Revenues from ordinary activities	Up	80%	to	2,097
(Loss) from ordinary activities after tax attributable to members	Down	30%	to	(5,473)
Net (loss) for the period attributable to members	Down	30%	to	(5,473)

No Interim or Final **dividends** have been declared or paid during the period year ended 31 December 2021 nor in the previous corresponding period.

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

Please refer to attached Half Year Financial Report for commentary on the results.

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ACRUX LIMITED AND CONTROLLED ENTITIES
ABN: 72 082 001 152

FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2021

This half-year financial report is to be read in conjunction with the Annual Report 2021



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FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2021

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DIRECTORS' REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2021

The Directors of the consolidated entity consisting of Acrux Limited ('Acrux') and its controlled entities (collectively 'the Group') have pleasure in presenting their financial report for the half-year ended 31 December 2021. To comply with the provisions of the *Corporations Act 2001*, the Directors report as follows:

DIRECTORS' NAMES

The names of the Directors in office during and since the end of the half-year ended 31 December 2021 are:

Ross Dobinson	Non-executive Chairman
Michael Kotsanis	Managing Director & Chief Executive Officer
Geoffrey Brooke	Non-executive Director
Don Brumley	Non-executive Director
Timothy Oldham	Non-executive Director

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

REVIEW OF OPERATIONS

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

Principal Activities

Acrux is a pharmaceutical company dedicated to the development and commercialisation of a portfolio of generic topical prescription pharmaceutical products which use dermal and transdermal drug delivery technology. There has been no significant change in the nature of these activities during the reporting period.

Business Strategy

Acrux currently has 15 products in its portfolio. The Company has 3 commercialised products which includes 2 brands of Estradiol spray currently sold as Evamist® and Lenzetto® in over 30 countries, including the United States, the European Union, the Commonwealth of Independent States and Latin America. Testosterone Topical Solution USP, 30mg, was also recently launched by our licensee, Dash Pharmaceuticals Inc.

Two additional products were approved by the FDA in 2021. Launch plans for Lidocaine 2.5% / Prilocaine 2.5% cream will commence following finalisation of a Commercialisation Agreement with a US pharmaceutical company. A generic version of Jublia® (Efinaconazole) topical solution, 10% will be launched when the Company is able to do so within the terms of the Settlement Agreement that was concluded following the Paragraph IV litigation related to this product.

At the date of this report, Acrux has 10 further generic topical products in various stages of development, including Abbreviated New Drug Applications (ANDA) for Dapsone gel, 5% and Dapsone gel, 7.5% which have been accepted for review by the FDA during 2021. The addressable market value for the total pipeline of products under development in the United States is over US\$930 million, based on IQVIA reported annual sales data at December 2021.

Further to those products which have been submitted for review by the FDA and those which are currently under development for the US market, Acrux continues to review and add additional topical products to its development pipeline. Several exciting new products are under active consideration and subject to further commercial and technical screening these projects are expected to be added to the development portfolio in coming months. For each development project Acrux uses its on-site laboratories, GMP suite, clinical and commercial experience to develop and commercialise the product.



Key Events During Half Year:

- In July 2021, the ANDA for Lidocaine 2.5%/Prilocaine 2.5% cream received FDA approval for the US market, being Acrux's third ANDA product to be approved. This is a topical anesthetic cream with a USD29 million annual addressable market, as measured by IQVIA as at December 2021. The Distribution Agreement for this product with Harris Pharmaceuticals Inc was entered in August 2020 and mutually terminated in October 2021 after Harris filed for Chapter 11 bankruptcy. Acrux is in advanced discussions with a well credentialed partner to be appointed to distribute this product in the US market.
- Through our licensee, Dash Pharmaceuticals Inc, Testosterone Topical Solution USP, 30mg was launched into the US market. Initial sales revenues have been impacted by COVID-19 related supply chain issues which delayed delivery of inventory to our licensee as well as to their customers. This is a competitive market with a USD15 million annual addressable market, as measured by IQVIA as at December 2021.
- In April 2021 Dapsone gel, 7.5% was reported as Acrux's fourth product to be accepted for FDA review and this strength has an annual addressable market of USD124 million, as measured by IQVIA as at December 2021. In September, 2021 the FDA accepted Acrux's Dapsone gel, 5% for review. The ANDA was Acrux's fifth ANDA dossier to be accepted for review. The 5% strength has a USD25 million annual addressable market, as measured by IQVIA, as at December 2021.
- Estradiol spray sales and revenue share income received by Acrux continues to grow strongly increasing by 29% relative to the prior corresponding reporting period.
- Acrux has received R&D Tax Incentive Rebates from the Australian Taxation Office in relation to the year ended 30 June 2021 totaling \$3.073 million. This was an increase of \$0.745 million over the prior year and is \$0.290 million higher than the estimate reported in the 2021 Annual Report.
- The Covid-19 pandemic continues to cause operational challenges with non-laboratory Australian staff being required to work from home periodically as well as a number of cases or close contact exposures that have required staff to isolate at home for mandatory periods of time.

Operating Results

The consolidated loss after tax was \$5.473 million (2020 loss: \$7.786 million) and is attributable to expenses incurred to progress the Group's generic development pipeline towards commercialisation.

Revenue

Relative to the prior comparable period, total reported Revenue for the half-year increased by \$0.933 million (80%) to \$2.097 million (2020: \$1.164 million) and is summarised in the table below.

	December 2021 \$'000	December 2020 \$'000
Product licensing income – commercialised products	702	543
Contractual milestones received – development products	-	245
R&D Incentive Rebate	1,382	-
Interest and other Government support	13	376
Total Revenue	2,097	1,164

Product licensing income from commercialised products (Estradiol in Europe, Commonwealth of Independent States, Latin America and the United States as well as Testosterone in the United States) totalled \$0.702 million, driven by an increase of 29% on \$0.543 million recorded in the prior corresponding period for Estradiol revenue. No project milestones were receivable from our development partner in the current reporting period (2021: \$0.245 million).



ACRUX LIMITED AND CONTROLLED ENTITIES (ABN: 72 082 001 152)

The R&D Incentive Rebate includes \$1.092 million which is an estimate of the balance receivable relating to eligible project development expenditure incurred for period to date December 2021. A balance was not accrued in the prior comparable period because it was not possible to make a reliable estimate at that time. Furthermore, \$0.290 million relating to higher than estimated R&D Tax Incentive Rebate was received for the financial year ended 30 June 2021 (received \$3.073 million).

In the prior comparative period \$0.364 million was received from the Australian government in the form of COVID-19 relief payments with nil receivable in the current reporting period.

Expenses

Total Expenses declined by \$1.318 million (15%) to \$7.408 million against the prior corresponding period. This reduction is attributable to the timing of external research and development project expenses which vary throughout the product development cycle depending on the development stage of the project.

Dividends

No dividends have been declared or paid in the period to 31 December 2021 (2020: nil).

After balance date events

No matters or circumstance has arisen since 31 December 2021 that significantly affect the Group's operations, results or state of affairs, or may do so in future periods.

Auditor's independence declaration

A copy of the Auditor's Independence Declaration in relation to the review for the period is provided with this report.

Rounding of amounts

The Company is a company of the kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in this Directors' Report and financial statements have been rounded to the nearest one thousand dollars, unless otherwise indicated.

Signed in accordance with a resolution of the Directors made pursuant to s306(3) of the *Corporations Act 2001*.

On behalf of the Directors

A handwritten signature in blue ink, appearing to read "Ross Dobinson".

Ross Dobinson
Non-executive Chairman
24 February 2022

**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 2021, 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.



N R BULL
Partner

24 February 2022



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 2021**

	Note	Consolidated Half Year Ended	
		31 December 2021 \$'000	31 December 2020 \$'000
Revenue			
Revenue from licensing agreements	1	702	788
Other revenue	1	1,395	376
Total Revenue		2,097	1,164
Less: Expenses			
Employee benefits expense		2,728	2,466
Directors' fees		93	92
Securities based payment expense		150	303
Depreciation and amortisation expense		338	331
Occupancy expense		98	132
External research and development expense		3,314	4,594
Professional fees		209	264
Other expense		478	544
Total Expenses		7,408	8,726
Loss Before Income Tax		(5,311)	(7,562)
Income tax expense		162	224
Net loss for the half year		(5,473)	(7,786)
Other comprehensive income		-	-
Total comprehensive loss for the half year		(5,473)	(7,786)
Total Comprehensive Loss attributable to:			
Members of the parent company		(5,473)	(7,786)
Non controlling interest		-	-
Loss Per Share:			
Basic loss per share		(1.93) cents	(4.46) cents
Diluted loss per share		(1.93) cents	(4.46) cents

The accompanying notes form part of these financial statements.

**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2021**

	Note	Consolidated	
		31 December 2021 \$'000	30 June 2021 \$'000
Current Assets			
Cash and cash equivalents		10,596	15,270
Receivables		1,449	3,159
Other current assets		609	165
Total Current Assets		12,654	18,594
Non-Current Assets			
Plant and equipment		643	538
Intangible assets	2	428	482
Deferred tax asset		1,446	1,607
Lease assets	3	1,990	2,106
Total Non-Current Assets		4,507	4,733
Total Assets		17,161	23,327
Current Liabilities			
Payables		949	1,780
Provisions		876	801
Lease liabilities	3	180	185
Total Current Liabilities		2,005	2,766
Non-Current Liabilities			
Provisions		38	41
Lease liabilities	3	1,970	2,049
Total Non-Current Liabilities		2,008	2,090
Total Liabilities		4,013	4,856
Net Assets		13,148	18,471
Equity			
Contributed equity		114,272	114,213
Reserves		8,238	8,147
Retained earnings / (Accumulated losses)		(109,362)	(103,889)
Equity attributable to equity holders of the Parent		13,148	18,471
Non-controlling interests		-	-
Total Equity		13,148	18,471

The accompanying notes form part of these financial statements.


**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE HALF-YEAR ENDED 31 DECEMBER 2021**

	Contributed equity \$'000	Reserves \$'000	Retained earnings /(losses) \$'000	Total Equity \$'000
Balance at 1 July 2021	114,213	8,147	(103,889)	18,471
Loss attributable to members of the consolidated entity	-	-	(5,473)	(5,473)
Other comprehensive income	-	-	-	-
Total comprehensive loss for the half year	-	-	(5,473)	(5,473)
Transactions with owners in their capacity as owners:				
Employee share scheme	59	91	-	150
Issue of shares	-	-	-	-
Capital raising expenses	-	-	-	-
Balance at the half year ended 31 December 2021	114,272	8,238	(109,362)	13,148
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	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 2021**

	Consolidated Half Year Ended	
	31 December 2021 \$'000	31 December 2020 \$'000
Cash flows from operating activities		
Receipts from licensing agreements	680	700
Payments to suppliers and employees	(8,122)	(7,630)
Interest received	13	27
Research and development tax incentive rebate	3,114	2,328
Government support received (COVID-19)	-	364
Net cash used in operating activities	(4,315)	(4,211)
Cash flows from investing activities		
Payment for property, plant and equipment	(272)	(52)
Net cash used in investing activities	(272)	(52)
Cash flows from financing activities		
Lease liability principal repayments	(84)	(82)
Finance costs	(3)	(94)
Proceeds from capital raising	-	6,694
Net proceeds from financing activities	(87)	6,518
Net (decrease) / increase in cash and cash equivalents	(4,674)	2,255
Cash and cash equivalents at beginning of half year	15,270	9,206
Cash at the end of the period	10,596	11,461

The accompanying notes form part of these financial statements



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2021**

General information

Statement of compliance

This half-year financial report is a general purpose financial report prepared in accordance with the *Corporations Act 2001* and AASB 134 Interim Financial Reporting. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 Interim Financial Reporting. The half-year financial report does not include notes of the type normally included in an annual financial report and should be read in conjunction with the most recent annual financial report.

Basis of preparation

The condensed consolidated financial statements have been prepared on the basis of historical cost. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars, unless otherwise noted.

The company is a company of the kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in the financial report are rounded to the nearest thousand dollars, unless otherwise indicated.

The accounting policies and methods of computation adopted in the preparation of the half-year financial report are consistent with those adopted and disclosed in the Company's Annual Report for the financial year ended 30 June 2021. The accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards. The Company has applied all new and revised Australian Accounting Standards and Interpretations that apply to reporting periods beginning on or after 1 July 2021. The application of new and revised Australian Accounting Standards Board did not have a material impact on this half year financial report.

1. SEGMENT REPORTING

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

Geographical segment information

	31 December 2021 \$'000	31 December 2020 \$'000
Australia	1,395	376
Europe and other countries	663	503
United States of America	39	285
	2,097	1,164

Revenue by product group and services provided

Income received from commercialised products	702	543
Contractual milestones received in relation to development products	-	245
R&D Incentive rebate	1,382	-
Other, including other government support and interest received	13	376
	2,097	1,164



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2021 (continued)**

2. INTANGIBLE ASSETS

	31 December 2021 \$'000	30 June 2021 \$'000
Capitalised development		
External development expenditure	1,071	1,071
Accumulated amortisation	(643)	(589)
Total intangible assets	428	482

Reconciliation of the carrying amounts of capitalised development at the beginning and end of the current reporting period:

	31 December 2021 \$'000	30 June 2021 \$'000
Capitalised development		
<i>Estradiol</i>		
Carrying amount at the start of the period	482	589
Additions	-	-
Amortisation	(54)	(107)
Carrying amount at the end of the period	428	482

The remaining useful life of Capitalised Development relating to Estradiol is less than 5 years.

3 LEASING

The Group has an operating lease for its office, laboratory and warehouse facilities which 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. There is no option to purchase the leased asset at the expiry of the lease period.

	31 December 2021 000's	30 June 2021 000's
Lease liabilities are presented in the consolidated statement of financial position as follows:		
Lease liabilities (current)	180	185
Lease liabilities (non-current)	1,970	2,049
Total carrying amount of lease liabilities	2,150	2,234



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2021 (continued)**

	31 December 2021 000's	30 June 2021 000's
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements		
At cost	2,409	2,409
Accumulated depreciation	(502)	(402)
Total carrying value of buildings under lease arrangements	1,907	2,007
Plant and equipment under lease arrangements		
At cost	134	134
Accumulated depreciation	(51)	(35)
Total carrying value of plant and equipment under lease arrangements	83	99
Total carrying value of leased assets	1,990	2,106

4 CONTINGENT LIABILITIES

There were no contingent liabilities as at 31 December 2021.

5 AFTER BALANCE DATE EVENTS

No matters or circumstance has arisen since 31 December 2021 that has significantly affected the Group's operations, results or state of affairs, or may do so in future periods.



DIRECTORS' DECLARATION

The directors declare that:

- (a) in the directors' opinion, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
- (b) in the directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the consolidated entity.

Signed in accordance with a resolution of the directors made pursuant to s.303(5) of the *Corporations Act 2001*.

On behalf of the Directors

A handwritten signature in blue ink, appearing to read 'R. Dobinson'.

Ross Dobinson
Non-executive Chairman
Melbourne
24 February 2022

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**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 2021, 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 the Group does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Group's financial position as at 31 December 2021 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 2021 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*.

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.



N R BULL
Partner
24 February 2022



PITCHER PARTNERS
Melbourne